

*Active Biotech develops innovative drugs that regulate the body's own immune defence. We focus on widespread diseases in need of new and more efficient forms of treatment. We have progressed furthest with our candidate drugs for the treatment of MS and cancer.*

03

## Maximum benefit with minimum bureaucracy

Active Biotech always designs its project programs to allow researchers' hypotheses to be tested as early as possible. This maximises the benefit of successful projects and enhances efficiency in development without compromising on safety and requirements from the authorities.

Read more about Active Biotech's registration strategy on page **13**



## "Projects progressing according to plan"

Today's Active Biotech began to take shape in 1997. Two years later, both the SAIK-MS and TTS projects reached the clinical phase. Since then, the company has been focused increasingly on pharmaceutical development and has achieved a large number of milestones.

Read more about Active Biotech's path to becoming a pharmaceutical development company on page **6**



## Unique concept against cancer

With its TTS project, Active Biotech is developing an immunological cancer treatment. The concept utilises the same powerful mechanisms that form the basis for the body's rejection of transplanted organs. During 2003, a Phase II study against renal cancer showed promising results. The company has now chosen to focus the development of TTS on optimised candidate drug CD3, which has a higher level of anti-tumour activity, lower toxicity and antigenity.

Read more about the TTS project on page **20**



## New treatment for MS

Current pharmaceuticals for the treatment of MS can slow the progression of the disease but have side effects and are administered through frequent injections. Active Biotech's substance laquinimod is administered in tablet form. The Phase II study involving MS patients, which was completed in 2003, showed positive results.

Read more about the SAIK-MS project on page **18**

## From Lead to Proof of Principle

Active Biotech focuses on managing a limited part of the pharmaceutical development chain – from Lead to Proof of Principle in clinical trials. The collective experience of employees in pharmaceuticals and their ability to cooperate and support one another represent the company's foremost competitive advantage – and an important reason why Active Biotech achieves progress more rapidly than is usual within the industry.

Read more about Active Biotech's core expertise on page **8**



## Focus on clinical projects

In the development of the company, 2003 was a highly important year. We were able to report positive results with regard to all clinical projects and are now advancing into the development process, moving on towards more extensive studies in patients. At the same time, the focus of the company is shifting to now focus entirely on projects at or close to the clinical phase. As a consequence of this, extensive reorganisation will take place during the spring of 2004.

Active Biotech's President & CEO writes this in his comments on page **3**



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### Financial information

Annual General Meeting	April 21, 2004
Interim report (Q1)	May 13, 2004
Interim report (Q2)	Aug 12, 2004
Interim report (Q3)	Nov 5, 2004
Year-end report for 2004	Feb 17, 2005
Annual Report 2004	March 2005

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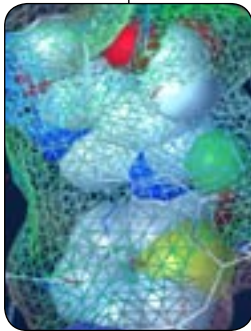
Information can also be obtained from our website [www.activebiotech.com](http://www.activebiotech.com)

# The year in brief



## *Successful clinical studies of laquinimod – may become the first orally administered drug against MS*

During the autumn of 2003, laquinimod (SAIK-MS) showed positive results in a clinical Phase II study. Treatment over six months with 0.3 mg of laquinimod daily resulted in an approximately 30-percent decrease in the number of new inflammatory lesions in the brain. Patients with active disease at study start showed a decrease of more than 40 percent. The study also confirmed laquinimod's favourable safety profile.



## *Promising results and new clinical studies for TTS*

A survival study from clinical Phase I trials of TTS CD2 showed a greater survival rate than that which would be expected given the normal progress of the disease. The final analysis of tumour response in a Phase II study of CD2 involving patients with advanced renal cancer at a progressive stage showed promising results.

A clinical Phase I study of the optimised candidate drug TTS CD3 against lung cancer started in the US at the beginning of May 2003 and in December, Active Biotech decided to focus future product development of TTS entirely on CD3. The CD3 development will primarily be directed towards approval for its use in the treatment of non-small cell lung cancer.



## *Clinical trials of TASQ against prostate cancer continue*

Within the TASQ project, a clinical Phase I study involving healthy volunteers was concluded in February 2004. The study shows that the candidate drug TASQ can be administered orally on a daily basis and at dosage levels expected to have an effect in the treatment of prostate cancer. An IND application to begin Phase I studies with patients will be submitted to the FDA during the first half of 2004.



## *Positive pre-clinical results for the SLE project*

The candidate drug 57-57 for the treatment of SLE has been shown to have the ability to inhibit the development of the disease in mice, which spontaneously develop a condition similar to SLE. Efforts are now being focused on scaling-up the production of the substance and preparations are being made to document safety. A clinical Phase I study is expected to begin during the first half of 2004.



## *Other events*

The 2003 Annual General Meeting approved the rights issue proposed by the Board and its proposal to lower the par value of shares to SEK 10. The issue was concluded during the second quarter and resulted in proceeds of SEK 216.7 million after transaction costs.

The Extraordinary General Meeting held in December resolved to introduce a personnel stock options program comprising one million stock options to be allocated to all personnel. The Extraordinary General Meeting also resolved to amend the Articles of Association to stipulate that all shares shall be of the same class and that separate class A and B shares will no longer be issued.

# Focus on clinical projects



*Our focus on drug development has been successful*

During 2003, we had the pleasure of reporting positive results with regard to all clinical projects. Our focus on drug development has been successful. This started with the spin-off of all non-drug-related operations in 1999, and continued with the divestment of SBL Vaccin. We have now concluded a number of clinical studies and are consequently progressing in the development towards more extensive studies in patients. On the condition that our success continues, the way towards registration of pharmaceuticals is then ahead.

During the past two years, Active Biotech has invested heavily in clinical development, with a cost level amounting to slightly more than SEK 300 million per year. These investments reflect our aggressive plan for the clinical program with the purpose of achieving "Proof of Principle" for our main projects, SAIK-MS (laquinimod) and TTS. In parallel, a clinical Phase I study was started for the TASQ prostate-cancer project, and the process of documenting the SLE project 57-57 was begun in preparation for clinical trials.

## **Favourable clinical results**

Of our projects, SAIK-MS (laquinimod), an oral treatment for multiple sclerosis, has advanced furthest. The SAIK-MS project achieved positive results in the Phase II study reported in September. The study comprised more than 200 patients at clinics in Sweden, the UK, Russia and the Netherlands. The study achieved its primary endpoint and showed a significant reduction in disease activity measured using magnetic imaging. The results now form the basis for the continuing Phase III trials.

The market for injectable MS products currently amounts to slightly more than USD 3 billion annually and shows a strong growth. An effective and safe therapy in tablet form would provide considerable advantages compared with today's products. In our view, SAIK-MS is the project that has advanced furthest in developing an orally administered drug for the treatment of MS.

We were also able to report promising results for the TTS cancer project during the year. Phase II data for the TTS CD2 study against renal cancer comprised 40 patients and showed a favourable effect in stabilising the disease. Another study of TTS CD2 against pancreatic cancer will be reported in early 2004.

In parallel with the development of this first-generation product, we have developed TTS CD3, a new, improved candidate drug currently at clinical Phase I. The goal with CD3 is to be able to administer considerably higher doses, which has been shown to have substantial importance for clinical results. Furthermore, CD3 can be administered in standardised doses. Phase I studies with CD3 are underway in Philadelphia, USA and in Oslo, Norway.

Against the background of the promising results that have been achieved, the company has decided to focus further clinical development of the TTS project on the new generation, TTS CD3. In this way, we obtain a commercially more attractive product profile and avoid doubling costs by working on two product generations in parallel.

During the year, the TASQ project entered a Phase I study involving healthy volunteers. This was concluded in early



2004 and confirmed that the substance is suitable to be administered orally.

The trials program will now continue including prostate-cancer patients. The patient study is planned to start in the US during 2004.

The 57-57 project, which is aimed primarily at the indication Systemic Lupus Erythematosus (SLE), is the next project being prepared for clinical studies. The positive pre-clinical results reported during 2003 mean that 57-57 is planned to enter Phase I during 2004.

Two projects in the early stages of research are close to the clinical phase. Both of these are intended for the treatment of autoimmune diseases. We have applied for patent protection for these projects.

#### **New share issue and ownership structure**

A new share issue was successfully conducted during the year and provided the company with proceeds of approximately SEK 217 million. This issue, which was oversubscribed by 24 percent, was guaranteed by MGA Holding AB. Since Pfizer did not participate in the issue, its ownership decreased to 8 percent. MGA is the company's largest owner with 26.5 percent of the share capital. At the close of 2003, institutional ownership amounted to 14.4 percent and the total number of shareholders to approximately 14 000.

An Extraordinary General Meeting in December resolved to amend the Articles of Association such that class A and B shares were replaced by a single class of shares with the same

voting rights. This change was implemented without compensation for holders of class A shares. At the same time, a new stock options program was established for all employees.

#### **Other significant events**

In mid-2003, the travel vaccine Dukoral received a recommendation from the Committee for Proprietary Medicinal Products with regard to European registration. Since the sale of SBL Vaccin in 2001, Active Biotech has an agreement granting the company rights to a payment amounting to between USD 5 million and USD 10 million. The final amount is conditional upon when Dukoral is formally registered by the European regulatory authority, the EMEA. At the same time, we are in arbitration proceedings initiated by PowderJect Pharmaceuticals, which claims that our sale of SBL Vaccin was based on inaccurate assumptions. The claim from the counterparty in the case amounts to a maximum of USD 20 million. We have rejected this as entirely without grounds, since we gave no guarantees regarding future results or sales were given.

#### **Partnership**

As previously, we expect to sign a partnership agreement for SAIK-MS before Phase III studies start. The investments and payments that a partner may carry out are considerable. We have previously been too optimistic in our planning regarding when such an agreement will be signed – discussions have taken longer than we initially expected.

*The Board has determined that our future focus shall be on projects in, or close to entering, the clinical phase*



For the TTS project, discussions are being conducted with a number of companies regarding process development and production – a particularly important area for this type of biotechnological pharmaceutical.

The licensing agreement signed with Avidex in Oxford, in the UK, in 2002, regarding CD80 antagonists, has developed well. A candidate drug was defined at the beginning of 2004.

#### **Earnings**

The operating loss for the year amounted to SEK 336.4 million, a level comparable to that of 2002. The large deficit reflects the company's investments in development programs for the advanced projects, which are in, or close to entering, the clinical phase.

Net financial items amounted to SEK 32.0 million. During the year, we continued to be successful in our capital management. At the end of the year, we had a cash balance equivalent to a market value of slightly more than SEK 256 million. The company is continuously assessing the future capital needs in relation to ongoing partnership discussions and other revenues.

#### **Reorganisation and cost reduction**

Interest in the biotech industry is growing and the climate in the capital market has improved compared with recent years. At the same time, the market and shareholders require positive cash flows within a reasonable timeframe.

This, combined with our success in our clinical projects,

meant that we were faced with making an important decision regarding our future direction and strategic focus. The Board has determined that our future focus shall be on projects in, or close to entering, the clinical phase. As a consequence of this, an extensive reorganisation will take place during the spring of 2004. This will allow us to reduce our cost level by approximately SEK 100 million annually.

This new business strategy means that we will discontinue our early discovery-research operations. However, discovery projects that are close to entering the clinical phase will be placed on hold, providing us with opportunities for a further product flow in addition to those we currently have in the clinical phase.

Nevertheless, during the spring, we will be substantially reducing our early-stage research activities. We have therefore given notice regarding the redundancies of a large number of employees (98 of 176) and negotiations in accordance with labor legislation in Sweden were initiated at the beginning of March.

In the development of the company, 2003 was a highly important year. We are now moving ahead with a strong project portfolio based on clinical projects and a further focused organisation.

Lund, March 2004

Sven Andréasson, President & CEO

# “Projects advancing as planned”

Over the years, Active Biotech has become increasingly focused in its role as a pharmaceutical development company. Its legacy from Pharmacia & Upjohn was an advantage: a unique infrastructure, ongoing development projects with enormous potential and a firmly rooted tradition of developing drugs with strong market potential.

However, just how far a company can go depends on its ability to establish – and achieve – new milestones.

## Focus on drugs

Active was founded in 1983 as an investment company and listed on the Stockholm Exchange in 1986. In 1997, the company acquired SBL Vaccin from the Swedish state, and in the following year, the Lund Research Center, from Pharmacia & Upjohn. At the same time, Active acquired the name Biotech, thus completing its transformation from an investment company to a biotechnology group. However, the company’s operations continued to point in various directions.

# 1999



In 1999, after further streamlining in the direction of pharmaceuticals and biotechnology, through events such as the distribution of Wilh. Sonesson, the company consisted of the research operations in Lund, Sweden, and Cambridge, UK, and a vaccine operation in Solna (Stockholm). The operations involved both infectious diseases – which includes vaccines – autoimmune/inflammatory diseases and cancer.

The SAIK-MS and TTS projects were in the beginning of Phase I clinical studies.

## First studies on patients

MS patients were introduced into the clinical SAIK-MS study for the first time in 2000. In the same year, Active Biotech took back the rights to the TTS project from Pharmacia and successfully concluded the Phase I study for TTS CD2.

# 2000



One of the projects run by the Cambridge research operations – which were phased out during the year – was spun off to form the company Isogenica, in which Active Biotech is still a minority owner.



# 2001

## Entirely focused on drug development

In 2001, the streamlining of the operations accelerated. The SBL Vaccin operations were sold to UK-based PowderJect Pharmaceuticals, which brought Active Biotech financial proceeds totalling SEK 542 million. The decision to sell was made to place the company in a better position to fully utilise its potential for future value growth – that is, the research operations in Lund. And the results of the Lund-based projects were indeed excellent.

Phase I studies were successfully completed in

2001, for both the SAIK-MS and the TTS projects. Phase II studies of TTS involving renal cancer patients started at year-end. The TASQ prostate cancer project advanced rapidly, demonstrating a clear effect on blood vessel growth and tumour growth in experimental models.



2002

#### Acquired all rights

In 2002, two new candidate drugs were identified – within the TASQ prostate cancer project and the 57-57 SLE project – and the patent portfolio was strengthened.

A double-blind multicenter Phase II study involving 200 MS patients was launched for the SAIK-MS project. The Clinical Phase II study for TTS proceeded and the FDA approved the IND application to start clinical studies of TTS in the US.

At year-end, Active Biotech took back all projects rights pertaining to both the SAIK-MS and the TTS projects from Pharmacia, which placed the company in a much better position to commercialise these research projects.



2003

#### Successful Phase II studies

In 2003, the multicentre study of SAIK-MS was concluded, with positive results. The TTS cancer project produced promising survival data after the Phase I study involving lung cancer. The Phase II study using renal cancer patients was concluded, also with promising results.

Based on the results of the Phase II study, the company decided to focus on the ongoing development of the TTS project involving the optimised candidate drug, TTS CD3. During the year, both the TTS and the TASQ projects started Phase I studies, in the US and Germany, respectively.

#### Business concept

Active Biotech's business concept is to use specialist expertise on the human immune defence to develop effective pharmaceuticals for diseases where a major medical need exists.

#### Goals

Active Biotech's goals are

- to generate long-term value for its shareholders through cutting-edge expertise within selected niches of the global market
- to be an attractive employer by offering a creative atmosphere that provides abundant opportunities for individual development
- to efficiently and cost-effectively develop new pharmaceuticals for diseases where current treatment options are inadequate

# From Lead to Proof of Principle



The discovery phase starts with identifying a target molecule for the drug to be developed



Despite advanced computer simulations compounds must be tested on cells before a sufficiently strong candidate drug can be identified

**A traditional pharmaceutical company develops, documents, manufactures and markets drugs. Active Biotech is not such a company: instead, it is one company in the growing cohort of Swedish biotech companies.**

At first, biotech companies were based on key expertise in biotechnology. Gradually, however, the term has come to include pharmaceutical companies that do not represent the entire chain of pharmaceutical research up to manufactured product, but rather out-license projects to larger companies that carry out the latest development phase as well as manufacturing of the drug. Active Biotech is one such company.

To describe Active Biotech, it is necessary to start by looking at what pharmaceutical research actually involves. It is an advanced process that is commonly divided into various phases. The earlier phase is called the discovery phase, and the later phase, the development phase.

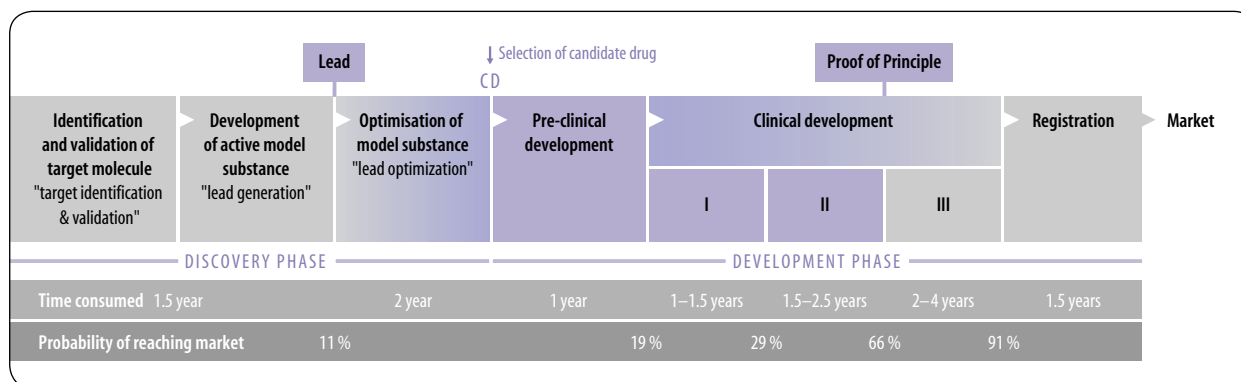
## The discovery phase

The discovery phase is usually based on a new idea or invention. This phase starts with the identification and validation of the target molecule to which the drug must bind to exert its effect. If the target molecule, or the idea, is unique, it may be patented.

Most target molecules are proteins occurring in the body. By isolating the target molecule and the unique cell systems in which it plays a key role, biological assays are created whereby various compounds that may become future drugs can be tested.

The second stage of the discovery phase involves the identification of compounds that bind to the target molecule of interest – that is, “hit compounds” or “leads.” Subsequently, the model compounds are optimised.

The discovery phase requires an extensive chemical synthesis program. A large number of compounds are



The purple shading marks the phases of the drug development process in which Active Biotech participates using primarily its own resources  
Source: *The Pharmaceutical R&D Compendium: CMR International/Scrip's Complete Guide to Trends in R&D, 1999 Edition, Volume 2.*



***“In the development phase, it is important to secure a strong patent for the new compound that prevents competitors from developing the same or similar compounds.”***

*Before any drug can be administered to humans, an appropriate formulation must be developed*

synthesised in order to obtain molecules with maximum effect and minimal side effects. A part of this work is supported by powerful computational tools. Even with access to advanced computer systems for docking of compounds into the active site of the target molecule, it is often necessary to produce and test thousands – sometimes tens of thousands – of compounds before an adequate candidate drug can be found.

During the optimisation process concerning binding affinity and effect in various biological models, it is also important to predict at an early stage if the compounds can find their way to the target organ inside the body in unaltered form and in sufficient quantity. First, various computer models are used, then human cells, to confirm that the compounds have the required properties.

Once positive results have been obtained in the experiments, the properties must be confirmed *in vivo*. While the pharmacological properties of the compounds are verified in various pre-clinical models, it is also confirmed that the compounds have the right pharmacokinetic properties – that is, is absorbed, distributed, metabolised and eventually secreted in an optimal manner.

Once a candidate drug's efficacy and its potential to function as a drug in the body, the next phase starts: the development phase. In this phase, it is important to secure a strong patent for the new compound that prevents competitors from developing the same or similar compounds.

### **The development phase**

The development phase starts with preparation for the initial studies of the candidate drug in humans. To obtain permis-

sion to initiate these studies, the candidate drug must have shown good effects in pre-clinical models. In addition, it is required that the compound can be given to humans without any risks. This requires controlled safety studies be conducted in animal models in accordance with the applicable guidelines from the authorities. This phase is called pre-clinical development.

The primary purpose is to show that serious side-effects do not occur in the dosage that produces the desired effect on the disease. Another key purpose is to confirm the pharmacokinetic properties. An ideal drug should be suitable for per-oral administration; it should pass through the stomach, be absorbed from the intestine and pass through various membranes in the body without being metabolised before it reaches the target organ in a sufficient quantity. It is also important that the drug is not accumulated in the body, but rather secreted within a reasonable period of time.

Before a drug can be given to humans, a suitable formulation must be found – for example, a solution, tablet or capsule. This requires extensive chemical and pharmaceutical studies and stability studies in accordance with established official requirements. A preliminary formulation is often used in the initial clinical studies, but is subsequently replaced by a more advanced formulation before the final formulation of the drug substance is developed.

The overall goal of clinical development is to demonstrate that the candidate drug can be used to treat patients effectively and safely. The clinical development starts with Phase I studies in which the new drug is first tested in a small number of healthy volunteers, then in patients. The purpose of Phase I studies



*Active Biotech's researchers in the pre-clinical discovery phase make significant contributions in the development phase, and vice versa*

is to establish that the pre-clinical pharmacokinetic studies were relevant and to determine the dosage and dosage interval to be used in the subsequent clinical studies.

Phases II and III involve patient studies on a larger number of individuals – up to a few hundred in Phase II and up to a thousand in Phase III. In Phase II the clinical effects on patients is demonstrated, and Phase III confirms this effect in comparison with a placebo or already established therapy for the disease.

#### **Active Biotech's flexibility and speed**

Development of a drug is a highly complex and lengthy process that cannot be directly compared with development process in other areas of research. It takes ten to fifteen years to develop a drug from idea to product, and the cost is very high – that is, SEK 5–10 billion.

The large pharmaceutical companies have thousands of employees working in all phases of drug research. Despite this fact, Active Biotech is dealing well with the competition. Instead of specialising in some specific area of technology, as do many small biotech companies, Active Biotech has opted to focus its operations on its outstanding expertise in specific development phases (see illustration on page 8).

The company has a large number of employees who are experienced in drug development. They are also highly familiar with the official requirements governing this type of operations. Most employees have backgrounds in the large pharmaceutical companies. At Active Biotech, they can benefit from the close collaboration between the various project teams and company management. This secures quick decision-making and, thus, enables Active Biotech to maintain high speed in its project.

#### **Active Biotech's focus**

Active Biotech has focused on handling a limited part of the research stages described – namely, advancing projects from lead compound to clinical proof of principle. The employees' collective pharmaceutical expertise and their ability to cooperate and support each other during this stage of drug development form the company's primary competitive advantages.

Active Biotech optimises lead compounds that have been developed by the company itself or obtained through cooperation with universities or other companies, and develops them to the point of proof of principle. Basic research on biological mechanisms is a resource-intensive task, as is the final drug development. In these fields of research, we are obliged to cooperate with other players.

#### **Cooperation a success factor**

Collaboration between researchers with various areas of responsibility and scientific background is a prerequisite for success in drug research. The large pharmaceutical companies often lose a great deal of time when projects advance from the discovery phase to the development phase, because different employees work in the different phases.

Active Biotech also defines a boundary between these phases, set at the selection of candidate drug (CD). Researchers in the pre-clinical discovery phase make a significant contribution in the development phase, and vice versa. This makes the transition less abrupt, which helps ensure that the high pace is not interrupted.

Another key aspect of Active Biotech's profile is its outsourcing to companies that specialise in certain parts of the



*It takes ten to fifteen years to develop a drug from idea to product*



*Operations that Active Biotech outsources include the production of drugs substance for clinical studies and toxicological evaluation*

research involved in pre-clinical development. An example of this is toxicological evaluation, which is carried out in cooperation with contract laboratories that have a high level of expertise in this particular area.

Active Biotech, on the other hand, has accumulated substantial expertise in conducting pharmacokinetic studies in house to generate value in the initial clinical studies. It is the company's employees who are most familiar with its own compounds, so they themselves carry out the preparatory conceptual studies regarding drug formulations, while specialised companies are contracted to manufacture the final formulations in accordance with established official requirements.

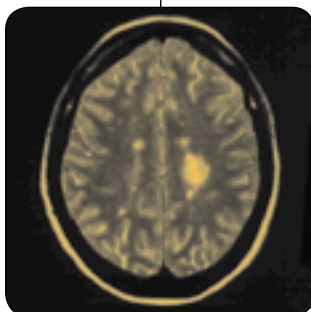
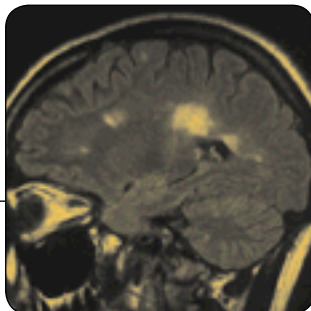
#### **Clinical development focuses on proof of principle**

Active Biotech has developed special expertise to ensure that the initial clinical phases are conducted in an optimal manner, so that the projects at an early stage will generate commercial value. The aim is to obtain proof of principle as soon as possible, generally during Phase II.

Proof of principle means that the candidate drug has an effect on a biomarker – that is, a measurable parameter that predicts the effect in a certain disease. There is a current trend toward using this type of study in drug research, made possible by the increased knowledge of the significance of biomarkers in disease development within various indications. A well-known example of a biomarker is PSA testing for prostate cancer.



**“Using a relatively small research organisation, Active Biotech has advanced the projects onward from proof of principle, faster than is usual in the industry.”**



*Magnetic Resonance Imaging (MRI) was a useful tool in Active Biotech's evaluation of the effects of SAIK-MS in Phase II*

**Microdose:** a literally microscopic dose of a substance that is administered to healthy volunteers. The dose is as little as around a thousandth of the amount believed necessary to treat the disease. The idea is to obtain information of the compound's pharmacokinetic profile in human beings – that is, how it is absorbed and eliminated by the body – as quickly and safely as possible. The analysis is conducted using High Performance Liquid Chromatography Tandem Mass Spectrometry (HPLC-MS/MS), that can analyse minute amounts of compounds in the blood. The method makes large toxicological studies unnecessary, thus significantly reducing the need for test animals.

One way to reach an early proof of principle is to use a single, lower dose in the first study using volunteers than would be used in conventional Phase I studies. This is called microdosing and can be performed with a high degree of safety. However, it requires access to advanced and highly sensitive analytical methods. The objective is to obtain important information on the pharmacokinetic properties of a drug at an early stage. By using this method, researchers in both the SAIK-MS and the TASQ projects could confirm that the compounds had suitable pharmacokinetic properties for per-oral administration. Information gained through microdosing has also been useful in calculating dosage level and dosage interval for repeated treatment in later development phases.

Based on microdosing and confirmation provided by tolerance studies carried out within conventional Phase I studies, Active Biotech carries out studies of proof of principle. In the past year, this procedure has been used by the SAIK-MS project, with great success. Over a period of six months, the drug was administered to MS patients who was monitored using Magnetic Resonance Imaging (MRI), an advanced X-ray-based scan of the brain. The candidate drug was shown to have a statistically significant effect on the pa-

rameter that predicts clinical effects on MS. The plan is to carry out similar studies using suitable biomarkers in the TASQ and 57-57 projects in the near future. TASQ will be studied in prostate cancer using PSA as a biomarker.

#### **Effective projects generate value**

During the past few years, Active Biotech has shown that it can quickly advance project positions by establishing the company's specific development expertise in cooperation with external partners. Quick decision making and a high pace of project work are ensured through an efficient project organisation that continuously reports to the company management. The company is sufficiently small that it can change direction quickly if necessary and sufficiently large to comprise and handle the technologies and areas of expertise that are required for the research – everything from lead to proof of principle.

A comparison with other companies shows that using a relatively small research organisation, Active Biotech has advanced the projects from lead to proof of principle faster than is usual in the industry. The clinical project portfolio, which has recently grown substantially, clearly demonstrates the strength of Active Biotech's research strategy.

# Development in harmony with official requirements

Lars M. Nilsson, Vice President - Regulatory & Quality Affairs, Active Biotech



**The pharmaceutical industry is the most regulated industry there is. Authorities in various countries oversee pharmaceutical companies in the development, testing, production and marketing/selling of their products. Before a pharmaceutical company can begin to market and sell its products, it must also obtain approval in the country in which the product is to be introduced.**

As government authorities raise their requirements, pharmaceutical companies' costs increase substantially, and the official requirements are often felt to be complicated and bureaucratic. While every research project is unique, government requirements are often general. In situations that are unclear, the simplest route is to fulfill all requirements that could conceivably be applicable. However, such a strategy increases bureaucracy. Active Biotech is a small company engaged in developing innovative drugs using limited resources in the shortest possible time, and is not in a position to choose such a strategy.

## **The fundamental principles of Regulatory & Quality Affairs**

The main task of Regulatory & Quality Affairs is to ensure that all of Active Biotech's activities comply with drug legislation while maintaining the capacity to effectively develop new drugs.

## **Government requirements and harmonisation**

Legislation in the pharmaceutical area follows common principles, but varies among countries and regions. Initially,

different sets of regulations were based on the same fundamental principles of quality, safety and effectiveness. In the 1960s and 1970s, however, national regulations were developed and divergent detailed requirements defined. As a result of the requirements on the pharmaceutical industry, many lengthy and expensive studies had to be duplicated to permit global marketing of new products. This was considered a problem, even by government authorities, the health-care system and patients, who wanted speedy access to new, safe drugs.

The first step toward harmonisation was taken by the EEC in the 1980s. In 1990, the ICH was founded, a body that created a set of common rules for the collection and presentation of technical data. The work of the ICH is ongoing, and has now reached the final stage of an agreement on the structure of a global registration application (CTD).

These harmonisation efforts are extremely helpful. However, much remains to be done before we may actually look ahead to a uniform global market.

## **Discovery phase**

During the discovery phase, the drug authorities' monitoring requirements are low. Most of Active Biotech's research operations take place in laboratories and involve testing of new substances in test tubes. Animal trials only occur to a limited extent.

However, the company has high internal standards regarding its procedures and documentation, since they form the basis of patent applications. Active Biotech's research and



*Each new step in clinical studies requires an application to a government authority*

development files contain all research reports with references to the corresponding raw data.

#### **Pre-clinical phase**

Most pre-clinical-phase studies are carried out to investigate and document the safety of a substance. Drug authorities stipulate exactly what studies are required and how that are to be performed. Requirements include a quality assurance function that is independent of the units performing the study and ensures that all studies are carried out correctly and that reports correctly reflect the data generated.

The Golden Rule of every drug development program is to ensure that the individuals participating in the clinical studies are not exposed to improper risk and that their personal integrity is respected. This is achieved through pre-clinical safety tests that include toxicological and pharmacokinetic studies.

#### **Clinical phase**

Studies involving humans require prior permission from government authorities. Harmonisation is not as well advanced in this area as in the pre-clinical area. The EU recently announced a new directive regarding uniform rules. This particularly improves harmonisation with the US – although practical discrepancies will remain for a long time.

Clinical studies on humans are conducted in close cooperation with physicians and hospitals, and are carefully regulated. The quality assurance function examines and

approves critical components of both the manufacture of the medicine and the implementation of the study.

If the initial studies yield favourable results, further studies are done involving increasingly large groups of patients. Each such progression requires a new application to the relevant authorities.

#### **Registration phase**

Once the clinical studies have been completed with positive results, all facts are compiled – that is, everything from the design and manufacturing of the new drug to safety tests on animals and investigations of effect and safety in clinical studies. This takes the form of an application for permission to market the new drug in a particular country. For the EU, it is possible to make a single application that applies to all member states.

#### **Active Biotech's registration strategy**

Government requirements are designed to provide a basis for registration. Even if the development chain is sequential, with clearly defined intermediate goals, the rules involved have not necessarily been devised to support the purpose of demonstrating proof of principle – that is, that the candidate drug has an effect on a particular biomarker.

Consequently, in cooperation with internal and external experts, and government authorities, Active Biotech designs project programs that make it possible to clearly test researchers' hypotheses while focusing on patient safety. Accordingly,

**“Active Biotech’s projects are well prepared for delivery to the next phase in which they can be further developed in cooperation with partners.”**

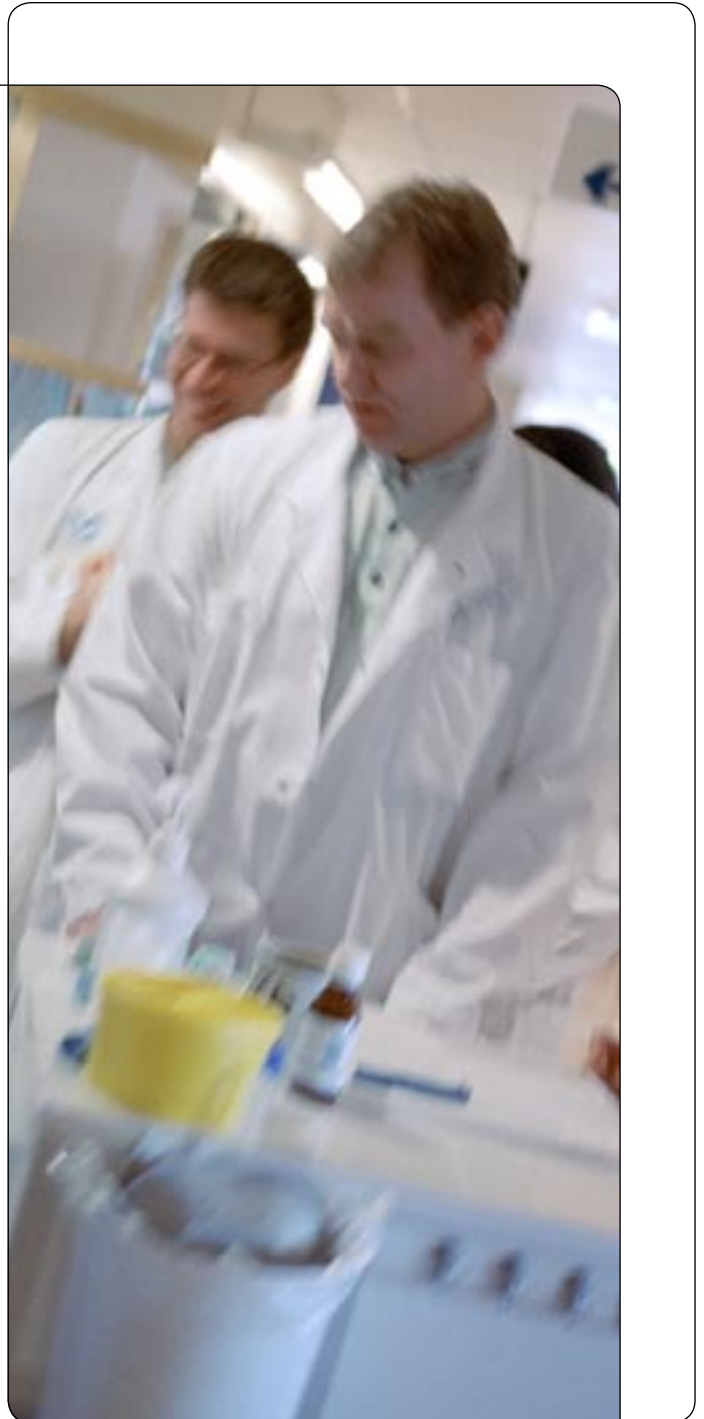


*The ideal drug is taken in the form of a tablet*

the company allows itself to postpone certain studies until the substance has demonstrated proof of principle. Active Biotech’s approach is, however, implemented in compliance with the applicable rules and guidelines, and meets registration requirements.

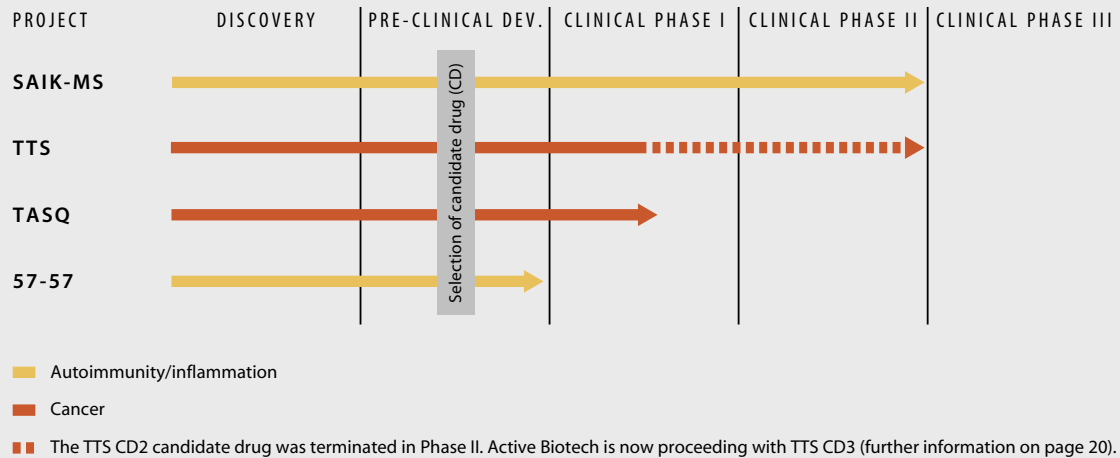
#### **Projects well prepared**

Active Biotech’s development strategy is based on independently driving the development of new products to the point of proof of principle. In each individual project, it focuses on relevant guidelines, taking the project’s current development phase into consideration. An overall development strategy that complies with applicable and anticipated government requirements is essential. This ensures that Active Biotech’s projects are well prepared for delivery to the next phase where they can be further developed in cooperation with partners.



*Clinical studies are performed in close cooperation with physicians at various clinics*

# The project portfolio



## SAIK-MS

### Indication

Multiple sclerosis

### Development status

Phase III to start in 2004

### Market and competition

In 2002, the total market for MS drugs amounted to USD 2.8 billion. Today, the market is split among four compounds: Avonex® from Biogen, Betaferon®/Betaseron® from Schering, Rebif® from Serono and Copaxone® from Teva. All medicines are administered by injection. SAIK-MS is given in tablet form.

### Information/miscellaneous

In autumn 2003, SAIK-MS produced positive results in clinical Phase II studies. Treatment with 0.3 mg of laquinimod a day resulted in an approximately 30% reduction in the number of new inflammatory lesions in the brain.

## 57-57

### Indication

Systemic Lupus Erythematosus (SLE)

### Development status

Phase I to start in 2004

### Market and competition

Current treatment is based on NSAIDs, malaria medicines, salicylic acid preparations, cortisone and cytostatic agents such as cyclophosphamide and methotrexate. Since these medicines can produce severe side-effects, there is a major medical need for new treatment alternatives. No new drugs for the treatment of SLE have been registered for the past 40 years.

### Information/miscellaneous

Phase I clinical trials are scheduled to begin in 2004.



### TTS

#### Indication

Non-small cell lung cancer

#### Development status

Phase I\*

#### Market and competition

The market for the treatment of lung cancer is estimated at slightly more than USD 1 billion (source: Blomqvist & Associates, Feb. 1, 2003). Currently, surgery offers the only cure, effective only when the tumour has not yet formed metastases. Cytotoxins such as cisplatin, paclitaxel and gemcitabine are used with limited success to treat metastasising disease. Interleukin-2 and alfa-interferon are examples of immune-boosting cytokines, the effect of which, while limited, has been established.

#### Information/miscellaneous

\*Results from Phase II clinical trials with TTS CD2:

- 68% of patients showed stabilisation of their disease
- One patient showed considerable tumour reduction

With the promising results from Phase II on TTS CD2, Active Biotech decided to focus on continued product development on the optimised candidate drug, TTS CD3.

### TASQ

#### Indication

Prostate cancer

#### Development status

Phase I

#### Market and competition

The global market for drugs for prostate cancer is estimated at approximately USD 3.1 billion a year (source: Blomqvist & Associates, Feb. 1, 2003). Drugs that influence angiogenesis are being developed by various centers worldwide, but having several companies working in the same area is not necessarily a disadvantage. On the contrary: Since combination treatment involving several products can produce considerably greater effect. Several new substances with antiangiogenic characteristics have entered clinical trials over the past few years. Data shows, however, that Active Biotech's substance has a mode of action that is clearly unlike that of other substances currently being developed.

#### Information/miscellaneous

A Phase I dose-escalation study with healthy volunteers was concluded in 2004. A Phase I study with prostate patients will start in 2004.

# SAIK-MS – unique oral treatment for MS

Within the SAIK-MS project, Active Biotech is developing the new active substance laquinimod for oral treatment of multiple sclerosis (MS).

## A chronic disease

MS is a chronic disease, often with an insidious progression. The disease affects the central nervous system in the brain and spinal cord. As the nervous system controls all bodily functions, the disease can affect the sense of touch, motor functions, coordination, eyesight and hearing.

The symptoms are caused by the body's own immune system attacking and damaging the myelin sheaths surrounding nerve fibers. This causes inflammation within the central nervous system causing the patient to suffer flare-ups that affect a variety of bodily functions.

## MS market potential

A total of about 1 250 000 people throughout the world suffer from MS, a little over half of them in Europe. The temperate zones of Europe are the most affected. In 2002, the total MS market was estimated at USD 2.8 billion (source: SG Cowen, 2003). The market is split among four products (see fact box, page 16).

While there are treatments that can slow the disease in some patients, the need for new and effective agents to fight MS is high. This is partly due to the fact that the established drugs (beta-interferon and peptide-based substances) all require frequent injections and many patients view this as a problem.

## New mode of action

Active Biotech's unique drug for MS has the considerable advantage of being administered in tablet form.

In pre-clinical studies, Active Biotech has shown that laquinimod inhibits the development of MS-like disease in relevant animal-based models. Even though the mode of



Thore Nederman, project manager of the SAIK-MS project



action of laquinimod, like that for the beta-interferon products, is not fully understood, the model trials indicate that the mode of action of laquinimod is different from that of beta-interferon. The animal studies also show that there are no serious side-effects from the dosages involved in clinical treatment.

Good tolerability, without serious side-effects, has been confirmed in clinical studies performed on healthy volunteers and on MS patients.

## Development in 2003

The results of the clinical Phase II study were presented in September 2003. Approximately 200 patients at 20 clinics in four countries were treated on a daily basis for six months.

The study showed biological activity in a mixed population of MS patients, and a highly advantageous safety profile. Treatment with 0.3 mg of laquinimod per day reduced the average level of disease activity by over 30 percent.

The effect was strongest in patients with high levels of disease activity.

# 57-57 – treatment for incurable disease

Within the framework of the 57-57 project, Active Biotech is developing its own patented substance for treatment of SLE (Systemic Lupus Erythematosus).

## Attacks many organs

SLE is a life-threatening disease that manifests itself through autoimmune attacks on numerous organ systems. Symptoms often begin with motor-organ problems. The disease has flare-ups separated by periods that are relatively free from symptoms. SLE causes inflammation and damage to the connective tissue of many organs in the body.

SLE patients are sensitive to light and ultraviolet rays can cause skin rashes and inflammation on their internal organs. Furthermore, patients may suffer hair loss, cold fingers and serious renal and blood vessel inflammations. The central nervous system can become seriously disturbed resulting in psychoses and depression. SLE is often difficult to diagnose since symptoms vary so widely. The disease may eventually lead to life threatening secondary symptoms, such as kidney failure.

## New treatment possibilities for SLE

SLE is most common among women of child-bearing age and affects one in 20 000. There are estimated to be about 5 000 SLE sufferers in Sweden, and there are new patients at a rate of 600 per year. The number of SLE patients in the US is estimated to be at least 500 000. SLE is two or three times more common among people of colour.

During flare-ups the patients may require intensive care treatment. The medications used for treatment of SLE are NSAIDs like acetylsalicylic acid, malaria medicines, Corticosteroids and cytostatic drugs such as cyclophosphamide and methotrexate. Many of these drugs have severe side-effects. There is a major medical need for new treatments for SLE. The number of patients is increasing and no new drugs have been registered for the past 40 years.

Within the framework of the 57-57-project, Active Biotech is developing its own compound for the treatment of SLE. It demonstrated favourable treatment effects in a



Peter Lando, project manager for the 57-57 project



SLE-like disease model, protecting test animals from developing the disease. The compound has also shown itself to be effective in reducing levels of blood and protein in urine, which suggests that the compound may be active against the kidney damage associated with the disease.

The compound will be administered orally, which is a major benefit for patients compared with injections.

## Development in 2003

Positive pre-clinical results for the 57-57 project were presented in October 2003. The 57-57 candidate drug had proven itself to have the capacity to retard the progression of the disease in mice that spontaneously develop a condition similar to SLE. As a consequence, the survival rate increased among the treated animals. A similar result was noted regardless of whether the animal was treated early or late in the course of the disease. The results were presented in October 2003 at the annual conference of the American College of Rheumatology, ACR, held in Orlando, in the US.

Work on the project is now focused on scaling-up production of the substance and the preparation of safety documentation. Phase I clinical trials are expected to start during the first half of 2004.

# TTS – aims immune defence at cancer

Within the framework of the TTS project, Active Biotech is developing an immunological cancer treatment that utilises the same powerful mechanisms causing rejection of transplanted organs.

## No effective treatment

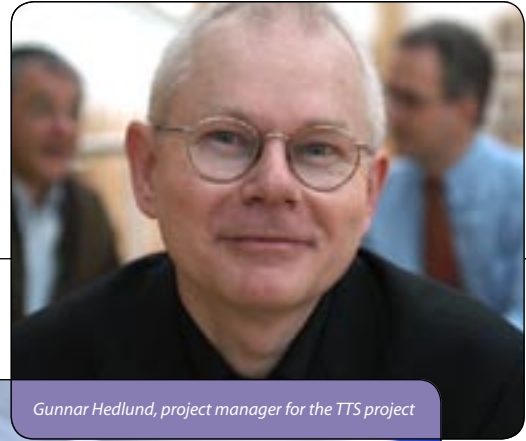
Active Biotech has chosen to focus on the development of candidate TTS products for lung cancer, renal cancer and pancreatic cancer. These forms of cancer are malignant diseases that strike more than 500 000 people in the US and Europe each year. When detected and diagnosed, the disease is often at an advanced stage and with metastasis.

Today, surgery offers the only curative treatment but is only effective before the tumour has developed metastases. Cytostatic drugs, such as cisplatin, paclitaxel and gemcitabine are used with limited success to treat metastasising disease. Interleukin-2 and alpha-interferon are examples of immunostimulatory cytokines with established, although limited effects.

## Powerful stimulation of the immune defence

TTS stands for Tumour Targeted Superantigens. The antibody constituent of TTS makes treatment tumour-specific and directs the activated cytotoxic T lymphocytes toward the tumour. The tumour cells are then forced into apoptosis – that is, programmed cell death.

The TTS method is unique in its category and will meet the overwhelming need for a new innovative cancer-treatment method. Active Biotech's TTS therapies, CD2 and CD3, both of which underwent clinical evaluation in 2003, have a tumour-specificity directed by the product's 5T4 antibody constituent. The 5T4 antibody constituent is the part of the TTS product that seeks out the 5T4 antigen on the surface of the tumour cells and binds to them. The 5T4 antigen is an oncofetal antigen found on the surface of many types of cancer cells but not in normal tissue. This antigen very likely possesses malignant properties, as its function is associated with migration and thus the formation of metastases.



Gunnar Hedlund, project manager for the TTS project



Very low concentrations of the TTS superantigen are required to activate T-lymphocytes with a force which is even greater than that of the antigens that trigger rejection mechanisms in unsuccessful transplants.

## Development in 2003

The final results of the Phase II clinical study of the effect of TTS CD2 on renal cancer were presented in December 2003. The favourable results showed that the disease appeared to stabilise in 68 percent of the patients following treatment with CD2. One patient, who received a higher dosage than the others, showed a dramatic tumour reduction. The tumour burden of this patient decreased by more than 90 percent after treatment with CD2.

In parallel with the development of CD2, Active Biotech optimised CD3. The anti-tumour activity of this compound is higher and the toxicity and antigenicity are lower. It will therefore be possible to administer CD3 in considerably higher dosages that need not be individually adapted.

Active Biotech has decided to focus future development of TTS entirely on CD3, primarily as a treatment for non-small cell lung cancer. A Phase I study of CD3 was begun in the US and Norway in 2003. It is expected that Phase II/III may be launched in 2005.

# TASQ – suffocates prostate cancer

Within the framework of the TASQ project, Active Biotech is developing its patented compounds for antiangiogenesis in the treatment of prostate cancer.

## Most common form of cancer among men

Prostate cancer has varying degrees of severity. Despite a relatively good prognosis, prostate cancer is the second most common cause of death among men.

In its early stages, prostate cancer is hormone-dependent and its growth is stimulated by the male hormone testosterone. Patients with advanced prostate cancer are often affected by secondary tumours, metastases, in skeletal tissue. These tumours grow regardless of hormone levels.

Prostate cancer is the most common form of cancer among men. In 2003, an estimated 334 000 new cases were diagnosed in Europe and the US. The global market for drugs for the treatment of prostate cancer is currently estimated at USD 3.1 billion annually.

## Treatment difficult

Prostate cancer cells divide at a remarkably slow rate – more slowly than cells in normal skin, bone marrow or intestines. This makes it difficult to treat the disease with normal cell-division inhibitors, since these compounds also affect the cell division of normal cells, thus resulting in toxic side-effects.

In the early stages, prostate tumours can be surgically removed or treated with radiation. In over half of the cases, however, the disease spreads to other locations in the body, whereupon surgery is no longer a viable alternative. Instead, treatment then focuses on removing the growth-promoting effect of testosterone – which, however, produces a number of undesirable effects, such as sterility and impotence.

Sooner or later, the prostate cancer starts to grow again, now as a hormone-independent cancer.

## Blood vessels nourish the tumour

TASQ stands for Tumour Angiogenesis Suppression by Quinolines. Active Biotech's TASQ project attacks the tumour's way of growing. Prostate carcinoma is a metastasising malignant



Anders Björk, project manager for the TASQ project



solid tumour that is highly dependent on blood vessel growth – that is, angiogenesis. Antiangiogenic compounds – alone or in combination with conventional anticancer treatment – make it possible to effectively retard the development of prostate cancer, or to use the compound as a preventative measure.

During the pre-clinical development of the TASQ project, the candidate drug showed itself to be capable of reducing blood vessel growth by 50 percent and reducing the growth of the actual tumour by 80 percent.

## Development in 2003

The first Phase I study of TASQ using healthy volunteers was presented in January 2003. The results shows that the TASQ candidate drug has pharmacokinetic characteristics that makes it suitable for oral administration. The study also provided a solid foundation for the future clinical development of the drug.

A Phase I trial designed to study tolerance of higher dosages of the compound in healthy volunteer research subjects was concluded in February 2004. The study showed that TASQ can be administered orally on a daily basis at the dosage levels at which it is expected to have an effect in the treatment of cancer. An initial clinical study involving patients with prostate cancer is planned to be initiated during the second half of the year.

# *A learning organisation with sound leadership*

**“One of the main factors in Active Biotech’s success is our ability to stimulate employees and develop teams, so that we can all work together to turn our expertise and resources into value for the company.”**

These are the words of department head Per Olov Gunnarsson. In 2003, Active Biotech conducted a management training program for department and section leaders – altogether some 20 people. The purpose of the program was to support the supervisor’s development from manager into leader.

Sound leadership is characterised by confidence in every employee’s ability to develop and perform under the proper conditions. Above all else, the leader’s task is to provide the proper conditions.

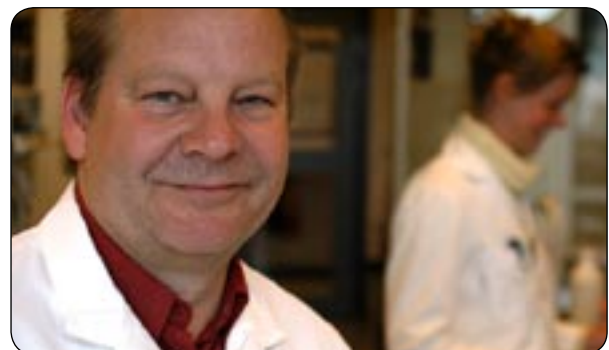
“During the total nine days of the program, we gained greater self-awareness and familiarity with a number of leadership tools,” says department head Dorthe da Graca Thrige.

Her views are echoed by section head Leif Svensson:

“More than anything, it opened the door to ongoing development. The tools are of course equally important in our own development in the role of leader as they are for handling concrete leadership issues in day-to-day operations.”

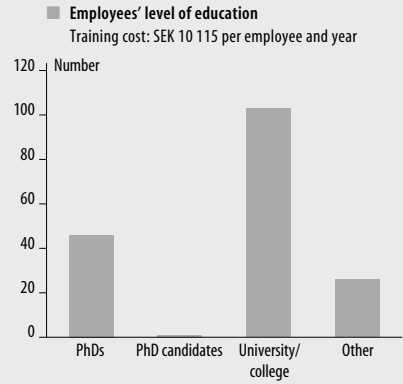
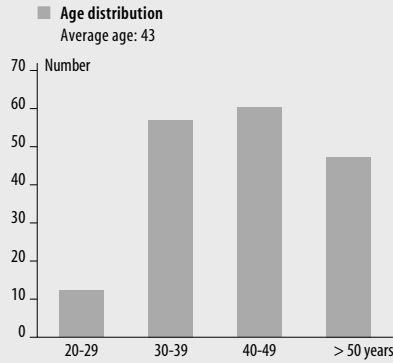
Apart from purely instructional course segments, the program also contained individual segments, including an extensive questionnaire on how the participants viewed themselves. Managers’ responses to the questionnaire were matched with those given by their personnel to the same questions.

The next stage will be a follow-up for the participants and a similar type of effort directed to project managers and new managers.



*Dorthe da Graca Thrige, Per Olov Gunnarsson and Leif Svensson*

- **No. of employees at Dec. 31, 2003**  
(permanent employees including PhD candidates)  
Women: 107  
Men: 69  
Total: 176
- **Employee turnover**  
176: resignations 7  
 $7/176 \times 100 = 4.0$  percent
- **Absence due to illness**  
1/1 2003–31/12 2003: 3.0 percent
- **Occupational injuries**  
Injuries reported at Dec. 31, 2003: 5  
(incl. accidents en route)



# Stable platform

**Safety, health, environment and patent protection are all crucial to the success of Active Biotech.**

## Energy-conserving investment

All environmental and safety-related work at Active Biotech is decentralised to the various departments of the Group. Managers and employees are all responsible for ensuring that the targets regarding the interior and exterior environment as well as safety are met. Parallel overall audits are carried out to help departments make the right decisions and adopt the right measures.

Each project is responsible for applying a lifecycle perspective to its products. This concerns everything from the project's own research to contracted manufacturing of candidate drugs and to production. Moreover, Active Biotech's external cooperation partners must have environmental and safety requirements of their own that agree with those of Active Biotech.

In 2004, Active Biotech is investing in measures to modulate the frequency of fan motors in its own facility. This is expected to reduce consumption of electrical energy by approximately 10 percent, and thus help reduce carbon dioxide consumption.

## Responsible use of research animals

Despite rapid development of non-animal-based models of medical research, there is no alternative yet that can fully replace the complex system that a living organism represents. The responsible use of research animals in scientific research is therefore ethically justifiable.

Active Biotech endeavors to replace, reduce and refine its use of research animals as much as possible. When there are no other alternatives, the animal-based research must be planned expediently and conducted in consideration of ethical requirements. Pain, suffering and stress are to be kept at a minimum and preferably eliminated.

Everyone who works with research animals possess the requisite training and skills. The animals are treated with

care, and their health and well-being are given the greatest possible consideration, in a careful balancing of the ethical and scientific interests. The care and maintenance of the animals must also be carried out in a manner that maximises the animals' comfort and prevents the spread of disease.

All work involving animals strictly complies with current local routines and national and international legislation. Legislation and other ethical considerations regarding the care and well-being of the research animals are followed closely and constantly provide the basis for revision and harmonisation of the animal-based research carried out by the company.

## Active patent strategy

A key component of Active Biotech's strategy is to protect its knowledge through strong patents. The patent protection covers inventions of chemical compounds, biotechnological structures, target organs, markers, methods and processes, and uses and equipment related to the company's operations in key markets.

Active Biotech has built up its position in the patent area through 22 strategically defined patent families, primarily in the areas of autoimmunity/inflammation and cancer.

Patents and patent applications refer mainly to the commercially most important markets, such as Europe, the US and Japan.

## High quality awareness

Active Biotech applies the following quality assurance system:

All preliminary testing focusing on safety is carried out in accordance with *GLP (Good Laboratory Practice)*. All raw materials and preparations of new compounds are manufacture in accordance with *GMP (Good Manufacturing Practice)*. Clinical trials are conducted in accordance with *GCP (Good Clinical Practice)*. These sets of regulations are international, and compliance is monitored by the Swedish Medical Products Agency. Active Biotech has a valid permit for GLP and is regularly inspected. The company does not manufacture any drugs for clinical use, nor does it have permission to do so.

Active Biotech is responsible, however, for ensuring that out-sourced manufacturing is performed in an acceptable manner. In the matter of clinical trials, the company follows the procedures stipulated by regulations.

The development of the regulations governing the clinical area, and the overall EU legislation, have made it clear that Active Biotech requires a manufacturing license. Consequently, the company plans to apply for a wholesaler's permit to maintain inventories of and distribute drugs for clinical studies.



NUMBER OF PATENT FAMILIES			
Owned	SAIK, TASQ, 57-57	5	
	TTS	6	
	All other projects	11	
<b>Total owned</b>		22	
<b>On license</b>		6	
<b>Total</b>		<b>28</b>	

PATENT PROTECTION FOR TASQ			
Patent family	Priority area	Status	Year of expiry
"product"	Europe	Granted	2019
	US	Granted	2019
	Japan	In progress	2019
"application"	Europe	In progress	2020
	US	Granted	2020
	Japan	In progress	2020

PATENT PROTECTION FOR SAIK-MS			
Patent family	Priority area	Status	Year of expiry
"product"	Europe	Granted	2019
	US	Granted	2019
	Japan	In progress	2019
"method"	Sweden	In progress	2023
	US	In progress	2023

PATENT PROTECTION FOR TTS			
Patent family	Prioriterat område	Status	Year of expiry
"application"	Europe	Granted	2010
	Japan	Granted	2010
"product"	Europe	Granted	2011
	US	Granted	2016
	Japan	Granted	2011
"product"	Europe	Granted	2015
	US	In progress	2018
	Japan	In progress	2015
"product"	Europe	In progress	2017
	US	Granted	2016
	Japan	In progress	2017
"product och method"	Europe	In progress	2018
	US	In progress	2018
	Japan	In progress	2018
"product"	Europe	In progress	2022
	US	In progress	2021
	Japan	In progress	2022

PATENT PROTECTION FOR 57-57			
Patent family	Priority area	Status	Year of expiry
"product"	Europe	Granted	2019
	US	Granted	2019
	Japan	In progress	2019
"method"	Sweden	In progress	2023
	US	In progress	2023

# *Risks affecting operations*

**An investment in a research-oriented company like Active Biotech may yield a positive return over the long term, but it also carries significant risk. The risk factors considered the most significant for the future trend of the Group's earnings and financial position are as follows:**

## **Ongoing losses and future capital requirements**

To date, Active Biotech's operations have generated a loss before items affecting comparability. Even if the company's projects continue their successful development, the Group will continue to report a loss for several more years.

## **Uncertainty regarding clinical studies**

Before a drug can be launched in the market, its safety and effectiveness must be demonstrated for each stated indication. This is achieved through extensive pre-clinical and clinical studies.

However, the results of pre-clinical studies do not always correctly show the results that may subsequently be obtained in humans. The results from early-stage clinical studies do not always give a reliable indication of the effects that will be seen in more extensive clinical studies. On the contrary, several drug companies have suffered significant setbacks and been forced to terminate development at a late stage of clinical studies despite initially promising trial results.

## **Uncertainty regarding cooperation agreements**

Active Biotech depends on cooperation agreements with external partners to carry out clinical studies, production, marketing and drug distribution. However, there are no guarantees that the necessary agreements can be signed, that they will endure, or that they will actually generate future royalty revenues.

## **Uncertain protection of intellectual property**

Active Biotech's future success is largely dependent on the Group's ability to protect its intellectual rights regarding

compounds, areas of application and production methods, and to protect know-how and research secrets in other ways. Neither patent applications nor even actual patents guarantee complete protection. Moreover, patent disputes can be extremely costly, even should their outcome be in Active Biotech's favour.

## **Stiff competition**

Development in the drug and biotech industries is rapid, and is expected to be significant in the future as well. Some of the company's potential competitors have considerably more resources than Active Biotech.

## **Dependency on key individuals**

Active Biotech is dependent on a limited number of key individuals. If one of them were to leave the Group, it would delay and/or complicate subsequent project development.

## **Drug registration**

All new drugs must be registered with the relevant government authority.

To minimise the risk associated with registration, Active Biotech regularly applies a standard adapted to the requirements of the American Food and Drug Administration (FDA), which the company considers to be one of the most demanding public authorities.

## **Environmental legislation**

The Group's safety routines are considered to be adequate and operations are conducted in accordance with applicable legislation, regulations and guidelines. However, there is no guarantee that environmental damage will not occur.

Active Biotech currently holds all the permits required to conduct its operations. Research and development, however, is subject to continuous regulation by authorities. The conditions governing this can change, causing permits to be withdrawn or restricted.

**Product liability and insurance**

The Group's operations involve the risk of product and environmental liability. While the Group's current insurance coverage is considered to be adequate, the extent of the coverage and compensation amounts are limited. There are thus no guarantees that the insurance would in fact fully cover possible legal claims.

**Financial risks**

Given that its operations are mainly conducted in Sweden, the Group's currency exposure is relatively limited. However, the proportion of costs in foreign currency – mainly USD and EUR – could increase in the future, when the projects advance to later development phases involving more international clinical studies.

The Group does not currently employ forward contracts or options to hedge currency risk.

The operations are limited to research and development, so the Group's level of invoicing is low. Consequently, the credit risk is marginal.

The Group's liquid funds are invested in accordance with a long-term policy established by the Board of Directors, designed to achieve a balance, in terms of risk, between fixed-income and share investments.

**Additional considerations**

Naturally, the above presentation of risk factors is incomplete. A comprehensive assessment of the company and the risks it can face must be based on the other information given in the Annual Report and on a general assessment of the Group's operating environment.



# The share

## Share capital at December 31, 2003

The share capital amounts to SEK 337.4 million and the number of ordinary shares amounts to 33 738 876. Each share has a par value of SEK 10.

During the year, the following changes in the shareholders' equity occurred: at the Annual General Meeting in April 2003, it was decided to reduce the company's share capital by SEK 168.7 million to SEK 112.5 million through an allocation to the statutory reserve; and the share par value was reduced from SEK 25 to SEK 10.

The Annual General Meeting also decided to carry out a new issue with preferential rights for the company's shareholders subject to the following conditions: Any existing share, regardless of class, entitles its holder to subscribe for two new Class B shares at the subscription price of SEK 10. The new issue was fully subscribed, resulting in an increase in the number of class B shares by 22 492 584 and an increase in shareholders' equity by SEK 224.9 million.

The Extraordinary General Meeting held on December 8, 2003, decided to amend the Articles of Association such that

all shares shall be of the same class and carry the same voting rights. The Extraordinary General Meeting also decided to introduce an employee stock options program under which all employees of Active Biotech would be invited to acquire not more than 1 000 000 shares in the company. To secure the company's commitments under the employee stock options program, it was decided to issue a total of not more than 1 330 000 warrants for new subscription to shares on conditions corresponding to those applying to the employee stock options program, to a wholly owned subsidiary. Full exercise of the employee stock options would result in a dilution effect of approximately 3.8 percent of the shareholders' equity.

## Active Biotech share

SEK	2003	2002
Profit/loss after full tax	-11.80	-23.38
Adjusted equity	8.58	33.81
Share price at year-end		
Active Biotech share	61	-
Class A shares	-	24
Class B shares	-	25

## Change share capital

Event	Active Biotech share	Class A shares	Class B shares	Par value	Change in share capital, SEK M	Total share capital, SEK M
1994 Conversion of debenture			9 142 856	1	9.2	55.3
1995 Share consolidation 1:10, par value SEK 10						
New issue 4 Class B shares		-20 840 940	-28 892 930	10	0	55.3
1996 Bonus issue				25	82.9	138.2
1997 Conversion SEK 4 000 000			40 000	25	1.0	139.2
1998 Non-cash issue			2 000 000	25	50.0	189.2
1998 New issue			1 891 496	25	47.3	236.5
1998 New issue, directed			1 400 000	25	35.0	271.5
1998 Conversion SEK 36 000 000			388 810	25	9.7	281.2
1998 Reclassification of A as B		-342 965	342 965	25	0	281.2
1999 Reclassification of A as B		-8 950	8 950	25	0	281.2
2000 Reclassification of A as B		-676 214	676 214	25	0	281.2
2001 Reclassification of A as B		-117 840	117 840	25	0	281.2
2002 Reclassification of A as B		-24 667	24 667	25	0	281.2
2003 Write-down of shareholders' equity				10	-168.7	112.5
2003 New issue. An A or B share carried right to subscribe for two new B shares			22 492 584	10	224.9	337.4
2003 Reclassification of A as B		-16 850	16 850	10	0.0	337.4
2003 Reorganisation as a single share class	33 738 876	-1 128 174	-32 610 702	10	0.0	337.4

## Shareholders

The following reflects circumstances as known to the company at January 31, 2004:

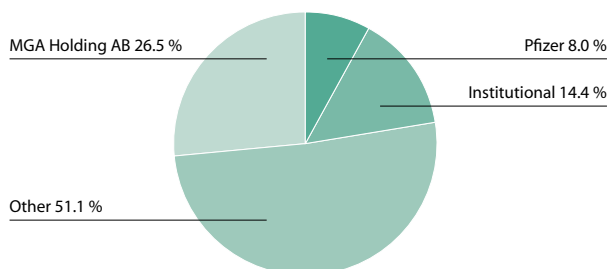
Owner	No. of shares	Holding, %
MGA Holding AB	8 931 028	26.5
Pfizer	2 714 286	8.0
Catella funds	2 110 000	6.3
Nordea SA	1 061 841	3.1
Robur	943 495	2.8
SIF	529 800	1.6
SEB Private Bank	522 775	1.5
Banque Carnegie Luxembourg S.A (Funds)	484 000	1.4
Livförsäkringsaktiebolaget	459 336	1.4
Borgelin	437 400	1.3
Other	15 544 915	46.1
<b>Total</b>	<b>33 738 876</b>	<b>100.0</b>

Max. dilution options percentage	1 330 000	3.8
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## Shareholder statistics

Shareholding interval	No. of owners	% of all shareholders	No. of shares	% of share capital	Average per shareholder
1-1 000	11 869	85.1	3 155 613	9.4	266
1 001-10 000	1 891	13.6	5 245 158	15.5	2 774
10 001-100 000	152	1.1	4 130 974	12.2	27 177
100 001-	30	0.2	21 207 131	62.9	706 904
Total	13 942	100.0	33 738 876	100.0	2 420

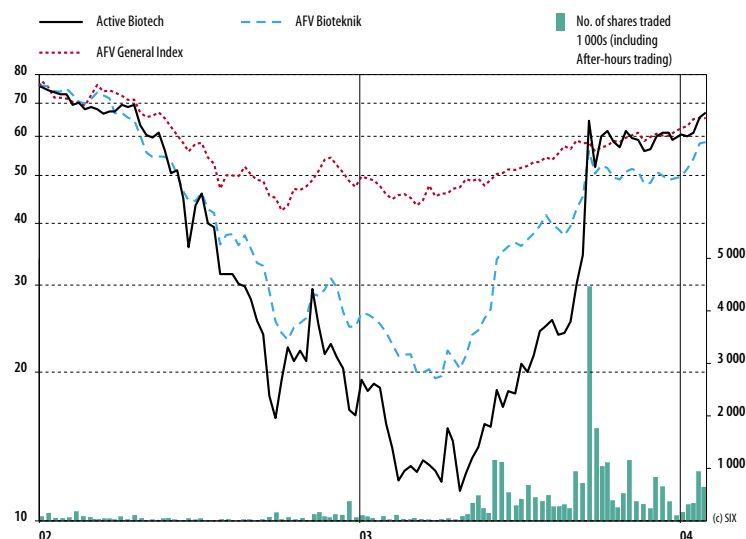
## Shareholder distribution



Total number of shares:	33 738 876
Total number of voting rights:	33 738 876
No. of shareholders:	13 942

Institutional ownership: 14.4 percent  
Closing share price in 2003: SEK 61.00

Price trend, January 2002 to January 2004



# The Directors' report

The Board of Directors and the President & CEO of Active Biotech AB (publ), Swedish corporate registration number 556223-9227 hereby submit their Annual Report and consolidated financial statements for the fiscal year January 1, 2003 to December 31, 2003.

Active Biotech conducts operations as a limited liability company and has its registered office in Lund, Sweden.

## Operations

Active Biotech is a company that focuses on pharmaceutical research and development within medical fields where the immune system plays a central role. The company's research portfolio includes the development of pharmaceuticals for the treatment of autoimmune/inflammatory diseases and cancer.

## The Group

The Group's legal structure is built around the Parent Company Active Biotech AB, which comprises Group-wide functions and asset management, as well as the wholly-owned subsidiary Active Biotech Research AB, which conducts pharmaceutical research in Lund.

The Group also owns 23.8 percent of shares in the associated company, Isogenica Ltd of the UK, which was founded in 2001 to develop molecular biology technologies.

## Research and development

Active Biotech has a broad project portfolio in the areas of autoimmune/inflammatory diseases and cancer. The projects have reached different development stages, ranging from early pre-clinical projects, in the "discovery" phase, to clinical projects in Phases I and II. During the latter part of 2003, the final results were reported from Phase II studies for SAIK-MS against multiple sclerosis and TTS CD2 against cancer.

In summary, research operations developed very favourably during the year, with positive results for all ongoing clinical projects.

Results from the Phase II study for SAIK-MS, Active Biotech's development project against multiple sclerosis, which included approximately 200 patients in four countries, were reported in September 2003. Treatment with 0.3 mg of laquinimod daily reduced disease activity by an average of approximately 30 percent. The treatment had an improved effect in

patients with a high level of disease activity. The degree of disease activity was measured using magnetic resonance imaging (MRI). The results of the study were positive and planning for a Phase III study, to start in 2004, has begun. The process continues of identifying potential collaborative partners for the continued clinical development and registration process, to ensure the fastest possible time to market. In addition to out-licensing revenues, milestone payments and royalties, a partnership agreement entails an assumption of costs being taken over by the partner company, which would strengthen Active Biotech's financial position both in the short and long term.

The clinical Phase II study for TTS CD2 against renal cancer was concluded in December 2003 and reported positive results. The study, which was conducted in the UK, comprised a total of 40 patients, in 68 percent of whom the cancer stabilised and one patient showed a considerable reduction in tumour size.

In addition to the renal-cancer study, the clinical development program for TTS CD2 also comprises a study targeting pancreatic cancer. A total of 20 patients are included in this study, for which results are expected to be reported during the first quarter of 2004.

In parallel with the development of TTS CD2, the company has developed the next generation candidate drug, TTS CD3, with the objective to possess an enhanced activity with a very strong safety profile. This means that it can be administered in considerably higher doses, which, in the TTS CD2 study, was shown to be of significance for the clinical results.

At the beginning of 2003, the company received approval from the US regulatory authority, the FDA, to begin a Phase I dose-escalation study against non-small cell lung cancer in Philadelphia, USA. This study was started during the summer and an additional, complementary study was begun in Oslo, Norway later in the year.

Having achieved the development targets for TTS CD2 and CD3, the company has decided to focus future clinical development of TTS CD3, permitting a more efficient development program and a commercially more attractive product profile. The company's intention is to speed up the continued commercialisation of the project in collaboration with a partner.

For the TASQ project, the company's development project for the oral treatment of prostate cancer, positive results

were reported from the initial Phase I study involving healthy volunteers. An additional Phase I dose-escalation study involving healthy volunteers started during the year to establish relevant doses before the planning of studies involving prostate-cancer patients begins in 2004.

During the fourth quarter, positive pre-clinical results were reported by 57-57, the company's project targeting the autoimmune disease SLE. The candidate drug was shown to inhibit the development of the disease in mice, which spontaneously develop a condition similar to SLE. The continued development process is focusing on up-scaling production of the substance and safety documentation. Phase I clinical trials are expected to start during the first half of 2004.

In addition to projects where pre-clinical or clinical trials are ongoing, Active Biotech's project portfolio includes a number of projects at early stages of research, in the "discovery" phase. Active Biotech's Discovery program is intended to develop candidate drugs that can later be further developed through clinical trials. The company currently has two projects in this phase, I-3D and Chemokines, as well as a number of project concepts being conducted within the framework of "Discovery Opportunities."

Research and development expenditure during the year amounted to SEK 284.2 million (285.2).

#### Comments on the Income Statement

The Group's sales amounted to SEK 0.3 million (3.8).

Research & development-, and administration costs decreased from SEK 320.6 million to SEK 317.1 million. The change is attributable to reduced costs for clinical trials and purchased research services in conjunction with the completion of Phase II studies for SAIK-MS and TTS CD2 during the year.

The Group's operating loss amounted to SEK 336.4 million (loss: 341.1). The change is attributable to lower costs and the fact that items affecting comparability were SEK 4.9 million lower in 2003. The preceding year's earnings were charged with SEK 24.6 million relating to the buy-back of commercial rights for SAIK-MS and TTS, the reversal of provisions and a capital loss in connection with the divestment of a subsidiary, compared with the compensation of SEK 19.7 million in 2003 for lack of guarantees in the sale of a subsidiary in 1996.

Consolidated net financial items amounted to SEK 32.0 million (35.8). During the year, parts of the Group's holdings in the interest hedge fund Nectar and all of its holdings of Swedish listed shares were sold. The capital gains amounted to SEK 2.6 million (27.4). Net interest amounted to SEK 3.7 million (8.7) – dividends received from share investments amounted to SEK 26.0 million (0.6) and exchange-rate differences amounted to a net loss of SEK 0.4 million (loss: 0.9). Participations in the earnings of the associated company Isogenica Ltd amounted to a loss of SEK 2.5 million (loss 3.0).

The Group's pre-tax loss amounted to SEK 307.0 million (loss: 308.3). Tax expense for the year amounted to SEK 0.6 million, which can be compared with the adjustment of preceding years' tax charges and the reversal of tax reserves in 2002, which resulted in a positive tax effect of SEK 9.4 million.

The Parent Company's pre-tax loss amounted to SEK 19.7 million (loss: 20.2).

#### Comments on the balance sheet

The Group's total assets amounted to SEK 345.4 million (467.5). The decline in assets is attributable to the negative cash flow for the year and the related reduction in liquid assets and financial investments.

Tangible fixed assets amounted to SEK 50.3 million (60.2) and mainly consisted of equipment, tools and technical installations. Financial fixed assets amounted to SEK 45.1 million (47.9), of which SEK 42.8 million (44.6) correspond to shares in limited partnership and associated companies. As planned, a new share issue was conducted by the associated company Isogenica Ltd, to which Active Biotech subscribed for SEK 1.0 million in accordance with its ownership share.

The Group's short-term investments and liquid assets amounted to SEK 227.6 million (329.1), of which SEK 45.3 million (169.2) in short-term interest-bearing investments, SEK 182.3 million (123.7) in medium-term interest-bearing investments, and SEK 0.0 million (36.2) in Swedish listed shares.

#### Comments on the cash-flow statement

The Group's negative cash flow for the 2003 full year amounted to SEK 101.4 million (neg: 266.7).

Cash flow from current operations during 2003 was negative in the amount of SEK -288.8 million (neg: 291.7),

cash flow from investing activities was negative in the amount of SEK 1.1 million (1.2) and cash flow from financing activities was positive in the amount of SEK 188.5 million (26.2).

Investments in tangible assets amounted to SEK 5.6 million (3.6), of which SEK 5.5 million (3.2) was attributable to financial leasing. The majority of investments concerned purchases of instruments and laboratory equipment for the research operations in Lund.

The Annual General Meeting on April 10, 2003 approved a rights issue for a maximum of SEK 224.9 million.

The issue was oversubscribed by 24 percent and provided the company with proceeds of SEK 216.7 million after transaction costs.

The short-term loan facility of SEK 26.7 million raised at the end of 2002 was amortised during the first quarter.

#### Liquid funds and financial status

At year-end, current liquid funds and short-term investments amounted to SEK 227.6 million (329.1). This represents SEK 101.4 million in negative cash flow during the period, which is attributable to the earnings trend for 2003, the amortisation of loans and the capital infusion entailed by the new share issue conducted in the spring of 2003.

The Board of Active Biotech has established a policy for the investment of the Group's liquid funds, which allows liquid funds to be invested at low risk in Swedish and foreign shares, interest-bearing securities denominated in Swedish kronor and interest and equity funds. The proportion of shares, including equity funds, may not exceed 40 percent of the total portfolio and the proportion of equity hedge funds may not exceed 50 percent of the total share portfolio. Interest-bearing investments are limited to securities issued by the Swedish government, Swedish mortgage institutions and Swedish banks.

The level of risk in investments decreased during the year with the sale of the company's portfolio of listed Swedish shares and the investment of remaining liquid funds and current assets in interest-bearing securities.

At year-end, liquid funds amounted to SEK 45.3 million (169.2). Short-term investments amounted to SEK 182.3 million (160.0), of which SEK 182.3 million (123.7) entailed short- and medium-term interest-bearing investments. During the year, the discretionarily managed share portfolio,

which, in December 2002, amounted to SEK 36.2 million, was phased out. At year-end, the market value of the short-term investments exceeded their book value by SEK 29.1 million.

Interest-bearing liabilities amounted to SEK 6.7 million (29.4). At the beginning of the year, SEK 26.7 million in external loans were amortised. At year-end, the Group had no external loans. Consolidated shareholders' equity amounted to SEK 289.6 million (380.3) and the equity/assets ratio to 83.8 percent (81.3).

#### Risk factors

A research company such as Active Biotech is characterised by a high operational and financial risk, since the projects in which the company is involved are either at the pre-clinical or the clinical phase, and there are a number of factors that have an impact on the likelihood of commercial success. The earlier in the development chain the project is, the higher the risk, while the risk decreases and the likelihood of reaching the market increases as each project completes the various specified development phases.

The risk level of a project must be weighed against the potential that the project will result in the development of a drug within the major areas of indications which the company addresses.

#### Exchange-rate effects

The Group has a relatively limited currency exposure since operations are mainly conducted in Sweden. Earnings are exposed to exchange-rate fluctuations with regard to the procurement of clinical trials, research services and clinical materials. Operating costs amounted to SEK 336.8 million during the fiscal year, of which about 22 percent corresponded to costs in foreign currencies. The proportion of costs in foreign currencies, principally in USD and EUR, may fluctuate as projects enter the later phases of development with more clinical studies potentially being conducted abroad. Since the Group does not make use of forward contracts or options to hedge foreign-exchange risk, the positive effect of the strengthening of the Swedish crown during the year has affected the income statement.

The company's credit risks are marginal, since the company's operations are only subject to low invoicing levels by virtue of the fact that it engages primarily in research and development.

### Personnel

The average number of employees in the Group amounted to 179 (183), of which 107 were women (110). The number of employees at December 31, 2003 was 176, representing a decline of seven. The average number of employees in the Parent Company, Active Biotech AB, remained unchanged at seven.

Research operations in Lund employed 172 persons (of which, women: 105), compared with 176 (of which, women: 108) in 2002. For further information, see Note 5.

### Incentive programs

The warrant programs stemming from decisions by the Annual General Meetings of April 16, 1998 and April 12, 2000 expired on February 25, 2003 without being exercised.

An Extraordinary General Meeting on December 8, 2003 resolved to implement a free employee stock options program comprising a total of 1.0 million shares for all employees of the Active Biotech Group.

The options program, in combination with the hedging of future social-security costs, comprises a total of 1 330 000 options, entailing a maximum dilution for existing shareholders of 3.8 percent, of which 2.9 percent is attributable to employee allotments.

Options will be allotted on three occasions: Series 1 in December 2003 (330 000 shares), Series 2 in June 2005 (330 000 shares) and Series 3 in June 2006 (340 000 shares).

The exercise price for Series 1 amounts to SEK 90.70 per share, and the exercise price for Series 2 and 3 has been set at 120 percent of the share price during the last five trading days of May 2005 and May 2006 respectively.

### Environmental information

Active Biotech conducts its operations in accordance with the permits issued by the authorities for the company. The company has, for example, a permit from the Swedish Radiation Protection Institute for the handling of radioactive materials, and from the Swedish Board of Agriculture and the Swedish Work Environment Authority regarding genetically modified organisms. In accordance with the Swedish Environmental Code, the company has registered its operations with the County Administrative Board. Inspections by the Swedish Work Environment Authority, the Lund Municipal Environmental Administration and the Swedish Radiation

Protection Institute all achieved satisfactory results. Active Biotech has a well-developed program for the sorting of waste at source and for the destruction of environmentally hazardous waste, and works actively to minimise energy consumption and the use of environmentally hazardous substances.

Active Biotech is not involved in any environmental disputes.

### Other information

In July 2001, Active Biotech divested its previously wholly owned subsidiary SBL Vaccin AB to UK company PowderJect Pharmaceuticals Plc. The purchase price amounted to USD 50 million with two additional payments of at most USD 10 million on registration of the travel vaccine Dukoral in Europe and of at most USD 10 million on registration of the vaccine ETEC in the US. In addition, Active Biotech has rights to royalties on sales of Dukoral and ETEC on the condition that each of the vaccines is registered before July 3, 2011 and that sales of Dukoral exceed USD 40 million annually and that sales of ETEC amount to USD 60 million annually. Royalty revenues are limited to a maximum of USD 20 million for each vaccine.

On June 12, Active Biotech received notice that arbitration had been initiated by PowderJect Pharmaceuticals Plc on the basis of claimed inaccurate assumptions in the transfer agreement for the sale of SBL Vaccin AB. The claim amounts to a maximum of USD 20 million. Active Biotech views the claim as groundless and an approval is expected during the year.

On July 25, the Committee for Proprietary Medicinal Products, the scientific committee of the European regulatory authority, the EMEA, gave a positive recommendation for the registration of the travel vaccine Dukoral and approval is expected during 2004.

### Outlook

At the outset of 2004, operations are being focused on the out-licensing of the SAIK-MS project, on the planning this entails and the start of Phase III trials for this project.

During the early part of the year, the TTS CD2 Phase II study against pancreatic cancer will be concluded. In addition, clinical Phase I trials for the TTS CD3 project are expected to continue during the year. Clinical Phase I trials for the TASQ and 57-57 projects are planned to begin during the year.

In parallel with these activities, discussions are being conducted with potential partners on the various projects. For the time being, it is not possible to state a specific point at which possible out-licensing or partnership agreements will start.

Ongoing partnership negotiations regarding the key projects, the milestone payments from PowderJect Pharmaceuticals Plc in connection with the European registration of the Dukoral diarrhoea vaccine, and a lower cost base in 2004 are expected to ensure the financial strength necessary for operations.

#### Events after the balance sheet date

On February 27, 2004, the company announced plans for a new strategic direction with the objective of focusing operations on projects in the clinical phase. The key expertise required to support projects in, or close to entering, the clinical phase are to be reinforced. A number of mature projects in the research will be placed on hold, with the possibility of being reactivated later. All projects in the discovery phase and related activities will be discontinued.

The new business strategy means that the company will have to make substantial personnel reductions and notice of termination of 98 employees, of a total 176, has been submitted.

These measures entail a substantial reduction in operating costs. Total operating costs are expected to decrease by about SEK 100 million annually with full effect from 2005.

#### Dividend

The Board of Directors proposes that no dividend be paid for the 2003 fiscal year.

#### Report on the work of the Board

The Board decides on the overall strategy of the Group, its organisation and administration pursuant to the Swedish Companies Act (1975:1385).

At the end of the year, the Board consisted of six members elected by the Annual General Meeting, two employee representatives and two deputy employee representatives. Other company officials take part in Board meetings as required in a reporting or administrative capacity. For individual information on Board members, see pages 59-60.

Nine Board meetings at which minutes were kept were held during the year. The President & CEO has kept both

the Chairman of the Board and the other Board members informed about developments within the company on an ongoing basis. Important issues addressed by the Board include the following:

- Progress of the research projects
- Business development projects
- Partnership strategy and discussions with prospective partners
- Active Biotech's strategic focus
- Information about the financial accounts
- Budget work

The nomination process for the Board involves the three largest shareholders, during the fourth quarter, each appointing a representative, who together and under the leadership of the Chairman of the Board prepare a proposal regarding the composition of the Board, which is presented to the Annual General Meeting for decision.

#### Remuneration issues are dealt with by the entire Board.

The company's auditors, who are elected by the Annual General Meeting, report on their auditing work directly to the Board at Board meetings.

Activities for adaptation to the IFRS (International Financial Reporting Standards) accounting principles, which become effective in 2005

Effective January 1, 2005, the company will apply IFRS in accordance with an EU decree applying to all listed companies within the EU. Reports for 2004 shall also include figures for 2004 recalculated in accordance with IFRS.

During 2003, Active Biotech, in collaboration with the company's auditors, identified the areas that will be affected by the introduction of IFRS. Based on the company's operations, the reporting of financial instruments, pensions and other employee benefits, and leasing contracts will be the areas primarily affected by the introduction of IFRS.

It is expected that it will be possible to conduct internal reporting in accordance with both current regulations and IFRA in parallel during the latter part of the year.

Since Swedish GAAP agrees relatively well with the existing IFRS standards in most areas, Active Biotech judges that the effect on financial reporting will not be extensive, although IFRS requires considerably more extensive supplementary information than current Swedish regulations.

# Income Statement

SEK thousands	note	Group		Parent Company	
		2003	2002	2003	2002
Net sales	1	335	3 847	3 500	6 528
Cost of goods sold		-	200	-	-
<b>GROSS PROFIT</b>		<b>335</b>	<b>4 047</b>	<b>3 500</b>	<b>6 528</b>
Administrative expenses	2, 3	-32 896	-35 405	-32 853	-35 237
Research and development expenses	2	-284 169	-285 170	-	-
Revenues affecting comparability	4	-	2 698	-	-
Expenses affecting comparability	4	-19 707	-27 283	-19 707	-26 484
<b>OPERATING LOSS</b>	5	<b>-336 437</b>	<b>-341 113</b>	<b>-49 060</b>	<b>-55 193</b>
Participations in the earnings of associated companies	6	-2 501	-3 014	-	-
<i>Profit/loss from financial investments</i>					
Profit/loss from shares in subsidiaries	7	-	-	-	2 699
Profit/loss from participations in associated companies	6	-	-	-2 871	-4 039
Interest revenue and similar items	8	34 711	38 229	32 650	36 509
Interest expenses and similar items	9	-2 760	-2 425	-383	-182
<b>LOSS AFTER FINANCIAL ITEMS</b>	10	<b>-306 987</b>	<b>-308 323</b>	<b>-19 664</b>	<b>-20 206</b>
Tax on profit for the year	11	-612	9 432	-612	369
<b>NET LOSS FOR THE YEAR</b>		<b>-307 599</b>	<b>-298 891</b>	<b>-20 276</b>	<b>-19 837</b>
Loss for the year		-307 599	-298 891		
Earnings per share, before dilution, SEK	12	-11.80	-23.38		
Weighted number of ordinary shares before dilution (thousands)		26 062	12 783		
Earnings per share after dilution, SEK	12	-11.80	-23.38		
Weighted number of ordinary shares after dilution (thousands)		26 062	12 783		
Proposed dividend per share		None	None		

# Balance Sheet

SEK thousands	note	Group		Parent Company	
		Dec 31, 03	Dec 31, 02	Dec 31, 03	Dec 31, 02
<b>ASSETS</b>					
Land improvements		491	519	-	-
Equipment, tools, fixtures and fittings		49 812	59 677	480	520
<b>Total tangible fixed assets</b>	13	<b>50 303</b>	60 196	<b>480</b>	520
Shares in subsidiaries	14	-	-	377 831	377 831
Participations in associated companies	14	2 767	4 616	2 767	4 616
Other long-term securities	14	40 000	40 000	40 000	40 000
Other long-term receivables		2 310	3 300	222	279
<b>Total financial fixed assets</b>		<b>45 077</b>	47 916	<b>420 820</b>	422 726
<b>Total fixed assets</b>		<b>95 380</b>	108 112	<b>421 300</b>	423 246
Accounts receivable		2 595	4 039	2 586	3 883
Receivables from subsidiaries		-	-	64 669	65 979
Tax receivables		1 897	1 897	-	-
Other receivables	15	8 063	11 831	3 113	7 129
Pre-paid costs and accrued revenues	16	9 900	12 494	1 934	2 099
<b>Total short-term receivables</b>		<b>22 455</b>	30 261	<b>72 302</b>	79 090
Short-term investments	17, 21	182 272	159 979	182 272	159 979
Cash and bank balances		45 293	169 153	34 734	161 059
<b>Total short-term investments</b>	18	<b>227 565</b>	329 132	<b>217 006</b>	321 038
<b>Total current assets</b>		<b>250 020</b>	359 393	<b>289 308</b>	400 128
<b>TOTAL ASSETS</b>		<b>345 400</b>	467 505	<b>710 608</b>	823 374

SEK thousands	note	Group		Parent Company	
		Dec 31, 03	Dec 31, 02	Dec 31, 03	Dec 31, 02
<b>SHAREHOLDER'S EQUITY AND LIABILITIES</b>					
<i>Restricted equity</i>					
Share capital		337 389	281 157	337 389	281 157
Restricted reserves		186 367	332 810	184 926	325 269
		<b>523 756</b>	613 967	<b>522 315</b>	606 426
<i>Unrestricted equity</i>					
Unrestricted reserves		73 421	65 191	-299 808	-289 200
Loss for the year		-307 599	-298 891	-20 276	-19 837
		<b>-234 178</b>	-233 700	<b>-320 084</b>	-309 037
<b>Total shareholders' equity</b>	19	<b>289 578</b>	380 267	<b>202 231</b>	297 389
Long-term interest-bearing liabilities	20, 21	4 930	2 679	-	-
<b>Total long-term liabilities</b>		<b>4 930</b>	2 679	<b>0</b>	0
Liabilities to credit institutes		-	26 700	-	26 700
Accounts payable, trade		25 029	32 923	1 725	968
Liabilities to subsidiaries		-	-	497 680	490 685
Tax liabilities		3 256	2 535	3 256	2 535
Other current liabilities	22	4 727	2 723	1 079	873
Accrued costs and pre-paid revenues	23	17 880	19 678	4 637	4 224
<b>Total short-term liabilities</b>		<b>50 892</b>	84 559	<b>508 377</b>	525 985
<b>TOTAL SHAREHOLDERS' EQUITY AND LIABILITIES</b>		<b>345 400</b>	467 505	<b>710 608</b>	823 374
Assets pledged	24	3 000	40 347	3 000	40 347
Contingent liabilities	24	-	18 374	7 575	24 366

# Changes in shareholders' equity

SEK thousands	note 19	Group			Parent Company		
		Share capital	Restricted reserves	Unrestricted equity	Share capital	Restricted reserves	Unrestricted equity
<b>Shareholders' equity, December 31, 2001</b>		<b>281 157</b>	<b>442 994</b>	<b>-45 368</b>	<b>281 157</b>	<b>425 977</b>	<b>-100 708</b>
Exchange-rate differences		-	-9 426	9 801	-	-	-
Treatment of profit/loss in preceding year		-	-100 688	100 688	-	-100 708	100 708
Transfers between restricted and non-restricted equity		-	-70	70	-	-	-
Loss for the year		-	-	-298 891	-	-	-19 837
Group contribution		-	-	-	-	-	-289 200
<b>Shareholders' equity, December 31, 2002</b>		<b>281 157</b>	<b>332 810</b>	<b>-233 700</b>	<b>281 157</b>	<b>325 269</b>	<b>-309 037</b>
Exchange-rate differences		-	-8 768	8 960	-	-	-
Treatment of profit/loss in preceding year		-	-309 037	309 037	-	-309 037	309 037
Transfers between restricted and non-restricted equity		-	2 668	-2 668	-	-	-
Profit for the year		-	-	-307 599	-	-	-20 276
Reduction of share capital		-168 694	168 694	-	-168 694	168 694	-
New share issue		224 926	-	-8 208	224 926	-	-8 208
Group contribution		-	-	-	-	-	-291 600
<b>Shareholders' equity, December 31, 2003</b>		<b>337 389</b>	<b>186 367</b>	<b>-234 178</b>	<b>337 389</b>	<b>184 926</b>	<b>-320 084</b>

# Cash-flow statement

SEK thousands	note 25	Group		Parent Company	
		2003	2002	2003	2002
<i>Operating activities</i>					
Profit/loss after financial items		-306 987	-308 323	-19 664	-20 206
Adjustments for items not included in the cash flow, etc.		18 857	23 537	2 911	5 382
		<b>-288 130</b>	-284 786	<b>-16 753</b>	-14 824
Taxes paid		0	-916	0	-319
<b>Cash flow from current operations before changes in working capital</b>		<b>-288 130</b>	-285 702	<b>-16 753</b>	-15 143
<i>Cash flow from changes in working capital</i>					
Increase(-)/reduction(+) in current receivables		8 595	-3 397	6 845	-4 332
Increase(-)/reduction(+) in current liabilities		-9 294	-2 616	-5 120	-4 340
<b>Cash flow from operating activities</b>		<b>-288 829</b>	-291 715	<b>-15 028</b>	-23 815
<i>Investment activities</i>					
Sales of subsidiaries		-	-818	-	-
Acquisition of tangible fixed assets		-67	-408	-	-12
Acquisition of financial fixed assets		-1 022	-	-1 022	-
<b>Cash flow from investing activities</b>		<b>-1 089</b>	-1 226	<b>-1 022</b>	-12
<i>Financing activities</i>					
New share issue		216 718	-	216 718	-
Loans raised		-	26 700	-	26 700
Amortisation of loans		-26 700	-	-26 700	-
Amortisation of financial leasing liabilities		-1 534	-508	-	-
Group contributions paid		-	-	-278 000	-270 000
<b>Cash flow from financing operations</b>		<b>188 484</b>	26 192	<b>-87 982</b>	-243 300
<b>Cash flow for the year</b>		<b>-101 434</b>	-266 749	<b>-104 032</b>	-267 127
<b>Liquid funds, January 1</b>		<b>329 132</b>	596 064	<b>321 038</b>	588 165
<b>Exchange-rate differences in liquid funds</b>		<b>-133</b>	-183	-	-
<b>LIQUID FUNDS AT YEAR-END</b>		<b>227 565</b>	329 132	<b>217 006</b>	321 038

# Accounting principles

The Annual Report has been prepared in accordance with the Annual Accounts Act and the recommendations of the Swedish Financial Accounting Standards Council and its Emerging Issues Task Force. Active Biotech monitors and applies the accounting recommendations currently of relevance to the Group.

Effective 2003, the following new recommendations of the Swedish Financial Accounting Standards Council:

- RR 22 Presentation of Financial Statements
- RR 25 Segment Reporting
- RR 26 Events after the Balance Sheet Date
- RR 27 Financial Instruments: Disclosures and Presentation

None of the recommendations introduced have entailed any changes in accounting principles and consequently no recalculation of comparative figures.

Amounts are expressed in SEK thousands, unless otherwise indicated.

## Consolidated accounts

The consolidated accounts include the Parent Company Active Biotech AB and those companies in which the Parent Company directly or indirectly holds more than 50 percent of the voting rights or exercises decisive influence as a result of agreements.

The consolidated financial statements have been prepared in accordance with the Swedish Financial Accounting Standards Council's recommendation on consolidated Financial statements (RR1:00) and applying the purchase method. The assets and liabilities of acquired subsidiaries are entered at market value according to the established acquisition analysis. These market values, together with direct costs attributable to the acquisition, constitute the Group's acquisition costs. The difference between the acquisition value of the subsidiary's shares and the acquisition value estimated by the acquisition analysis of acquired identifiable assets and liabilities are entered as consolidated goodwill, or alternatively, negative goodwill.

The earnings of acquired companies are included in the consolidated accounts from the time of acquisition.

Companies divested during the year are included in consolidated earnings up until the time of divestment.

## Translation of foreign subsidiaries

In the preparation of the consolidated financial statements, foreign subsidiaries are translated according to the current-rate method, since the Group's foreign subsidiaries form independent units in which the Parent Company has a net investment. The current-rate method entails all assets, provisions and liabilities being translated at the exchange rate on the closing date and that all items in the income statement are translated at the average exchange rate for the year. Exchange-rate differences that arise are charged directly against shareholders' equity without affecting earnings for the year.

## Associated companies

Any company which is not a subsidiary but where the Parent Company directly or indirectly holds 20 percent of the total votes, or where the Parent Company directly or indirectly exercises a significant influence is considered an associated company.

Participations in associated companies are accounted for according to the equity method. The value of holdings in associated companies reported in the consolidated accounts is equivalent to the Group's share in the shareholders' equity of the associated companies and any remaining consolidated surplus or deficit value. In the consolidated income statement, "Profit/loss from participations in associated companies" includes the Group's participations in the earnings of associated companies after financial income and expenses, adjusted for any amortisation or reversals of acquired surplus or deficit values. The Group's share of the reported taxes of the associated company is included directly in consolidated tax expenses. Participations in earnings generated following the acquisition of associated companies not yet realised through dividends are placed in the equity method reserve, which forms part of the Group's restricted shareholders' equity.

The operations conducted by associated company Iso-genica Ltd are fundamentally different from the Group's other operations and is consequently reported after operating profit/loss.

**Elimination of transactions between Group companies**

Intra-Group receivables and liabilities, transactions between Group companies and related unrealised gains are eliminated in their entirety. Unrealised losses are eliminated in the same way as unrealised gains, unless a need to conduct a write-down exists.

**Classifications**

Fixed assets, long-term liabilities and provisions primarily consist of amounts that are expected to be recovered or paid after more than 12 months from the balance-sheet date. Current assets and liabilities primarily consist of amounts that are expected to be recovered or paid within 12 months from the balance-sheet date.

**Valuation principles**

Assets and liabilities have been valued at their acquisition value unless otherwise indicated below.

**Intangible fixed assets**

In accordance with the Swedish Financial Accounting Standards Council's recommendation RR 15 Intangible Assets, intangible assets are reported in the balance sheets when it is likely that the future financial benefits attributable to those assets will become available to the company and when the acquisition value of the assets can be calculated in a reliable manner.

Since the period in which the company's research and development projects are expected to be registered as pharmaceuticals lies well into the future, it is highly uncertain when possible future financial benefits will become available to the company. Development expenditure is only capitalised on the condition that it is technically and financially possible to realise the asset, that the intention is to utilise the asset in operations and that this is possible, or that the asset will be sold, and that its value can be calculated in a reliable manner. All research expenditure is charged against earnings on an ongoing basis.

Expenses in connection with patents, technology and brand rights and other similar assets are not capitalised but are expensed against earnings on an ongoing basis. No assets of this kind have been acquired.

**Fixed assets and depreciation**

Tangible fixed assets are reported at their acquisition value following deductions for straight-line depreciation and possible write-downs. The acquisition value includes the purchase price, including customs and excise duties and costs directly attributable to getting the asset into place and into condition for use in accordance with the purpose of the purchase. The purchase price is reduced by discounts, etc. Examples of directly attributable costs included in acquisition value are costs for delivery, handling, installation, land certification, consultant fees and legal services. Further expenses are added to the acquisition value to the extent that the performance of the asset is improved in comparison with the level applicable upon its original acquisition. All other additional expenses are reported as costs during the period in which they are incurred. Straight-line depreciation is based on original acquisition values less residual value. Straight-line depreciation is implemented over the asset's useful life and is reported as an expense in the income statement.

In accordance with the Swedish Financial Accounting Standards Council's recommendation RR 17 Impairment of assets, an evaluation is made on each balance-sheet date as to whether there are any indications of a decline in value.

Straight-line depreciation is applied with the following percentages:

Plant and machinery	10-20%
Computer equipment	20-30%
Land improvements	3-14%

**Shares and participations**

Shares and participations are valued in accordance with the Annual Accounts Act at the lower of acquisition value and fair value item for item.

**Short-term investments**

Short-term investments are valued in accordance with the Annual Accounts Act at the lower of acquisition value and fair value item for item.

### Financial instruments

The balance sheets include all financial instruments with the exception of derivative instruments.

A financial asset or liability is included in the balance sheets when the company becomes a party to the contractual terms of the instrument. Accounts receivable are included in the balance sheets upon invoicing. Accounts payable are included when invoices have been received.

A financial asset is removed from the balance sheets when the contractual rights have been realised, have matured or when the company loses control over them. The same applies for any part of a financial asset. A financial liability is removed from the balance sheets once the contractual commitments have been fulfilled or otherwise nullified. The same applies to any part of a financial liability.

### Valuation of receivables and liabilities

Receivables have been included in the amounts in which they are expected to be received. Liabilities have been included in nominal amounts.

Receivables and liabilities in foreign currencies have been translated at the exchange rate on the balance-sheet date in accordance with the Swedish Financial Accounting Standards Council's recommendation RR 8 The Effects of Changes in Foreign Exchange Rates. Exchange-rate differences on current receivables and liabilities are included in operating loss/profit, while differences pertaining to financial receivables and liabilities are included among financial items.

### Borrowing costs

Borrowing costs are reported in accordance with the Swedish Financial Accounting Standards Council's recommendation RR 21 Borrowing Costs, and are charged against earnings in the period to which they pertain, regardless of how the borrowed funds have been used. The company does not capitalise borrowing costs.

### Reporting of revenues

Active Biotech currently receives marginal revenues for invoiced research services. These are reported as revenue in the reporting period during which the work is conducted.

In the out-licensing of research projects, non-recurring revenues in connection with contracts are recognised on the contract date. Any partial payments are recognised as revenue as and when Active Biotech meets the agreed criteria and agreement has been reached with the counterparty. Possible future royalty revenues are recognised in accordance with the financial import of the agreements.

Interest revenues are distributed over time to provide a uniform return during the lifetime of the holding.

Dividends are recognised as revenue when the right to receive payment is considered secure.

### Income taxes

The company applies the Swedish Financial Accounting Standards Council's recommendation RR 9 Income Taxes. Total tax comprises current taxes and deferred taxes. Deferred taxes are calculated in accordance with the balance-sheet method based on temporary differences between the reported and taxation values of assets and liabilities.

Deferred tax receivables pertaining to loss carryforwards are reported to the extent that it is likely that the loss carryforwards can be settled against future surplus. Since it is not deemed likely that the Group will report taxable revenues exceeding its accumulated loss carryforwards in the near future, no deferred tax receivables are reported.

### Leasing

The Swedish Financial Accounting Standards Council's recommendation RR 6:99 Leasing Agreements, is applied in the consolidated accounts for leasing agreements that have been entered into. Leasing is classified in the consolidated accounts as either financial or operational leasing. Financial leasing applies when the financial risks and benefits associated with ownership have, to all intents and purposes, been transferred to the lessee. Where this is not the case, operational leasing applies. Assets leased through financial leasing agreements have been reported as assets in the consolidated balance sheet. The commitment to pay future leasing fees has been reported as long-term and current liabilities. These assets are subject to straight-line depreciation while leasing fees are reported as interest and amortisation of liabilities.

### Items affecting comparability

The Swedish Financial Accounting Standards Council's recommendation RR 4 Reporting of Extraordinary Revenues and Expenses and Comparative Information is applied, with the result that the effect on earnings of special events and transactions is reported separately in the income statement.

### Segment reporting

In accordance with the Swedish Financial Accounting Standards Council's recommendation RR 25 Segment Reporting, companies shall provide information on the various parts of their operations according to types of business and geographic segments.

Since operations within the Active Biotech Group are organised as a cohesive unit, with similar risks and opportunities for the products and services produced, the company reports its operations jointly as a single type of operations forming its primary segment and its geographic distribution as its secondary segment. Because all operations are conducted in Sweden, all of the Groups earnings, assets and investments are reported as a single secondary segment.

### Employee remunerations

Both defined-benefit and defined-contribution pension plans exist within the Group. The company pays pension premiums to separate legal entities and has no legal commitment or informal obligation to pay further premiums if these should lack the assets necessary to provide the promised benefits.

Active Biotech has chosen to subscribe to the Alecta pension plan for all salaried employees of the company. This means that the company shall report its proportional share of the managed assets and costs associated with the plan. Alecta is currently unable to provide sufficient information for the Group to be able to report its proportional share of defined-benefit commitments and the managed assets and costs associated with the plan. Consequently, information pertaining to the Group's proportional share of surplus or deficit in the plan is also lacking. For this reason, the plan is reported as if it were a defined-contribution plan, although the ITP plan is actually a defined-benefit plan. Surpluses occurring in the

plan are determined by the General Board of Alecta. Surpluses are primarily used to index-link the value of pensions and for paid-up policies. The Group's future premiums may be affected by future premium reductions determined by Alecta.

The Group's payments with regard to defined-contribution plans are reported as costs during the period in which employees conducted the services to which the payments are related.

### Provisions

In accordance with the Swedish Financial Accounting Standards Council's recommendation RR 16 Provisions, Contingent Liabilities and Contingent Assets, provisions are reported when the Group has, or may be considered to have a commitment as the result of events and it is likely that payment will be demanded to meet that commitment. A condition for this is that it is possible to make a reliable estimate of the amount that is to be paid.

### Contingent liabilities

A contingent liability is reported as such in memorandum items when a possible commitment exists stemming from events that have occurred, the validity of which can only be confirmed by the occurrence or absence of one or more future events not entirely under the company's control. Alternatively, a contingent liability may be reported when a commitment exists stemming from events but which is not reported as a liability or provision since it is unlikely that an outflow of resources will be necessary, or the size of the commitment cannot be calculated with sufficient accuracy.

### Transactions with closely-related parties

#### *Close relationships entailing influence over decisions*

The Parent Company has a close relationship with its subsidiaries entailing influence over decisions, see Note 14.

#### *Closely-related party transactions*

With regard to salaries, other remunerations, costs and commitments related to pensions and similar benefits, as well as severance agreements for the members of the Board, the President and other Senior Executives, see Note 5.

**Associated companies**

No transactions with associated companies have taken place during the year. The associated company has no receivables or liabilities relative to the Group.

**Group contributions**

Group contributions are reported against shareholders' equity among earnings carried forward.

**Write-downs**

The company follows the Swedish Financial Accounting Standards Council's recommendation RR 17 Impairment of

assets. The reported values of the Group's assets are verified at each balance-sheet date to determine whether any write-downs are necessary. If there are any such indications, the recoverable value of the asset is determined as the higher of its utilisation value and its net realisable value. A write-down is made if the recoverable value is less than the carrying amount.

**Group details**

Of the Parent Company's total purchases, measured in SEK, 0 percent of purchases and 100 percent of sales are attributable to other companies within the entire group of companies to which the company belongs.

# Definitions

**Return on shareholders' equity**

Profit/loss for the year as a percentage of average shareholders' equity.

**Return on capital employed**

Operating profit/loss after net financial items plus financial expenses, as a percentage of average capital employed. Capital employed has been calculated as total assets less non-interest bearing liabilities.

**Equity/assets ratio**

Shareholders' equity plus minority interests, as a percentage of total assets.

**Proportion of risk-bearing capital**

Shareholders' equity plus minority interests and deferred tax liabilities as a percentage of the balance sheet total.

**Interest coverage ratio**

Operating profit/loss after financial items plus financial expenses, divided by financial expenses.

**Net debt/equity ratio**

Net interest-bearing liabilities (interest-bearing liabilities less short-term investments) divided by shareholders' equity, including minority interests.

# Notes

## Note 1 Net sales

Net sales per market	Group		Net sales per type of revenue	Group	
	2003	2002		2003	2002
SEK thousands			SEK thousands		
Sweden	335	3 608	Research services	335	819
Denmark	-	108	Licensing revenues	-	3 028
Rest of Europe	-	63	Total	335	3 847
Total Europe	335	3 779			
Rest of the world	-	68			
Total	335	3 847			

## Note 2 Depreciation according to plan

SEK thousands	Group			
	2003		2002	
	Tangible assets	Total assets	Tangible assets	Total assets
<i>Distribution by function</i>				
Administration	40	40	164	164
Research and development	15 445	15 445	17 491	17 491
Total depreciation	15 485	15 485	17 655	17 655
<i>Type of assets</i>				
Equipment, tools, fixtures and fittings	15 457	15 457	17 626	17 626
Land improvements	28	28	29	29
Total depreciation	15 485	15 485	17 655	17 655

Depreciation for financial leasing assets in the Group has been entered at SEK 2 087 thousands (842 thousands) and refers to equipment, tools, fixtures and fittings within the research and development function

### PARENT COMPANY

The Parent Company's depreciation for 2003 amounted to SEK 40 thousands (109 thousands) and related to equipment, tools, fixtures and fittings within the administration

## Note 3 Auditors' remuneration

SEK thousands	Group and Parent Company	
	2003	2002
KPMG, auditing assignments	661	333
KPMG, other assignments	846	115

## Note 4 Items affecting comparability

SEK thousands	Group		Parent Company	
	2003	2002	2003	2002
Remunerations for affirmed lack of guarantees in sale of subsidiary Peltor AB in 1996	-19 707	-	-19 707	-
Buyback of future commercial rights	-	-26 484	-	-26 484
Capital gains from divestment of subsidiaries	-	-799	-	-
<b>Total costs affecting comparability</b>	<b>-19 707</b>	<b>-27 283</b>	<b>-19 707</b>	<b>-26 484</b>
Reversal of allocated costs in connection with divestment of subsidiaries	-	2 698	-	-
<b>Total revenues affecting comparability</b>	<b>0</b>	<b>2 698</b>	<b>0</b>	<b>0</b>

In 1996, Active Biotech sold its subsidiary Peltor Holding AB to Aero Corporation of the US. The buyer's claims for lack of guarantees concerned additional taxes levied against Peltor Holding AB subsidiary Peltor AB in accordance with a ruling by the Administrative Court of Appeal in February 2002. The ruling was appealed to the Supreme Administrative Court, which announced in 2003 that the appeal had not been granted. This confirmed the earlier ruling by the Administrative Court of Appeal.

As announced in the new share-issue prospectus in 2003, Active Biotech has accepted responsibility for the payment of the tax amount levied.

The main reason for the company choosing to classify the cost as an item affecting comparability is the fact that Peltor Holding AB's operations are of an entirely different nature than those currently conducted by Active Biotech and that the divestment occurred before Active Biotech's current focus of operations was established.

**Note 5 Employees, personnel expenses and Board members' fees**

Personnel, number of employees	2003		2002	
	Number of employees	of which, women	Number of employees	of which, women
<b>Parent Company</b>				
Sweden	7	2 (29 %)	7	2 (29 %)
Parent Company total	7	2 (29 %)	7	2 (29 %)
<b>Subsidiaries</b>				
Sweden	172	105 (61 %)	176	108 (61 %)
<b>Group total</b>	<b>179</b>	<b>107 (60 %)</b>	<b>183</b>	<b>110 (60 %)</b>

Gender distribution in Senior Management	2003		2003	
	2003	2002	July 1-Dec 31	Jan 1-Dec 31
	Proportion women		Sick leave in percent	
<b>Parent Company</b>			<b>Group total</b>	
Board of Directors	(13 %)	(13 %)	All employees	3.1 %
Other Senior Management	(20 %)	(20 %)	Men	1.3 %
<b>Group total</b>			Women	4.2 %
Board of Directors	(13 %)	(13 %)	Employees under 30 years of age	2.3 %
Other Senior Management	(20 %)	(20 %)	Employees 30-49 years of age	2.3 %
			Employees over 49 years of age	5.1 %
			Absence of at least 60 days as % of total absence due to illness	53.2 %
				54.0 %

Salaries, other remunerations and social security costs	2003			2002		
	Board and CEO	Of which, earnings-related salary	Other employees	Board and CEO	Of which, earnings-related salary	Other employees
SEK thousands						
Parent Company						
Sweden	4 253	-	7 254	4 653	-	6 687
<b>Total Parent Company</b>	<b>4 253</b>	<b>0</b>	<b>7 254</b>	<b>4 653</b>	<b>0</b>	<b>6 687</b>
Subsidiaries in Sweden	-	-	62 418	-	-	61 802
<b>Total subsidiaries</b>	<b>0</b>	<b>0</b>	<b>62 418</b>	<b>0</b>	<b>0</b>	<b>61 802</b>
<b>Group total</b>	<b>4 253</b>	<b>0</b>	<b>69 672</b>	<b>4 653</b>	<b>0</b>	<b>68 489</b>

SEK thousands	Group		Parent Company	
	2003	2002	2003	2002
Board and CEO	4 253	4 653	4 253	4 653
Other employees	69 672	68 489	7 254	6 687
<b>Total salaries and remunerations</b>	<b>73 925</b>	<b>73 142</b>	<b>11 507</b>	<b>11 340</b>
Social security costs	41 429	39 217	7 969	8 199
of which, pension costs	16 742	14 781	4 223	4 476
(of which, to Board and CEO)	1 292	1 007	1 292	1 007
<b>Total payroll costs</b>	<b>115 354</b>	<b>112 359</b>	<b>19 476</b>	<b>19 539</b>

**Senior management's conditions of employment**

**Principles:** The Board of Directors will be remunerated in accordance with the decisions of the Annual General Meeting. Remuneration paid to The President & CEO and senior executives consists of fixed salary, other benefits and pensions as indicated below. Decisions on remunerations to the President and CEO are made by the Board. Remunerations for other senior executives are determined jointly by the Board and the President & CEO.

**The Board:** In accordance with a resolution of the Annual General Meeting, a total fee of SEK 750 000 was paid during 2003 to Board Members who are not employed within Active Biotech. The Chairman of the Board received a fee of SEK 250 000. The other members of the Board not employed by the company received fees of SEK 125 000 each (four members). The members of the Board have not received any other remuneration.

**President & CEO:** In 2003, the President & CEO Sven Andréasson received remuneration and other benefits of SEK 3 290 763 (of which other benefits amounted to SEK 2 720). Retirement is at 65 years of age with a defined-contribution pension. Pension premiums shall amount to 30% of pensionable income, which consists of basic salary. A mutual period of notice of 12 months applies to both the company and the President & CEO. Severance pay will not be paid and there are no loans. In December 2003, the President & CEO was allocated 11 200 Series 1 employee stock options, in accordance with a decision by the Extraordinary General Meeting on December 8.

**Other senior executives:** The four other senior executives received remuneration and other benefits of SEK 6 107 282 (of which other benefits amounted to SEK 233 251). A mutual period of notice of six months applies to both the company and the senior executives. No severance pay will be paid. Pension benefits for other senior executives are payable in the interval between ITP conditions and up to 25 percent of salary. Retirement age is between 60 and 65 years of age with defined-contribution pensions. Senior executives have not been granted any loans. In December 2003, the other senior executives were together allocated 30 000 Series 1 employee stock options.

#### **Incentive programs from 1998 and 2000**

On each of two occasions, April 16, 1998 and April 12, 2000, the Annual General Meeting has resolved to issue at most 500 000 warrants for sale to employees of the Active Biotech Group.

On the first occasion, 489 350 warrants were issued, generating proceeds of SEK 4 775 thousands for the Group. Each warrant entitled the holder to subscribe for one Class B share during the period November 25, 2002 to February 25, 2003 at an exercise price of SEK 314.

On the second occasion, 389,700 warrants were issued, generating proceeds of SEK 1 007 thousands for the Group. Each warrant entitled the holder to subscribe for a Class B share during the period November 25, 2002 to February 25, 2003 at an exercise price of SEK 282.

Accordingly, both warrants programs expired during 2003 and no warrants were exercised to subscribe for shares.

#### **Incentive program from 2003**

The Extraordinary General Meeting of December 8, 2003 resolved to introduce an employee stock options program, according to which, employees of the Active Biotech Group will be offered the opportunity to jointly acquire at most 1 000 000 shares in the company. It was also decided to hedge the commitments implied by the employee stock options program by issuing a total of at most 1 330 000 options for subscription for shares to a subsidiary on the same conditions as those applicable to the employee stock options program. The full exercise of the employee stock options will entail a dilution of approximately 3.8 percent of the share capital.

#### **The principal conditions for the employee stock options are as follows:**

Series 1 employee stock options were issued in December 2003 and grant employees the opportunity to acquire at most 330 000 shares during the period June 1, 2006 to May 31, 2009. Series 2 and 3 employee stock options will be issued in June 2005 and June 2006 and will grant employees the opportunity to acquire at most 330 000 shares during the period June 1, 2007 to May 31, 2010, and at most 340 000 shares during the period June 1, 2008 to May 31, 2011.

The exercise price for the Series 1 employee stock options has been set at SEK 90.70. The exercise price for Series 2 and 3 employee stock options will be set at 120 percent of the average share price during the final five trading days of May 2005

and May 2006 respectively.

The employee stock options will be allotted free of charge, with at most 33 600 being allocated to the President & CEO, and with a lower number per person to other employees. The options shall not be considered securities and it will not be possible to transfer them to a third party. The exercise of the options primarily requires that the holder is employed by the Active Biotech Group at the time of exercise. The Board may, pending a special decision, permit holders to exercise their options even after their employment has terminated. Holders' estates have the right to exercise the options on the condition that the holder remained in the employ of Active Biotech at the time of his/her death or was granted right of exercise through a special decision by the Board.

#### **Issue of debentures linked to options to subscribe for new shares and disposition of options**

To hedge the commitments entailed by the employee stock options program described above, debentures have been issued linked to options to subscribe for new shares on the following principal conditions:

Debentures of a nominal amount not exceeding SEK 1 330 associated with at most 438 900 Series 1 options, 1 438 900 Series 2 options and 452 200 Series 3 options for subscription for new shares shall be issued to a fully-owned subsidiary of Active Biotech AB (publ), waiving the rights of existing shareholders. Debentures are to be issued at a price corresponding to their nominal value and shall apply without interest and mature for payment on March 31, 2004.

Each Series 1 option entitles the holder to subscribe for one share during the period June 1, 2006 to May 31, 2009 at an exercise price of SEK 90.70.

Each Series 2 option shall entitle the holder to subscribe for one share during the period June 1, 2007 to May 31, 2010 at a subscription price corresponding to 120 percent of the average stock-market price for shares in Active Biotech AB (publ) during the final five trading days of May 2005.

Each Series 3 option shall entitle the holder to subscribe for one share during the period June 1, 2008 to May 31, 2011 at a subscription price corresponding to 120 percent of the average stock-market price for shares in Active Biotech AB (publ) during the final five trading days of May 2006.

In the event that the Articles of Association permit the issue of different classes of shares at the time at which the subscription price and the exercise of the options are determined, the subscription price and the shares purchased using the options shall be Class B shares.

Having subscribed for debentures with options, the subsidiary shall detach the options and hold them in order to meet their commitments in accordance with the employee stock options program described above. The subsidiary shall have the right to divest at most 330 000 options with the purpose of financing possible social security fees, etc. in connection with the implementation of the employee stock options program.

#### **Dilution effect and costs for the program**

Full exercise of the proposed options would increase the share capital by at most SEK 13 300 000, with reservation for the increase that could be caused by the recalculation of the number of shares to which each option provides purchase rights, which may occur as a consequence of share issues, etc. The dilution effect on full exercise of the options corresponds to about 3.8 percent (of which 2.9 percent as a consequence of allotments to employees). With the application of the Swedish Financial Accounting Standards Council's recommendation RR 18, the proposed options would not result in the dilution of the reported earnings per share for 2003. The proposed options may

cause costs, partly in the form of social security costs on exercise of the options, and partly accounting costs during the lifetime of the options in accordance with the regulations proposed by the IASB, which are expected to come into force on January 1, 2005. On full exercise of all 1 000 000 options, on reaching maturity, the social security costs are estimated to amount to approximately SEK 7.8 million at an assumed original share price of SEK 60 and an annual increase in the price of Active Biotech shares of 10 percent. The intention is to finance this cost through the sale of options in the market.

#### Valuation of options

At the request of the Board, Handelsbanken Capital Markets has valued the options. Applying the customary valuation model (Black & Scholes) and without consideration for limitations on the right of disposition, the value of the options allotted in December 2003 is calculated at SEK 21.10 per option, giving a combined value of

approximately SEK 7.0 million. The value of the options to be allotted in 2005 and 2006 is calculated in the same way and assuming a share price on each occasion of allotment of SEK 69 and SEK 76 respectively, amounts to SEK 27.30 and SEK 30.10 per option respectively, totalling SEK 19.2 million. Consequently, the total value of all options allocated through the program can be calculated at approximately SEK 26.2 million.

#### The reasons for the proposal

The reasons for the options program, which involves the waiving of the rights of existing shareholders are as follows: A share-related incentives program contributes to employees' continued focus on the growth of value in the company's projects and creates the conditions whereby all employees are able to share in the future growth in the value of the company, generated through the employees' efforts.

#### Note 6 Participations in the earnings of associated companies

Pertains to the Active Biotech Group's share in the earnings of the associated company Isogenica Ltd and the Parent Company's write-down of its shares in associated companies. Isogenica Ltd has reported no tax expense for 2003.

#### Note 7 Earnings from shares in subsidiaries

	Group		Parent Company	
SEK thousands	2003	2002	2003	2002
Reversal of cost provisions in connection with divestment of subsidiaries	-	-	-	2 699

#### Note 8 Interest revenues and similar profit/loss items

	Group		Parent Company	
SEK thousands	2003	2002	2003	2002
Dividend	26 002	561	26 002	561
Interest	4 498	8 999	4 066	8 516
Exchange-rate differences	1 629	1 252	-	15
Capital gains on the sale of securities	2 582	27 417	2 582	27 417
	34 711	38 229	32 650	36 509

No interest revenues have been received from subsidiaries.

#### Note 9 Interest expenses and similar profit/loss items

	Group		Parent Company	
SEK thousands	2003	2002	2003	2002
Interest	-766	-304	-383	-182
Exchange-rate differences	-1 994	-2 121	-	-
	-2 760	-2 425	-383	-182

No interest expenses have been paid to subsidiaries.

#### Note 10 Exchange-rate differences affecting earnings

	Group		Parent Company	
SEK thousands	2003	2002	2003	2002
Exchange-rate differences affecting earnings	51	305	55	-
Financial exchange-rate differences	-365	-869	-	15
	-314	-564	55	15

## Note 11 Tax

SEK thousands	Group		Parent Company	
	2003	2002	2003	2002
<i>Current tax expenses (-) / tax income (+)</i>				
Tax expenses/tax income for the period	-	-	-	-
Tax adjustments brought forward from previous years	-612	9 432	-612	369
	-612	9 432	-612	369
Group				
SEK thousands			2003	2002
<i>Reconciliation of effective tax</i>				
Profit/loss before tax			-306 987	-308 323
Tax on the Parent Company according to current rates			85 956	86 331
Effect of other tax rates for foreign subsidiaries			45	57
Other non-deductible expenses			-6 726	-1 586
Non-taxable revenues			13	11
Increase in loss carryforward without equivalent capitalisation of deferred taxes			81 104	86 236
Reduction of temporary differences for which deferred tax has not previously been capitalised			1 816	1 423
Tax attributable to prior years			-612	9 432
Reported effective tax			-612	9 432

In 2003, the Parent Company reported a pre-tax loss and a negative taxable loss before tax. As a result, the Parent Company has not reported any current tax expenses for 2003. As the Parent Company does not capitalise loss carryforwards, there was no deferred tax income in 2003.

Because of the Group's activities with considerable research and development costs, the company is not liable for tax. At the end of 2003, the Group's accumulated loss carryforwards amounted to SEK 980 million and are attributable to the Group's Swedish companies. The time of the company's expected revenues cannot yet be specified in accordance with RR 9, and for this reason, no deferred tax demands can be booked.

Since no significant taxable or deductible temporary differences exist, no deferred tax assets or tax liabilities have been reported.

## Note 12 Earnings per share

*The calculation of earnings per share is subject to the following:*

**New share issue:** The number of shares outstanding before the new share issue was 11 246 296 (1 145 024 Class A shares and 10 101 268 Class B shares). The new share issue was conducted in accordance with the following: Two new Class B shares were issued for each old Class A share held (in total, 22 492 584 new shares). Issue price of SEK 10, resulting in proceeds from the new share issue of SEK 224 925 840. The date for the detachment of subscription rights was April 23. The value of the ordinary shares immediately prior to the detachment of subscription rights on April 23, was SEK 12.20 each.

**Employee stock options:** The number of potential ordinary shares after the decision by the Extraordinary General Meeting on December 8 amounts to 1 330 000.

*Calculation of the number of shares during 2002*

The new share issue carried out during 2003 was a rights issue for existing shareholders where the issue price was lower than the actual value of the shares. This gives rise to a bonus issue element with the consequence that the number of ordinary shares used in the calculation of earnings per share for periods preceding the issue shall be adjusted in accordance with the following: The number of shares outstanding at the time of issue, adjusted by the fair value of ordinary shares immediately prior to the detachment of the subscription rights in relation to the theoretical value of the ordinary shares after the detachment of the subscription rights.

The theoretical value of ordinary shares is calculated in accordance with the following formula:

$\frac{\text{Fair value of all outstanding ordinary shares} + \text{proceeds of new share issue}}{\text{Number of shares prior to new share issue} + \text{number of newly issued shares}}$	giving a theoretical value of SEK 10.73 for ordinary shares following the detachment of subscription rights.
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The bonus issue element (adjustment factor) is calculated in accordance with the following:

$\frac{\text{Actual value of ordinary shares immediately prior to detachment of subscription rights}}{\text{Theoretical value of ordinary shares after detachment of subscription rights}}$	giving a bonus issue element of 1.13665
---	---

The adjusted number of shares for 2002 is calculated as 11 246 292 multiplied by the bonus issue element, giving 12 783 098 shares.

*Calculation of the number of shares in 2003*

For 2003, the newly issued shares have been included in the weighted average number of shares from the settlement date. Payment for the newly issued shares took place gradually during the month of May. The weighted average number of shares has been calculated at 26 062 252.

*Earnings per share after dilution*

Outstanding options have not resulted in any dilution in the calculation of the number of shares after full dilution.

*Summary of share data*

	2003	2002
Profit/loss for the year	<b>-307 598 529</b>	-298 890 844
Weighted number of ordinary shares before dilution	<b>26 062 252</b>	12 783 098
Weighted number of ordinary shares after dilution	<b>26 062 252</b>	12 783 098
Earnings per share before and after dilution	<b>-11,80</b>	-23,38
Number of shares at end of period	<b>33 738 876</b>	11 246 292
Number of shares at end of period, including warrants	<b>35 068 876</b>	11 246 292

**Note 13 Tangible assets**

Group	2003			2002		
	Land improvements	Equipment, tools, fixtures and fittings	Total	Land improvements	Equipment, tools, fixtures and fittings	Total
SEK thousands						
Opening acquisition values	564	149 499	<b>150 063</b>	564	146 852	147 416
Acquisitions	-	5 592	<b>5 592</b>	-	3 595	3 595
Divestments/scrappings	-	-	<b>0</b>	-	-948	-948
Reclassifications	-	-	<b>0</b>	-	-	0
<b>Closing accumulated acquisition values</b>	<b>564</b>	<b>155 091</b>	<b>155 655</b>	564	149 499	150 063
Opening depreciation	45	89 822	<b>89 867</b>	16	73 144	73 160
Divestments/scrappings	-	-	<b>0</b>	-	-948	-948
Depreciation according to plan for the year	28	15 457	<b>15 485</b>	29	17 626	17 655
<b>Closing accumulated depreciation according to plan</b>	<b>73</b>	<b>105 279</b>	<b>105 352</b>	45	89 822	89 867
<b>Closing residual value according to plan</b>	<b>491</b>	<b>49 812</b>	<b>50 303</b>	519	59 677	60 196

During the year, tangible fixed assets for SEK 5 592 thousands were acquired, of which SEK 5 525 thousands was financed through financial leasing agreements.

*Financial leasing in the Group*

In 2002, the company and a leasing company signed an agreement on financial leasing of machinery and other technical facilities. The main terms of the agreement are as follows: rental period 36-60 months, final residual value three percent of the acquisition cost and an interest rate linked to a floating market rate. The Group has also signed agreements on the financial leasing of cars. Property leased through the above-mentioned agreements is entered in the consolidated balance sheet under equipment, tools, fixtures and fittings. At December 31, 2003 the book value of property covered by financial leasing agreements amounted to SEK 5 784 thousands. See also Note 20, Long-term interest-bearing liabilities. Variable fees are included in the period's earnings in the amount of SEK 359 thousands (83 thousands).

*Operational leasing in the Group*

Group companies rent the building Stockholmsledet 7, Lund, where Active Biotech conducts its research operations. The building is owned by the Stockholmsledet 7 limited partnership, in which Active Biotech is a limited partner with a partnership share of SEK 40 million. The rental agreement is valid until January 31, 2009, but notice of termination may only be served provided that the limited partnership continues to receive external financing. If notice to terminate the agreement is not served at the latest three years prior to the termination of the lease, the agreement will, on each occasion, be extended by a further ten years. In the case of an extension, the terms of the agreement will remain unchanged. During the year, rent of SEK 21 million was paid. Estimated future rent payments, provided that the rental agreement is not extended, are due as follows: SEK 21 million within one year; later than one year but within five years SEK 90 million; and later than five years SEK 0 million (calculated on the basis of an assumed price index and unchanged interest rates). Between January 31, 2006 and January 31, 2009, Active Biotech AB will be entitled to acquire remaining shares in the limited partnership.

Parent Company	2003		2002	
	Equipment, tools fixtures and fittings	Total	Equipment, tools fixtures and fittings	Total
SEK thousands				
Opening acquisition values	1 012	<b>1 012</b>	1 893	1 893
Acquisitions	-	<b>0</b>	12	12
Divestments/scrappings	-	<b>0</b>	-893	-893
<b>Closing accumulated acquisition values</b>	<b>1 012</b>	<b>1 012</b>	1 012	1 012
Opening depreciation	492	<b>492</b>	1 276	1 276
Divestments/scrappings	-	<b>0</b>	-893	-893
Depreciation according to plan for the year	40	<b>40</b>	109	109
<b>Closing accumulated depreciation according to plan</b>	<b>532</b>	<b>532</b>	492	492
<b>Closing residual value according to plan</b>	<b>480</b>	<b>480</b>	520	520

#### Note 14 Shares in subsidiaries and participations in associated companies and other long-term holdings of securities

##### Shares in subsidiaries

December 31, 2003 (SEK thousands)	Corp. Reg. No.	Registered office	No. of shares	Proportion	Nominal value	Book value
Lund Research Center AB	556168-8515	Lund	200	100 %	200	350 781
Active Biotech Research AB	556541-8323	Lund	1 000	100 %	100	100
Actinova Ltd		Cambridge	4 500 000	100 %	450 000 GBP	0
Actinova AB	556532-8860	Lund	1 000	100 %	100	
Movera Holding AB	556157-8385	Lund	500	100 %	100	26 950
Transport AB Movera	556256-9441	Lund	45 667 000	100 %	45 667	
Active Security Trading AB	556092-7096	Lund	400	100 %	400	
Active i Malmö AB	556254-0947	Lund	1 000	100 %	100	
						<b>377 831</b>

Book values, ownership shares and nominal values are the same as at December 31, 2002.

##### Participations in associated companies

SEK thousands	Corp. Reg. No.	Registered office	No. of shares	Proportion	Nominal value	Book value
Isogenica Ltd, 2003 12 31	3571781	Cambridge	1 453 011	23.8 %	648 967 GBP	<b>2 767</b>
Isogenica Ltd, 2002 12 31	3571781	Cambridge	571 429	23.8 %	571 429 GBP	<b>4 616</b>

SEK thousands	Group		Parent Company	
	2003	2002	2003	2002
<i>Accumulated acquisition values</i>				
Opening balance	<b>4 616</b>	7 630	<b>8 655</b>	8 655
New share issue	<b>1 022</b>	-	<b>1 022</b>	-
Participations in earnings of associated companies for the year	<b>-2 501</b>	-3 014	-	-
Exchange-rate differences for the year	<b>-370</b>	-	-	-
	<b>2 767</b>	4 616	<b>9 677</b>	8 655
<i>Accumulated depreciation</i>				
Opening balance	<b>0</b>	0	<b>-4 039</b>	-
Depreciation for the year	-	-	<b>-2 871</b>	-4 039
	<b>0</b>	0	<b>-6 910</b>	-4 039
<b>Residual value at close of period</b>	<b>2 767</b>	4 616	<b>2 767</b>	4 616

In the Parent Company, participations have been written-down to correspond to the Parent Company's share in the shareholders' equity of the associated company.

##### Other long-term securities

Other long-term securities pertain to the holding in the limited partnership Stockholmsledet 7 (Corp. Reg. No. 969646-1677). See also Note 13 on operational leasing.

**Note 15 Other receivables**

	Group		Parent Company	
	2003	2002	2003	2002
SEK thousands				
VAT receivable	5 130	10 725	576	6 523
Other current receivables	2 933	1 106	2 537	606
	<b>8 063</b>	11 831	<b>3 113</b>	7 129

**Note 16 Pre-paid expenses and accrued revenues**

	Group		Parent Company	
	2003	2002	2003	2002
SEK thousands				
Interest	1 424	1 714	1 424	1 714
Pre-paid rent	4 936	5 645	26	5
Pre-paid insurance	599	452	362	174
Other pre-paid expenses	2 941	4 683	122	206
	<b>9 900</b>	12 494	<b>1 934</b>	2 099

**Note 17 Short-term investments**

	Group		Parent Company	
	2003	2002	2003	2002
SEK thousands				
Interest-rate hedge fund	176 048	117 522	176 048	117 522
Swedish interest-bearing bonds	6 224	6 224	6 224	6 224
Swedish listed shares	-	36 233	-	36 233
Total short-term investments	<b>182 272</b>	159 979	<b>182 272</b>	159 979
Market value, short-term investments	<b>211 376</b>	196 351	<b>211 376</b>	196 351

**Note 18 Available liquid funds**

	Group		Parent Company	
	2003	2002	2003	2002
SEK thousands				
Cash and bank balances	45 293	169 153	34 734	161 059
Short-term investments	182 272	159 979	182 272	159 979
Total liquid funds	<b>227 565</b>	329 132	<b>217 006</b>	321 038
Blocked bank balances	-3 000	-	-3 000	-
Available liquid funds	<b>224 565</b>	329 132	<b>214 006</b>	321 038

**Note 19 Shareholders' equity****Restricted reserves**

Restricted reserves may not be diminished through payment of dividends.

*Statutory reserve* The purpose of the statutory reserve is to save part of the net profit and is not used to cover the loss carried forward.

*Share premium reserve* When shares are issued at a premium rate, that is, at a price exceeding their nominal value, the amount exceeding the nominal value is placed in the share premium reserve.

**Unrestricted shareholders' equity**

*Unrestricted reserves* These comprise the unrestricted shareholders' equity of prior years following transfers to the statutory reserve and after the payment of any dividends.

In combination with the profit/loss for the year, forms total unrestricted shareholders' equity, that is, the amount available for distribution to shareholders.

	No. of A shares	No. of B shares	No. of Active Biotech shares	Total No. of shares	Shares capital (SEK)
<b>Share capital</b>					
<b>Opening balance, January 1, 2003</b>	<b>1 145 024</b>	<b>10 101 268</b>	-	<b>11 246 292</b>	<b>281 157 300</b>
Reduction of share capital	-	-	-	0	-168 694 380
New share issue	-	22 492 584	-	22 492 584	224 925 840
Reclassification from class A to class B shares	-16 850	16 850	-	0	-
Transition to single share class	-1 128 174	-32 610 702	33 738 876	0	-
<b>Closing balance, December 31, 2003</b>	<b>0</b>	<b>0</b>	<b>33 738 876</b>	<b>33 738 876</b>	<b>337 388 760</b>

At the Annual General Meeting in April 2003, it was resolved to reduce the company's share capital by SEK 168 694 380 to SEK 112 462 920 for transfer to the statutory reserve through a reduction in the par value of shares from SEK 25 to SEK 10.

The Annual General Meeting also decided to conduct a new share issue with preferential rights for the company's shareholders under the following conditions: An existing share, regardless of class, entitled the holder to subscribe for two new Class B shares at the subscription price of SEK 10. The new share issue was fully subscribed, increasing the number of B shares by 22 492 584 and increasing share capital by SEK 224 925 840.

The Extraordinary General Meeting of December 8, 2003 resolved to amend the Articles of Association such that all shares shall be of the same class and consequently carry the same number of voting rights.

At the Extraordinary General Meeting of December 8, 2003 it was furthermore resolved to introduce an employee stock options program, according to which, all employees of the Active Biotech Group will be offered the opportunity to acquire at most 1 000 000 shares in the company. It was also decided to hedge the commitments entailed by the employee stock options program by issuing a total of at most 1 330 000 options for subscription for new shares to a fully-owned subsidiary on the same conditions as those applicable to the employee stock options. Full exercise of the employee stock options will entail a dilution effect of approximately 3.8 percent of the share capital. The principal conditions for the employee stock options are as follows:

- Series 1 employee stock options were allocated in December 2003 and grant the employees the opportunity to acquire at most 330,000 shares during the period June 1, 2006 to May 31, 2009. Series 2 and 3 employee stock options will be allocated in June 2005 and June 2006 respectively and grant the employees the opportunity to acquire at most 330 000 shares during the period June 1, 2007 to May 31 2010 and at most 340,000 shares during the period June 1 2008 to May 31, 2011.
- The exercise price for Series 1 employee stock options has been set at SEK 90.70. The exercise price for the Series 2 and 3 employee stock options will be set at 120 percent of the average share price during the final five trading days of May 2005 and May 2006 respectively.

The employee stock options will be allotted free of charge with at most 33 600 being allocated to the President & CEO and a lower number per person for other employees.

## Note 20 Long-term interest-bearing liabilities

Long-term interest-bearing liabilities concerning the Group's financial leasing agreements primarily involve future leasing fees attributable to agreements under financial leasing. Commitments involving financial leasing mature for payment as follows:

SEK thousands	Amortisation	Interest	Total payment
Within one year	1 739	399	2 138
Between one and five years	4 930	991	5 921
Later than five years	-	-	-
	6 669	1 390	8 059

Amortisation maturing within one year is reported as a current liability. Interest on financial leasing agreements is linked to floating market interest rates.

## Note 21 Financial instruments and financial risk management

Through its operations, the Group is exposed to various forms of financial risk. Financial risk denotes fluctuations in the company's earnings and cash flow resulting from changes in exchange rates, interest levels, refinancing and credit risks.

The Group's financial policy for the management of financial risk has been formulated by the Board and acts as a framework of guidelines and regulations in the form of risk mandates and limits for financial operations. Responsibility for the Group's financial transactions is managed centrally by the Parent Company's finance department. The general objective for the finance function is to provide cost-efficient financing and to minimise negative effects on the Group's earnings from market fluctuations.

### Previously adopted warrant program

On each of two occasions, April 16, 1998 and April 12, 2000, the Annual General Meeting has resolved to issue at most 500 000 warrants for sale to employees of the Active Biotech Group.

On the first occasion, 489 350 warrants were subscribed providing proceeds of SEK 4 775 000 for the Group. Each warrant entitled the owner to subscribe for one Class B share during the period November 25, 2002 to February 25, 2003 at an exercise price of SEK 314. On the second occasion, 389,700 warrants were subscribed, providing proceeds of SEK 1 007 000 for the Group. Each warrant entitled the owner to subscribe for one Class B share during the period November 25, 2002 to February 25, 2003 at an exercise price of SEK 282. Both warrant programs have matured with no shares being subscribed.

Restricted reserves	Parent Company	
SEK thousands	2003	2002
Statutory reserve	184 926	30 674
Share premium reserve	0	294 595
	184 926	325 269

### Specification of exchange-rate differences on shareholders' equity for the year

SEK thousands	Group	
2003	2002	
Exchange-rate difference in foreign subsidiaries for the year	562	375
Exchange-rate difference in foreign associated companies for the year	-370	-
	192	375

### Specification of accumulated exchange-rate differences in shareholders' Equity

SEK thousands	Group	
2003	2002	
Accumulated exchange-rate difference, January 1	904	529
Exchange-rate difference in foreign subsidiaries	562	375
Exchange-rate difference in foreign associated companies	-370	-
Accumulated exchange-rate differences at year-end	1 096	904

The proportion of costs in foreign currencies, primarily USD and EUR, may fluctuate as projects advance to later stages of development, potentially necessitating an increased number of clinical trials abroad.

The Group does not utilise any currency forward contracts or options to hedge its exchange-rate risks. Consequently, the strengthening of SEK during the year had a positive effect on the year's earnings.

#### Credit risks

The Group's credit risks are marginal, since operations have a low invoicing level, due to the fact that the business activities currently comprise mainly research and development.

#### Interest-rate risks

The Group's financing sources primarily consist of shareholders' equity and liabilities for financial leasing commitments.

Outstanding interest-bearing liabilities are reported in Note 20.

The Board of Active Biotech has established a policy for the investment of the Group's liquid funds, which allows liquid funds to be invested at low risk in Swedish and foreign shares, interest-bearing securities denominated in Swedish kronor and interest and equity funds. The proportion of shares, including equity funds, may not exceed 40 percent of the total portfolio and the proportion of equity hedge funds may not exceed 50 percent of the total share portfolio. Interest-bearing investments are limited to securities issued by the Swedish government, Swedish mortgage institutions and Swedish banks.

Interest-rate risk refers to the risk of negative impact on the Group's earnings due to fluctuations in market interest rates. The speed with which a sustained change in interest rates affects the Group's net interest income/expense depends on the fixed-interest term of borrowing and investments.

Outstanding interest-bearing investments are reported in note 17.

### Note 22 Other current liabilities

SEK thousands	Group		Parent Company	
	2003	2002	2003	2002
Personnel tax at source	2 186	1 893	277	68
Current interest-bearing liabilities	1 739	-	-	-
Other current liabilities	802	830	802	805
	<b>4 727</b>	2 723	<b>1 079</b>	873

### Note 23 Accrued expenses and pre-paid revenues

SEK thousands	Group		Parent Company	
	2003	2002	2003	2002
Accrued vacation liability	8 911	7 187	2 076	1 403
Accrued employer's contributions	1 993	1 963	269	271
Other accrued personnel costs	2 988	2 830	735	937
Other items	3 988	7 698	1 557	1 613
	<b>17 880</b>	19 678	<b>4 637</b>	4 224

### Note 24 Pledged assets and contingent liabilities

SEK thousands	Group		Parent Company	
	2003	2002	2003	2002
<i>Assets pledged</i>				
For liabilities to credit institutions	3 000	40 347	3 000	40 347
	<b>3 000</b>	40 347	<b>3 000</b>	40 347
<i>Contingent liabilities</i>				
Guarantees for the benefit of Group companies	-	-	7 575	5 992
Guarantee commitments	-	18 374	-	18 374
	<b>0</b>	18 374	<b>7 575</b>	24 366
<b>Total pledged assets and contingent liabilities</b>	<b>3 000</b>	58 721	<b>10 575</b>	64 713
<i>Pledged assets for liabilities to credit institutions</i>				
Blocked bank balance	3 000	5 148	3 000	5 148
Other shares	-	35 199	-	35 199
	<b>3 000</b>	40 347	<b>3 000</b>	40 347

## Note 25 Supplementary data to the cash-flow statement

SEK thousands	Group		Parent Company	
	2003	2002	2003	2002
<b>Interest paid and dividends received</b>				
Dividends received	26 002	561	26 002	561
Interest received	4 788	8 983	4 356	8 500
Interest paid	-783	-287	-400	-165
<b>Total</b>	<b>30 007</b>	<b>9 257</b>	<b>29 958</b>	<b>8 896</b>
<b>Adjustments for items not included in the cash flow</b>				
Depreciation and write-down of assets	15 485	18 890	2 911	5 382
Deduction for participations in earnings of associated companies	2 501	3 014	-	-
Gain/loss on sale of subsidiaries	-	799	-	-
Unrealised exchange-rate differences	871	834	-	-
<b>Total</b>	<b>18 857</b>	<b>23 537</b>	<b>2 911</b>	<b>5 382</b>
<b>Transactions not involving payment</b>				
Acquisition of assets through financial leasing	5 525	3 187		
<hr/>				
SEK thousands	Group		Parent Company	
	2003	2002	2003	2002
<b>Sales of subsidiaries and other business units</b>				
Liquid funds	-	818		
Total assets	0	818		
Current liabilities	-	19		
Total liabilities and provisions	0	19		
Sale price	-	0		
Purchase price received	0	0		
Deduction for liquid funds in divested operations	-	-818		
Affect on liquid funds	0	-818		
<b>Liquid funds</b>				
Liquid funds consist of the following components:				
Cash and bank balances	45 293	169 153	34 734	161 059
Current investments classifiable as liquid funds	182 272	159 979	182 272	159 979
<b>Total</b>	<b>227 565</b>	<b>329 132</b>	<b>217 006</b>	<b>321 038</b>

The above items have been classified as liquid funds based on the fact that:

- They are subject to insignificant risk for value fluctuations.
- They are easily converted to cash (with the exception of an amount of SEK 3 million, which is not available for use).
- They have a maturity of at most three months from the time of acquisition.

The consolidated income statement and balance sheet, and the Parent Company's income statement and balance sheet are subject to approval by the Annual General Meeting on April 21, 2004.

# *Proposed appropriation of earnings*

It is proposed that no transfer to restricted shareholders' equity be made in the Group.

The Board of Directors and the President & CEO propose that the balanced loss in the Parent Company of SEK 320 084 167 of which SEK 20 275 783 is the loss for the year, be dealt with as follows:

That SEK 184 926 344 be withdrawn from the statutory reserve,  
and that the remaining SEK 135 157 823 be carried forward.

Lund, March 11, 2004

The Board of Directors of Active Biotech AB (publ)

MATS ARNHÖG  
Chairman

SVEN ANDRÉASSON  
President & CEO

MARIA BORELIUS

KLAS KÄRRE

PETER SJÖSTRAND

PETER STRÖM

HANS WÄNNMAN

MATS ÅKESSON

# Audit Report

To the general meeting of the shareholders of  
Active Biotech AB (publ)  
Corporate identity number 556223-9227

We have audited the annual accounts, the consolidated accounts, the accounting records and the administration of the board of directors and the President & CEO of Active Biotech AB for the year 2003. These accounts and the administration of the company are the responsibility of the board of directors and the President & CEO. Our responsibility is to express an opinion on the annual accounts, the consolidated accounts and the administration based on our audit.

We conducted our audit in accordance with generally accepted auditing standards in Sweden. Those standards require that we plan and perform the audit to obtain reasonable assurance that the annual accounts and the consolidated accounts are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the accounts. An audit also includes assessing the accounting principles used and their application by the board of directors and the President & CEO, as well as evaluating the overall presentation of information in the annual accounts and the consolidated accounts. As a basis for our opinion concerning discharge from liability, we examined significant decisions, actions taken and circumstances of the company in order to be able to determine the liability,

if any, to the company of any board member or the President & CEO. We also examined whether any board member or the President & CEO has, in any other way, acted in contravention of the Companies Act, the Annual Accounts Act or the Articles of Association. We believe that our audit provides a reasonable basis for our opinion set out below.

The annual accounts and the consolidated accounts have been prepared in accordance with the Annual Accounts Act and, thereby, give a true and fair view of the company's and the group's financial position and results of operations in accordance with generally accepted accounting principles in Sweden.

We recommend to the general meeting of shareholders that the income statements and balance sheets of the parent company and the group be adopted, that the loss for the parent company be dealt with in accordance with the proposal in the administration report and that the members of the board of directors and the President & CEO be discharged from liability for the financial year.

Lund, March 12, 2004  
KPMG Bohlins AB

Stefan Holmström  
Authorized Public Accountant

# Five-year summary

SEK millions	2003	2002	2001	2000	1999
<b>Condensed income statements</b>					
Net sales	0.3	3.8	102.3	280.4	267.3
Operating profit/loss (of which items affecting comparability)	-336.4	-341.1	17.1	-509.4	-112.3
Participations in the earnings of associated companies	-2.5	-3.0	-1.0	-	-
Net financial items	32.0	35.8	18.7	90.0	54.7
Operating profit/loss after financial items	-307.0	-308.3	34.8	-419.4	-57.6
Operating profit/loss before tax	-307.0	-308.3	34.8	-419.4	-57.6
Tax	-0.6	9.4	-1.8	0.1	-4.5
<b>Profit/loss for the year</b>	<b>-307.6</b>	<b>-298.9</b>	<b>33.0</b>	<b>-419.3</b>	<b>-62.0</b>
<b>Condensed balance sheets</b>					
Fixed assets	95.4	108.1	126.3	297.9	589.1
Current assets	250.0	359.4	621.4	571.0	848.2
<b>Total assets</b>	<b>345.4</b>	<b>467.5</b>	<b>747.7</b>	<b>868.9</b>	<b>1 437.3</b>
Shareholders' equity	289.6	380.3	678.8	646.0	1 064.3
Non-interest-bearing liabilities	49.1	57.8	68.9	222.9	322.0
Interest-bearing liabilities	6.7	29.4	-	-	51.0
<b>Total liabilities and shareholders' equity</b>	<b>345.4</b>	<b>467.5</b>	<b>747.7</b>	<b>868.9</b>	<b>1 437.3</b>
<b>Condensed cash-flow statements</b>					
Cash flow from operating activities before changes in working capital	-288.1	-285.7	-281.9	-105.7	-176.7
Changes in working capital	-0.7	-6.0	-72.7	65.5	282.0
Cash flow from investment activities	-1.1	-1.2	508.6	-46.9	-140.5
Cash flow from financing activities	188.5	26.2	34.0	-50.0	-32.1
<b>Cash flow for the year</b>	<b>-101.4</b>	<b>-266.7</b>	<b>188.0</b>	<b>-137.2</b>	<b>-67.3</b>
Net debt	-260.9	-339.7	-636.1	-447.9	-494.1
<b>Key ratios</b>					
Return on shareholders' equity, %	-91.8	-56.4	5.0	-49.0	-5.1
Return on capital employed, %	-86.2	-56.2	5.5	-45.4	-3.9
Equity/assets ratio, Group, %	83.8	81.3	90.8	74.3	74.0
Equity/assets ratio, Parent Company, %	28.5	36.1	55.6	59.5	64.5
Interest coverage ratio, multiple	neg	neg	22.3	neg	neg
Net debt/equity ratio, multiple	neg	neg	neg	neg	neg
Average number of employees	179	183	258	337	341
<b>Share data</b>					
Number of shares at end of period (thousands)	33 739	11 246	11 246	11 246	11 246
Number of shares at end of period including subscription rights (thousands)	35 069	11 246	11 246	11 246	11 246
Earnings per share before and after dilution (SEK)	-11.80	-23.38	2.58	-32.80	-4.85
Adjusted shareholders' equity (SEK)	8.58	33.81	60.36	57.44	94.64
Market price at year-end (SEK)	6.66	29.27	53.00	36.28	48.47
Active Biotech shares	61	-	-	-	-
Class A shares	-	24	105	109	185
Class B shares	-	25	108	117	186
Dividends	0*	0	0	0	0

\* proposed dividend

Definitions, see page 44.

# Board of Directors, President and Auditors



## Sven Andréasson

Born 1952, Board member since 1999.  
MSc Stockholm School of Economics,  
President & CEO Active Biotech AB.  
Holding: 38 250 shares, 175 000 call  
options, 11 200 employee stock options.  
Other Board assignments: TiGenix B.V.,  
Leuven, Belgium.



## Mats Arnhög

Chairman of the Board  
Born 1951, Board Member since 2000.  
MSc Stockholm School of Economics,  
owner of MGA Holding AB.  
Holding: 8 931 028 shares, through  
companies.  
Other Board assignments: MGA Holding AB  
and in subsidiaries in the MGA Holding  
Group, North Trade Stockholm AB.



## Maria Borelius

Born 1960, Board member since 2000.  
BSc Biology, MSc Scientific Journalism,  
Scientific journalist and author, columnist  
in Swedish financial daily Dagens Industri.  
Holding: 2 000 shares.  
Other Board assignments: SWECO AB  
(publ).



## Peter Sjöstrand

Born 1946, Board member since 2000.  
BSc Economics, MD, former Executive  
Vice President, Astra AB.  
Holding: 0.  
Other Board assignments: Meda AB.



## Klas Kärre

Born 1954, Board member since 2003.  
Professor of Molecular immunology at the  
Karolinska Institute in Stockholm.  
Holding: 4 000 shares.  
Other Board assignments: Accuro Immuno-  
logy AB, Karolinska Institute, Kalmar  
University.



## Peter Ström

Born 1952, Board member since 2003.  
MSc Stockholm School of Economics,  
Vice President IMS Health.  
Holding: 5 000 shares.  
Other Board assignments: Chairman,  
Medical Radar.



## Employee representative Hans Wännman

Born 1959, employed since 1980,  
Board member since 1999.  
Chemical Engineer.  
Pre-clinical development.  
Holding: 2 500 employee stock options.



## Employee representative Mats Åkesson

Born 1957, employed since 1991,  
Board member since 2001.  
Biomedical analyst.  
Pharmaceutical development.  
Holding: 1 375 employee stock options.



## Auditors KPMG Bohlins AB with Stefan Holmström

as principle auditor.  
Born 1949, company auditor at Active  
Biotech AB since 2001.  
Authorised Public Accountant KPMG.

# Management group

## Sven Andréasson

President & CEO

Born 1952

Holding: 38 250 shares, 175 000 call options, 11 200 employee stock options

Sven Andréasson has been President & CEO and a Board Member of Active Biotech since 1999. He has longstanding experience in the international pharmaceuticals industry, including time spent as President and Vice President of mainly Swedish, French and German companies within the Pharmacia Corporation.



## Hans Kolam

Chief Financial Officer

Born 1951

Holding: 5 000 shares, 7 500 employee stock options

Hans Kolam has worked for Active Biotech since 2000. He has more than 20 years of experience in the pharmaceuticals industry, having held different positions in Pharmacia's financial organisation, most recently as Vice President of Finance, Europe.



## Tomas Leanderson

Chief Scientific Officer

Born 1956

Holding: 0 shares, 7 500 employee stock options

Tomas Leanderson has been employed at Active Biotech since 1999. He has previously carried out research at the Basel Institute for Immunology in Switzerland, worked as a lecturer in molecular immunology, and as a council researcher in cellular differentiation at Uppsala University. In 1990, Tomas Leanderson was appointed Professor of Immunology at Lund University.



## Lars M Nilsson

VP Regulatory & Quality Affairs

Born 1943

Holding: 1 000 shares, 7 500 employee stock options

Lars M Nilsson has been employed at Active Biotech since 2001. He has a veterinary degree and has longstanding experience in the international pharmaceutical industry. His most recent position was as head of registration and quality assurance at Pharmacia Consumer Health Care.



## An van Es

VP Business Development

Born 1960

Holding: 0 shares, 7 500 employee stock options

An van Es was employed at Active Biotech since 2002. She left the company on February 29, 2004.

# Glossary

**Animal model:** disease developed in an animal, closely resembling a human disease.

**Angiogenesis:** the formation of new blood vessels.

**Antiandrogen treatment:** hormone treatment that inhibits the male sex traits.

**Antibody:** a protein secreted by a certain type of cell in the immune defence and which recognises a specific antigen.

**Antigen:** a molecule capable of activating the immune defence.

**Antigenicity:** antibody-binding capacity.

**Apoptosis:** programmed cell death.

**Autoimmunity:** when the body's immune system reacts against structures in the body itself. Autoimmune diseases arise when the immune system attacks healthy tissue in the body.

**Biomarker:** a specific antigen on the surface of a cell, for example PSA, which is used in the diagnosis of prostate cancer.

**Candidate Drug (CD):** a specific substance selected during the pre-clinical phase. The candidate drug is the substance, which will continue on to testing in humans.

**Carcinoma:** cancer tumour that arises in epithelium.

**Clinical studies:** studies of the effects of a drug on human beings.

**CPMP:** Committee for Proprietary Medical Products (scientific committee of the EMEA).

**Cytokines:** signal substances used by various cells in the immune system. These can, for example, stimulate cells into being more aggressive and kill tumour cells.

**Cytotoxic T-lymphocytes:** white blood cells that act as highly selective killer cells.

**Cytostatics:** cell toxins.

**Discovery:** explorative research.

**Discretionary management:** management outside formal rules.

**EMEA:** European Agency for the Evaluation of Medical Products.

**Flare-up:** temporary changes in disease symptoms.

**Inflammation:** the body's response to localised damage.

**Lead:** chemical compound that binds to the target molecule, a possible candidate drug, also known as a model compound.

**Malign:** malignant

**Metastases:** secondary tumours in cancer diseases.

**Migration:** movement.

**MS:** multiple sclerosis, a chronic autoimmune disease.

**Multicenter-study:** studies carried out at several clinics simultaneously.

**Myelin:** a fatty substance that surrounds the nerve fibres in the brain and other places.

**NSAIDS:** non-steroidal anti-inflammatory drugs.

**Oncofetal antigen:** molecule produced during fetal development and by cancer cells, but not by normal cells after fetal development.

**Oncologist:** cancer specialist.

**Oral:** by mouth.

**Orally administered (peroral):** a drug taken through the mouth in tablet or liquid form.

**Patent:** exclusive rights to a discovery or invention.

**Pharmacology:** the science of the properties of drugs and their effects on the body.

**Pharmacokinetics:** study of how drugs are handled by the body from absorption to excretion; studies how and when the drug is distributed to the target organ and how it is absorbed there.

**Phase (I, II and III):** the various stages in the study of a drug's effect on humans.

**Placebo:** a substance with no effect, a "sugar pill". Used for comparative purposes, for example when studying the effect of a new drug.

**Pre-clinical:** the part of drug development that takes place prior to the drug being tested on human beings.

**Proof of principle:** when a candidate drug has an effect on a biomarker, that is, a measurable parameter predicting the effect on a certain disease.

**PSA:** Prostate-Specific Antigen, used to diagnose prostate cancer.

**SAIK:** Substances for Autoimmune diseases/Ketoamides, Active Biotech's concept for the treatment of autoimmune diseases such as MS.

**Solid tumour:** tumour that grows in the form of a lump; as against blood cancer, which grows through individual cells in the circulation.

**SLE:** Systemic Lupus Erythematosus.

**Superantigen:** a protein that is 10 000 times better than a regular antigen at activating the body's immune system.

**Synthesise:** to produce in a synthetic manner or to produce a substance that does not occur in nature.

**TASQ:** tumour angiogenesis suppression, quinolines. Active Biotech's prostate cancer project.

**T-cell (T-lymphocyte):** a type of white blood cell; lymphocyte. Is the cause of transplant rejection, influences the formation of antibodies and the body's best defence against, for example, viruses and parasitic infections.

**Therapeutic:** relating to the treatment of disease.

**Toxicology:** the study of poisons or toxins and toxicity.

**Tumour cell:** a cell that divides uncontrollably.

**TTS:** tumour targeted superantigens, Active Biotech's method of treating cancer.



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