Active Biotech
Interim report
January – September 2003

- **SAIK-MS Phase II study indicates that laquinimod has the potential to become the first oral pharmaceutical developed specifically for the treatment of multiple sclerosis**

- **Final result of the laquinimod (SAIK-MS) Phase II study confirms that the primary endpoint of the study has been reached**

- **Extended analysis using independent statistical methods confirms the previously reported result:**

  - Treatment with laquinimod yields 28 to 44% reduction in new inflammatory lesions in the brain after 24 weeks of treatment
  - Patients with active disease at study start responded more favourably to treatment with laquinimod, a 52% reduction in inflammatory lesions

- **The final analysis confirms the favourable safety profile of laquinimod**

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- **The clinical Phase I study with TTS CD3 in non-small cell lung cancer patients is proceeding according to plan with further escalation of dose levels**

- **Phase IIa clinical study with TTS CD2 – report planned before the end of the year**

- **The Phase I study of prostate-cancer project TASQ is proceeding according to plan**

- **Positive pre-clinical results for SLE-project 57-57**

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- **Loss after net financial items of SEK 229.8 M (loss: 215.7)**

- **Loss per share for the period amounted to SEK 10.87 (loss: 19.12)**

Primary endpoint confirmed in SAIK-MS Phase II study
The final analysis confirms that the primary endpoint of Phase II clinical study for the candidate drug SAIK-MS (laquinimod), intended for oral treatment of multiple sclerosis (MS), has been reached.

Using magnetic resonance imaging (MRI), the primary endpoint of the study was to demonstrate a statistically significant decrease in disease activity in patients treated with laquinimod over a 24-week period. Patients treated with a laquinimod dose of 0.3 mg/day showed a statistically significant reduction in MRI-activity, compared with patients who received a non-active substance (placebo).

A reduction was also shown in patients receiving the lower dose, 0.1 mg/day, but the decrease was not statistically significant after 24 weeks.

A more extended evaluation of the study has been made using several different statistical methods to analyse the data.

This analysis further strengthen the previously published results of approximately 30% decrease in disease activity. Regardless of analytical method, a statistically significant effect was achieved throughout the entire treatment period for the group that received a laquinimod dose of 0.3 mg/day. Depending on the analytical method used, laquinimod induced a decrease of 28 to 44 % in the number of new inflammatory lesions in the brain (p-value 0.0007–0.0498).

Patients monitored during the study generally showed a low level of disease activity. A more pronounced effect was observed in patients with higher disease activity. Patients with at least one active lesion in the brain at study start (73 percent of the patients), experienced a 52-percent decline in the number of new MS-related inflammatory lesions.

The highly advantageous safety profile initially reported was confirmed in the final analysis.

Statistical significance was not achieved in evaluations of laquinimod's clinical effects. This was not to be expected given the short duration of the study.

Thus, in summary, Phase II data support continued development of laquinimod aiming at becoming the first oral product for treatment of MS.

The total market for MS drugs in 2002 was valued at USD 2.8 billion. By 2005, the market value is expected to reach USD 4 billion (Source: SG Cowen, 2003).

Background
The study was conducted along three groups of treatment, one using a placebo and two groups receiving active treatment. One of the groups was given a dose of 0.1 mg/day and another 0.3 mg/day. The study was a so-called blind, randomised study, meaning that during its progression, no one was aware which patients were receiving the placebo and which were given the active treatment substance. The study comprised slightly more than 200 patients at some 20 different clinics in the Netherlands, the UK, Russia and Sweden.

Today, multiple sclerosis (MS) is an incurable disease that results from the body's immune system attacking the myelin sheaths surrounding the nerve fibers in the brain and elsewhere, thus disrupting or completely blocking their passage and preventing sensory inputs from continuing to reach the brain. The brain is no longer able to communicate with the body's muscles. MS can lead to anything from minor symptoms for lengthy periods to severely incapacitating symptoms within a few years. Initially, MS comes in "flare-ups" with alternating periods of deterioration and improvement. The disease mainly affects young people, and more women than men; the average age of onset of the disease is about 30.

Clinical program for TTS cancer project proceeding according to plan
The clinical Phase I study for the optimised candidate drug TTS CD3 against non small cell lung cancer, which was initiated in the US at the beginning of May 2003, is proceeding according to plan. Patients with non-small cell lung cancer are being treated in the study, which is conducted under the leadership of Professor Roger B. Cohen at the Fox Chase Cancer Center in Philadelphia, US. A second center will be initiated at the Radium Hospital in Oslo, Norway, during the fourth quarter of 2003. In total, it is planned that about 30 patients will participate in the study.

The primary objective of the study is to establish safe dose levels for treatment with TTS CD3, but the patients will also be monitored for effects of the treatment on the disease. TTS CD3 has been developed to enable the administration of a standard dose to all patients during the first treatment cycle. In addition, toxicity has been further reduced, making it possible to administer higher dose levels. In the ongoing Phase I study, dose levels have already been reached that are approximately 10 times higher than those used during treatment with TTS CD2.

The Phase IIa clinical studies of TTS involving candidate drug TTS CD2, initiated in the UK at the beginning of 2002, are progressing according to plan. Treatment has been completed on all patients and follow-up studies are now being conducted.

Interim results from the first half of the ongoing Phase II study, presented in June, showed favourable tolerance of the treatment by the patients, as well as promising effects of the drug. According to current plans, the final results of the renal-cancer study will be available for presentation towards the end of 2003, and the results of the pancreatic cancer study will be released during the first quarter of 2004.

The markets for drugs used in the treatment of lung, renal and pancreatic cancer are currently valued at slightly more than USD 1 billion, USD 150 million and USD 500 million, respectively (Source: Blomquist & Associates, February 1, 2003).

Background
TTS stands for "Tumor Targeted Superantigens." Superantigens is a collective term used for a number of substances included among the most powerful stimulators of the human immune system's T-cells, the body's tool for killing undesirable cells. By targeting superantigens against tumour cells via a tumour-specific antibody, Active Biotech has created a unique product that recognises cancer cells and stimulates the body's own immune defenses to eradicate them. Although the TTS technology can, in principle, be used to treat several different types of cancer, Active Biotech has chosen to focus its development efforts on the treatment of lung, renal and pancreatic cancer.

Phase I clinical study of TASQ prostate cancer project proceeding according to plan
A Phase I dose escalation study involving healthy volunteers is currently being conducted with the company's candidate drug TASQ (Tumor Angiogenesis Suppression by Quinolines).

The dose is increased gradually, first as a single dose and, subsequently, as a repeated treatment. This study is conducted to determine safe doses of the TASQ substance and to continue the documentation of how the substance is metabolised. This is pertinent in order to optimise the following Phase I study with prostate-cancer patients. The ongoing study, which is planned to comprise some 30 patients, is being conducted in Germany.

The preparation for the Phase I study in patients is ongoing. According to current plans, this patient study will be conducted in co-operation with Johns Hopkins University in Baltimore, USA.

The documentation was reinforced during the period in respect of pre-clinical effect data and additional documentation has been compiled on the anti-angiogenic effect of the TASQ substance.

Work is now in progress in order to compare the substance with competing compounds, as well as studying effects in combination with other compounds. Since the mode of action of the TASQ substance is unique, there is a theoretical possibility to obtain a synergistic, or additive, effect in combination with, for example IGVF-inhibitors.

The global market for prostate-cancer treatment drugs is currently estimated to about USD 3.1 billion annually (Source: Blomquist & Associates, February 1, 2003).

Background
The purpose of the company's TASQ project is to develop an orally active substance – meaning in tablet form – for the treatment of prostate cancer. Active Biotech is collaborating with Professor John T. Isaacs of Johns Hopkins University in Baltimore, in the US, in this project. In various disease models, this candidate drug has shown favourable anti-angiogenesis effects, which means it is able to cut off nutrition to tumour cells, and has also shown a direct anti-tumour effect in pre-clinical models. Moreover, recently completed studies have also shown that the TASQ substance does not inhibit the enzyme systems (so-called kinases) that are the target molecules for most of the current anti-angiogenesis compounds. This implies that the TASQ substance's active mechanism differs from that of such drugs.

Prostate cancer is the most common form of cancer among men and accounts for almost one third of all cancers. The disease principally affects men in their 50s and older. Prostate cancer has varying degrees of severity. Despite a relatively good prognosis, prostate cancer is the second most common cause of death among men.

Positive pre-clinical results for 57-57 project
Candidate drug ABR-215757 for the treatment of SLE has proven to have the ability to slow down the progression of the disease in mice, which spontaneously develop a condition similar to SLE. The results were presented at a conference of the American College of Rheumatology (ACR) on October 27, 2003.

Data show that oral treatment with 2 and 12 mg/kg/day, respectively, of ABR-215757 yield a statistically significant decrease in renal inflammation, measured as blood content in the urine, compared to the control group. As a consequence, the survival rate increased for the treated animals. A similar result was noted regardless of whether the animals were treated early or late in the course of the disease. The results indicate that ABR-215757 might offer a new treatment alternative for SLE-patients.

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

SLE (Systemic Lupus Erythematosus) is a life-threatening, degenerative autoimmune disease for which very few treatment options are available at present. No new drug has been registered for the treatment of this indication in the past 40 years. It is estimated that at least 500 000 people in the US currently suffer from SLE. Nine out of ten are women.

Background
SLE - Systemic Lupus Erythematosus – is a disease of the connective tissues that can cause inflammation and damage to the connective tissue in any organ in the body. Progress and symptoms of the disease vary widely, depending on the organs affected. The disease primarily affects women of childbearing age. It progresses in "flare-ups" interspersed by relatively symptom-free periods. The autoimmune attacks affect many different organ systems, and the disease eventually leads to many patients experiencing serious secondary symptoms, such as kidney failure.

Other projects
Active Biotech's discovery projects include the INDRA and 13-D lead-optimisation projects, early exploratory projects and projects intended to characterise the molecular mechanism for the biological activity of quinoline-substances (laquinimod, TASQ, 57-57). The successfully completed Phase II study for MS reinforces the high priority of projects focused on the mechanism of action for the quinoline substances. Since Active Biotech is not in a position to, at the present time, allocate new resources for its drug discovery activities, the company has decided to re-prioritise objectives within its discovery portfolio. As a result of this decision, activities within the INDRA-project will be scaled down and phased out as soon as adequate patent protection has been established.

Financial information

Comments on Group results during the first nine months of 2003

The Group's net sales during the period amounted to SEK 0.2 M (2.7).

Operating costs for research and administration increased by 0.2% to SEK 235.6 M (235.1). The cost trend reflects the progress of the clinical development program, which includes the Phase II study of SAIK-MS that was completed in September, the ongoing Phase II study of TTS CD2, the recently started Phase I study of TTS CD3 against lung cancer and the TASQ prostate-cancer project. Also included are start-up costs for the planned Phase I study for the 57-57 project against SLE.

In line with previously released interim reports, SEK 19.7 M was booked during the period for retroactive taxes levied against Peltor AB, a former subsidiary divested in 1996.

An operating loss of SEK 255.1 M (loss: 230.7) was reported. The increased loss was attributed mainly to expenses for the supplemental taxation of Peltor AB.

Net financial items for the period amounted to income of SEK 27.6 M (17.0). The improved financial net is mainly attributable to a dividend from the fixed-income hedge fund Nectar and capital gains in securities-management activities.

Participations in the results of the associated UK company Isogenica Ltd amounted to a loss of SEK 2.2 M (loss: 2.0). As planned, the company conducted a new share issue during the third quarter, and Active Biotech subscribed for its ownership percentage.

The operating loss after financial items was SEK 229.8 M (loss: 215.0). Adjusted for items affecting comparability, loss after net financial items amounted to SEK 210.1 M (loss: 217.2).

Liquidity and financial status
The negative cash flow for the first nine months amounted to SEK 40.9 M (negative: 212.8). The new share issue during the second quarter resulted in net proceeds of SEK 216.2 M. At the close of the period, the Group had no external loans, with the exception of liabilities to leasing companies amounting to SEK 6.8 M.

Investments in tangible assets during the period, consisting mainly of laboratory equipment, amounted to SEK 5.2 M (0.4).

The book value of the Group's short-term investments and liquid assets was SEK 288.1 M at the close of the period, compared with SEK 329.1 M at year-end 2002. The market value of the financial investments exceeded book value by SEK 34.7 M at the close of the period.

Liquid funds amounted to SEK 8.54 per share, compared with SEK 29.27 per share at year-end 2002.

Shareholders' equity
Group shareholders' equity amounted to SEK 367.3 M at the close of the period, compared with SEK 380.3 M at the end of the preceding year.

At the close of the period, the Group had an equity/asset ratio of 89.8 percent, compared with 81.3 percent at the end of 2002. The corresponding figures for the parent company Active Biotech AB were 43.7 percent and 36.1 percent respectively.

Forecast
The company is currently in a period during which efforts are focused on out-licensing some of its key projects.

Priority activities include the preparation of reports on the recently completed Phase II study of SAIK-MS, ongoing Phase II clinical trials for the TTS CD2 project, with results scheduled to be reported during the fourth quarter of 2003, and the Phase I studies of the candidate drug TTS CD3 and the TASQ prostate-cancer project, which were initiated during the year.

Because ongoing discussions regarding the aforementioned projects and products could significantly affect the Company's financial position and results, no forecast is being issued for full-year 2003.

Extra ordinary general meeting
The Board of Directors has resolved to propose the following at an extra ordinary general meeting of shareholders:

- The offer to all employees of Active Biotech of a total of 1,000,000 options. To hedge future social security contributions, the total options program comprises a total of 1,330,000 options, which will lead to a maximum dilution factor for existing shareholders of 3.8 percent. Of these, 2.9 percent is attributable to the allocation of options to employees.

- A change in the Articles of Association whereby all shares in the Company will be of the same category, carrying equal voting rights, and whereby the Articles of Association will no longer allow the issue of A and B-series shares.

The extra ordinary general meeting will be held on December 8, beginning at 3:00 p.m., in the Company's offices at Scheelevägen 22 in Lund. An announcement will be distributed in the near future.

Election committee
In compliance with a decision by the general meeting held on April 10, 2003, an election committee has been established consisting of Mats Arnhög; Chairman, Ronni Sand, Johnny Sommarlund, Managing Director of MGA Holding AB; Per Åberg, Pfizer AB.

Accounting and valuation principles
This interim report has been prepared in accordance with the Swedish Financial Accounting Standards Council's recommendations (RR20 Interim Reporting). The accounting and valuation principles used in this quarterly report are identical to those used in the 2002 annual report.

Because of the company's structure and considerable research and development costs, it is currently not required to pay income taxes. The parent company's accumulated tax loss carryforwards at the end of 2002 amounted to SEK 648.8 M, including the currently unconfirmed tax assessment for the 2001 fiscal year.

Communications and reporting dates
A capital market meeting will be held on November 6, 2003, beginning at 10:00 AM, at IVA, Grev Turegatan 16, 112 42 Stockholm. Internet users can listen to the meeting via the company's website, www.activebiotech.com, which will also contain the program for the meeting and a slide presentation.

Year-end financial report for 2003: February 12, 2004

As of the above date, the report will be available on www.activebiotech.com.

Lund, November 6, 2003
Active Biotech AB
Sven Andréasson
President & CEO

This report is unaudited.

For additional information, contact:
Sven Andréasson, President & CEO, Tel: +46-46 19 20 49,
sven.andreasson@activebiotech.com
Hans Kolam, CFO, Tel: +46-46 19 20 44,
hans.kolam@activebiotech.com
Cecilia Hofvander, Manager Corporate Communication, Tel: +46-46 19 11 22,
cecilia.hofvander@activebiotech.com

Active Biotech AB *is a biotechnology company focusing on research in and development of pharmaceuticals. Active Biotech has a strong R&D portfolio and pipeline products with focus primarily on autoimmune/inflammatory diseases and cancer. Most advanced projects include orally administered small molecules with unique immunomodulatory properties (SAIK-MS) for the treatment of multiple sclerosis, as well as a novel concept for use in cancer immunotherapy(TTS).*

Active Biotech AB (corporate identity number 556223-9227)
Box 724, SE-220 07 Lund
Tel: +46 46-19 20 00
Fax +46 46-19 20 50
www.activebiotech.com

The Active Biotech Group

Income statement	**Jul-Sep**	**Jul-Sep**	**Jan-Sep**	**Jan-Sep**	**Jan-Dec**
MSEK	**2003**	**2002**	**2003**	**2002**	**2002**
Net sales	**0.1**	**0.3**	**0.2**	**2.7**	**3.8**
Cost of goods sold	0.0	0.1	0.0	0.2	0.2
Gross Profit	**0.1**	**0.3**	**0.2**	**2.9**	**4.0**
Administrative expenses	-6.7	-8.4	-24.2	-25.6	-35.4
Research and development costs	-65.7	-75.8	-211.4	-209.5	-285.2
Items affecting comparability	-19.7	0.0	-19.7	1.5	-24.6
Operating loss	**-92.0**	**-83.9**	**-255.1**	**-230.7**	**-341.1**
Loss from share in associated companies	-0.6	-0.4	-2.2	-2.0	-3.0
Net financial items	2.2	0.6	27.6	17.0	35.8
Loss after financial items	**-90.5**	**-83.7**	**-229.8**	**-215.7**	**-308.3**
Tax on profit for the period	-	0.7	-	0.7	9.4
Net loss for the period	**-90.5**	**-83.1**	**-229.8**	**-215.0**	**-298.9**
Depreciation incl. in an amount of	3.7	4.2	11.9	12.9	17.7
Investment s in fixed assets	0.9	0.0	5.2	0.4	3.6
Loss per share (SEK)	-2.68	-7.38	-10.87	-19.12	-26.58
Average number of shares -000	33 739	11 246	21 133	11 246	11 246
Number of shares at close of period, -000	33 739	11 246	33 739	11 246	11 246

Balance sheet	**Sep 30,**	**Sep 30,**	**Dec 31,**
MSEK	**2003**	**2002**	**2002**
Tangible fixed assets	53.5	61.8	60.2
Financial fixed assets	46.5	49.2	47.9
Total fixed assets	**100.1**	**111.0**	**108.1**
Current receivables	20.9	20.0	30.3
Short-term investments and liquid assets	288.1	383.1	329.1
Total current assets	**309.0**	**403.2**	**359.4**
Total assets	**409.0**	**514.1**	**467.5**
Shareholders' equity*	367.3	464.0	380.3
Provisions	-	9.1	-
Long-term liabilities	6.8	-	2.7
Current liabilities	35.0	41.1	84.6
Total liabilities and shareholders' equity	**409.0**	**514.1**	**467.5**
***Changes in shareholders' equity**			
Total at start of period	380.3	678.8	678.8
New share issue	216.2	-	-
Translation differences	0.6	0.2	0.4
Net loss for the period	-229.8	-215.0	-298.9
Total at end of period	**367.3**	**464.0**	**380.3**

Cash flow statement MSEK	Jan-Sep 2003	Jan-Sep 2002	Jan-Dec 2002
Loss after financial items	**-229.8**	**-215.7**	**-308.3**
Adjustments for items not included in cash flow etc.	14.0	16.2	23.0
Tax paid	-2.9	-0.4	-0.9
Cash flow from current operations before Changes in working capital	**-218.7**	**-199.9**	**-286.2**
Changes in working capital	-10.6	-11.7	-6.0
Cash flow from current operations	**-229.3**	**-211.6**	**-292.2**
Net investments in fixed assets	-1.1	-1.2	-1.2
Cash flow from investing activities	**-1.1**	**-1.2**	**-1.2**
New share issue	216.2	-	-
Loans raised/amortisation of borrowing	-26.7	-	26.7
Cash flow from financing activities	**189.5**	**0.0**	**26.7**
Cash flow for the period	**-40.9**	**-212.8**	**-266.7**
Liquid funds, beginning of period	**329.1**	**596.1**	**596.1**
Exchange-rate differences in liquid funds	**-0.1**	**-0.1**	**-0.2**
Liquid funds, end of period	**288.1**	**383.1**	**329.1**

N Y C K E L T A L	Sep 30, 2003	Sep 30, 2002	Dec 31, 2002
Shareholders' equity, MSEK	367.3	464.0	380.3
Shareholders' equity per share, SEK	10.89	41.25	33.81
Available liquid funds, MSEK	288.1	383.1	329.1
Available liquid funds per share, SEK	8.54	34.07	29.27
Equity/assets ratio of parent company, %	43.7%	50.5%	36.1%
Equity/assets ratio of Group, %	89.8%	90.2%	81.3%
Average number of annual employees	179	183	183