

**Active Biotech  
Interim report  
January – June 2006**

- **Final report from Phase II study of laquinimod to be presented before year-end**
- **ANYARA Phase II/III renal cancer study to start in Q4**
- **Recruitment for Phase I TASQ study completed; evaluation scheduled for Q3**
- **Preclinical data for 57-57 supports ongoing clinical development**
- **Net sales: SEK 11.4 million (5.8)**
- **Operating loss: SEK 79.3 million (loss: 100.5)**
- **Loss after tax: SEK 83.4 million (loss: 110.3)**
- **Loss per share for the period: SEK 2.10 (loss: 3.18)**

**Phase II study of laquinimod is being concluded as planned, report to be presented before year-end**

Teva's additional Phase II multi-center study to establish the optimal dose for pivotal Phase III studies is being concluded according to plan and the final report will be delivered before year-end.

Recruitment for this study commenced in the first half of 2005 and it now involves slightly more than 300 patients with relapsing MS. The study measures the effect of laquinimod versus placebo, administered once daily in tablet form, at dosages of 0.3 mg/day and 0.6 mg/day during nine months.

Based on the results of this Phase II study, a pivotal Phase III program will be initiated with the aim of confirming laquinimod's efficacy and safety in the treatment of relapsing MS.

*MS is a chronic, progressive disease affecting the central nervous system. It is described as an autoimmune disease since it belongs to a large group of diseases that cause the body's immune defense system to attack healthy areas of the body as if they were foreign bodies. MS can cause 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 stability. The disease mainly affects young people, and more women than men; the average age of onset of the disease is about 30. The total market for MS pharmaceuticals amounted to USD 5 billion in 2005 (Cowen). Given that MS patients must take drugs throughout their lives, an oral treatment represents a significant advantage over the products currently on the market, all of which must be injected.*

### **ANYARA cancer project presented at ASCO in Atlanta**

At the Conference of the American Society of Clinical Oncology (ASCO) held early in June 2006 in Atlanta, US, Active Biotech presented a poster entitled “An open-label Phase I study of ABR-217620, a fusion protein of the 5T4 antibody moiety and an engineered superantigen, in patients with non-small cell lung, renal or pancreatic cancer.” Interim data from an ongoing Phase I study of ANYARA for treatment of advanced non-small cell lung cancer, renal cancer and pancreatic cancer were presented at the conference.

The results show that the criteria established during the development of ANYARA have been fulfilled. The project has demonstrated reproducible induction of the immune-stimulating cytokine Interleukin-2 (IL-2) as a measure of T-lymphocyte activation in direct conjunction with the ANYARA injections. A connection between IL-2 induction and the prolonged survival of renal cancer patients was demonstrated earlier for the first generation of ANYARA. Moreover, a selective increase in ANYARA-specific T-lymphocytes after treatment has been shown, which indicates that ANYARA not only activates T-lymphocytes in patients generally but also that a selective increase in specifically ANYARA-reactive T-lymphocytes is obtained.

Both the Phase I dose-escalation study involving ANYARA and the Phase I combination study involving ANYARA and the Taxotere® cancer drug are proceeding as planned. The dose-escalation study, which is being carried out in the US, Norway and the UK, involves a total of 50 patients. The combination study, which is being carried out at clinics in the US, Denmark and Russia, involves approximately 30 patients. Supplementary results for all ANYARA studies will be presented before year-end.

A phase II/III clinical study involving renal cancer patients is scheduled to start before year-end. The study will involve approximately 200 patients, with prolonged survival as primary endpoint, and is expected to be pivotal for registration.

The American patent office has issued a Notice of Allowance concerning a new patent for the new generation of superantigen variants on which ANYARA is based, including the protein sequence for ANYARA. The patent applies until 2021.

*Non-small cell lung cancer is one of the most common types of cancer. It is also the form of cancer with the highest annual mortality rate (WHO). Each year, 1.2 million people are afflicted by lung cancer. Non-small cell cancer accounts for approximately 80% of the number of lung cancer cases with a mortality rate of 85–90%. The market for treatment of lung cancer is estimated at over USD 1 billion a year.*

*Renal cancer affects approximately 36,000 people annually in the US (American Cancer Society, 2005). The usual age of onset of the disease is between 50 and 70, and it affects more men than women. Five-year survival for non-metastatic forms of the disease is approximately 64%. If the disease has metastasized to the lymphatic glands, five-year survival declines to 5–15%. The market for treatment of renal cancer is estimated at over USD 800 million a year.*

### **Expanded clinical trials with prostate cancer patients proceeding according to plan for TASQ**

The prostate cancer patients included in the Phase I dose-escalation study are continuing treatment in a follow-up study, which is principally intended to document the drug’s long-term tolerance and safety, but also includes efficacy parameters.

In the autumn of 2005, permission was obtained from the Swedish Medical Products Agency to include an additional ten patients in the study, making it possible to obtain extended safety and efficacy data earlier than planned. All patients are included and it is estimated that the study can be evaluated in the third quarter of the year.

The study is being performed at the urological departments at Sahlgrenska University Hospital in Gothenburg and the University Hospitals in Uppsala, Lund and Malmö. Phase II/III studies are scheduled to commence in 2007.

*The objective for the company's TASQ project is to develop a pharmaceutical product that can be administered orally for the treatment of prostate cancer. Active Biotech is collaborating on this project with Professor John T. Isaacs of Johns Hopkins University in Baltimore, Maryland, in the US. Prostate cancer is one of the most common forms of cancer among men and accounts for almost one third of all cancers. Each year, more than half a million people are diagnosed with the disease, which 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. The pharmaceutical market for prostate cancer is estimated to be over USD 3 billion a year.*

### **Phase I clinical study with patients for the 57-57 project against SLE proceeding according to plan**

The clinical program for the 57-57 project with the primary indication Systemic Lupus Erythematosus (SLE) and the treatment of patients with SLE or Rheumatoid Arthritis (RA) is continuing according to plan. The clinical study will primarily document the candidate drug's safety and pharmacokinetic properties, but it will also monitor a number of biological markers to determine the effect of 57-57 on disease progression. This multi-center, dose-escalation study is being conducted at three hospitals in Sweden – the Karolinska University Hospital in Stockholm, Uppsala University Hospital and Lund University Hospital.

In mid-June, Active Biotech presented new preclinical data at the Annual Conference of the European Congress of Rheumatology (EULAR) in Amsterdam in the Netherlands. The results show that 57-57 significantly inhibits disease development in experimental models for Rheumatoid Arthritis (RA). This is reflected in reduced joint deterioration and inflammation, for example. A strengthening of the inhibitory effect on disease progression is achieved when 57-57 is combined with prednisolone. Prednisolone is an anti-inflammatory corticosteroid that is the customary treatment for a number of inflammatory diseases.

The results support further clinical development of 57-57 for treatment of SLE and RA, alone or in combination with prednisolone. Phase II/III studies for the project are scheduled to take place in 2007.

The WHO has assigned 57-57 the international generic name (INN) of **paquinimod**.

*SLE – Systemic Lupus Erythematosus – is a disease of the connective tissues that can cause inflammation and damage to the connective tissue in many different organs. The disease, which progresses in “flare-ups” interspersed by relatively symptom-free periods, primarily affects women of child-bearing age. Progress and symptoms of the disease vary widely, depending on the organs affected. Without treatment, SLE can be life-threatening. According to the Lupus Foundation of America ([www.lupus.com](http://www.lupus.com)), an estimated 1.5 million people in the US have some form of lupus.*

### **RhuDex®**

In March 2006, Active Biotech partner Avidex Ltd. successfully concluded two Phase I studies in which it monitored the RhuDex® candidate drug's safety, tolerance and pharmacokinetic properties in healthy volunteers.

The next step in the clinical program is a Phase I/II double-blind, dose-escalation study in RA patients. The purpose of the study is to examine the drug's safety and its pharmacokinetic properties as well as the interaction between RhuDex® and other drugs.

For Active Biotech, the agreement with Avidex entails an initial payment, which was made in 2002, and milestone revenues that may amount to a maximum of GBP 5.8 million. In addition, Active Biotech will receive royalties on future sales. Active Biotech received a milestone payment from Avidex when the Phase I study commenced in the first half of 2005.

### **Partnership agreement signed with regard to I-3D project**

As earlier communicated, Active Biotech and Chelsea Therapeutics International, Ltd. (NASDAQ: CHTP) signed a partnership agreement in May 2006 with regard to the development and commercialization of I-3D, a group of orally active, dihydroorotate dehydrogenase (DHODH) inhibiting compounds for the treatment of autoimmune diseases and transplant rejection. The aim is to commence clinical trials during the first half of 2007.

Under the agreement, Active Biotech and Chelsea will jointly conduct and fund the clinical development of the I-3D portfolio via a Joint Development Committee with equal representation from both parties. The partnership agreement grants Chelsea the exclusive North and South American commercial rights, while Active Biotech will retain the rights for the remaining global markets. In addition to sharing development costs, both Chelsea and Active Biotech will pay the other partner royalty payments on sales in their respective markets. Active Biotech will also receive defined milestone payments related to clinical development and commercialization.

### **Financial information**

#### **Comment on the Group's results for January–June 2006**

Consolidated net sales for the period amounted to SEK 11.4 million (5.8). The increase in sales is attributable to the partnership agreement with Chelsea Therapeutics on the I-3D project, and to increased rental and service revenues.

The operations' research and administration expenses totaled SEK 90.7 M (106.3), which corresponds to a 15% cost reduction attributable to a lower purchase level of external research services. The clinical development program comprises three Phase I projects – ANYARA, TASQ and 57-57, all of which are self-financing – and two other projects – laquinimod, in Phase II, and RhuDex, in Phase I, both of which are financed through partners. In addition, a partnership agreement concerning the preclinical I-3D project was signed in the second quarter.

The operating loss amounted to SEK 79.3 million (loss: 100.5), and the improvement in earnings is mainly attributable to increased revenues and lower level of expenses.

The net financial expense for the period was SEK 8.9 million (8.7). The current year's net financial expense includes interest expenses attributable to the convertible debenture issued in 2004 in an amount of SEK 6.0 million (6.4) and interest expenses related to the purchase of the property in which Active Biotech conducts operations in an amount of SEK 3.2 million (5.7).

The consolidated earnings after financial items amounted to a loss of SEK 83.4 million (loss: 110.3).

### **Liquidity and financial position**

At the end of the period, the Group's cash and cash equivalents amounted to SEK 130.8 million, compared with SEK 178.4 million at year-end 2005. At the end of the period, unrestricted liquidity amounted to SEK 3.29 per share, compared with SEK 4.51 per share at year-end 2005.

Consolidated cash flow for the first quarter was negative in an amount of SEK 47.6 million (neg: 113.4), which is attributable to the development of earnings during the period and the sale of divided property in Lund amounting to SEK 25.0 million.

### **Parent Company Active Biotech AB**

The operations of the Parent Company, Active Biotech AB, comprise Group-wide administrative functions. The Parent Company's net sales for the period amounted to SEK 1.8 million (6.3).

Operating expenses during the period totaled SEK 14.7 million (15.4). Net financial expenses for the period amounted to SEK 5.2 million (3.9). The loss after financial items amounted to SEK 18.1 million (13.9).

Only marginal investments in fixed assets were made during the period.

Cash and cash equivalents, and financial investments, amounted to SEK 98.0 million at the end of the period, compared with SEK 157.4 million on January 1, 2006.

### **Share capital**

Consolidated shareholders' equity at the end of the period amounted to SEK 112.8 million, compared with SEK 176.8 million at year-end 2005. A total of 39,772,410 shares were outstanding at the end of the period, representing an increase of 180,186 shares following the conversion of convertible debentures since the end of 2005. After full conversion of the convertible debentures issued in 2004 and the redemption of outstanding warrants, the number of shares in Active Biotech could increase to a maximum of 44.5 million shares.

At the end of the period, the equity/assets ratio for the Group was 22.5%, compared with 31.1% at year-end 2005. The corresponding figures for the Parent Company, Active Biotech AB, were 36.8% and 45.7%, respectively.

### **Organization**

At the end of the period, the Group had 89 employees (94), an increase of two employees since December 31, 2005. Seventy-three (71) of the Group's employees work in research and development.

### **Outlook**

The decision to focus operations on clinical projects combined with the partnership agreements entered into previously will entail a further income improvement in 2006.

No earnings forecast has been issued for full-year 2006 as exact dates for signing additional partnership agreements and receiving milestone payments from existing agreements cannot be specified.

## Active Biotech – Group

Income statement, condensed SEK M	April–June		Jan.–June		Full-year
	2006	2005	2006	2005	2005
<b>Net sales</b>	<b>9.7</b>	<b>5.0</b>	<b>11.4</b>	<b>5.8</b>	<b>9.2</b>
Administration expenses	-7.1	-8.4	-12.6	-15.4	-27.6
Research and development costs	-38.8	-49.1	-78.1	-90.9	-169.5
Other revenue	–	–	–	–	54.7
<b>Operating loss</b>	<b>-36.3</b>	<b>-52.4</b>	<b>-79.3</b>	<b>-100.5</b>	<b>-133.2</b>
Loss from participations in associated companies	–	-0.4	–	-1.0	-1.1
Net financial items	-4.5	-4.1	-8.9	-8.7	-15.1
<b>Loss after financial items</b>	<b>-40.8</b>	<b>-56.9</b>	<b>-88.2</b>	<b>-110.3</b>	<b>-149.3</b>
Tax	4.8	–	4.8	–	13.9
<b>Loss for the period</b>	<b>-36.0</b>	<b>-56.9</b>	<b>-83.4</b>	<b>-110.3</b>	<b>-135.4</b>
Depreciation/amortization included in an amount of	3.5	5.1	8.6	10.3	20.1
Investment in tangible fixed assets	0.0	0.2	0.0	0.3	5.9
Earnings per share before dilution (SEK)	-0.90	-1.64	-2.10	-3.18	-3.70
Earnings per share after dilution (SEK)	-0.90	-1.64	-2.10	-3.18	-3.70
Weighed number of common shares before dilution (000s)	39 759	34 708	39 724	34 686	36 610
Weighed number of common shares after dilution (000s)	39 759	34 708	39 724	34 686	36 610
Number of shares at close of period (000s)	39 772	33 741	39 772	33 741	39 592
Number of shares at close of period, including warrants (000s)	41 102	35 071	41 102	35 071	40 922
<b>Balance sheet, condensed</b> SEK M			<b>June 30,</b> <b>2006</b>	<b>2005</b>	<b>Dec. 31,</b> <b>2005</b>
Tangible fixed assets			358.2	303.1	376.9
Financial assets			2.9	43.6	2.9
<b>Total fixed assets</b>			<b>361.1</b>	<b>346.7</b>	<b>379.8</b>
Current receivables			9.1	69.7	9.6
Cash and cash equivalents			130.8	101.5	178.4
<b>Total current assets</b>			<b>139.9</b>	<b>171.1</b>	<b>188.1</b>
<b>Total assets</b>			<b>501.0</b>	<b>517.8</b>	<b>567.9</b>
Shareholders' equity			112.8	47.0	176.8
Long-term liabilities			354.0	393.6	354.7
Current liabilities			34.3	77.2	36.3
<b>Total shareholders' equity and liabilities</b>			<b>501.0</b>	<b>517.8</b>	<b>567.9</b>
<b>Changes in shareholders' equity, condensed</b>					
Opening balance			176.8	104.1	104.1
Personnel options program			1.7	0.8	2.4
New share issue			–	53.0	164.2
Convertible issue			4.9	0.0	6.1
Revaluation reserve			9.2	–	35.8
Profit brought forward			3.2	–	–
Translation differences			0.3	-0.7	-0.5
Net loss for the period			-83.4	-110.3	-135.4
<b>Balance at close of period</b>			<b>112.8</b>	<b>47.0</b>	<b>176.8</b>

<b>Cash-flow statement, condensed</b> SEK M	<b>Jan.–June</b>		<b>Full-year</b>
	<b>2006</b>	<b>2005</b>	<b>2005</b>
<b>Loss after financial items</b>	<b>-88.2</b>	<b>-110.3</b>	<b>-149.3</b>
Adjustments for items not included in the cash flow, etc.	13.2	11.5	-31.8
Tax paid	–	–	–
<b>Cash flow from operating activities before changes in working capital</b>	<b>-75.0</b>	<b>-98.8</b>	<b>-181.1</b>
Changes in working capital	5.1	-15.5	-11.4
<b>Cash flow from operating activities</b>	<b>-69.9</b>	<b>-114.3</b>	<b>-192.5</b>
Net investments in fixed assets	25.0	0.0	-15.1
<b>Cash flow from investing activities</b>	<b>25.0</b>	<b>0.0</b>	<b>-15.1</b>
Convertible issue	–	–	–
New share issue	–	–	164.2
Borrowings/repayment of debt	-2.7	0.9	6.9
<b>Cash flow from financing activities</b>	<b>-2.7</b>	<b>0.9</b>	<b>171.2</b>
<b>Cash flow for the period</b>	<b>-47.6</b>	<b>-113.4</b>	<b>-36.4</b>
<b>Cash and cash equivalents, beginning of the period</b>	<b>178.4</b>	<b>214.8</b>	<b>214.8</b>
<b>Exchange-rate differences in cash and cash equivalents</b>	<b>0.0</b>	<b>0.1</b>	<b>0.0</b>
<b>Cash and cash equivalents, end of the period</b>	<b>130.8</b>	<b>101.5</b>	<b>178.4</b>
		<b>June 30</b>	<b>Dec. 31</b>
<b>Key figures</b>	<b>2006</b>	<b>2005</b>	<b>2005</b>
Shareholders' equity (SEK)	112.8	47.0	176.8
Shareholders' equity per share (SEK)	2.84	1.39	4.47
Unrestricted liquidity (SEK)	130.8	97.6	178.4
Unrestricted liquidity/share (SEK)	3.29	2.89	4.51
Equity/assets ratio in Parent Company (%)	36.8%	26.1%	45.7%
Equity/assets ratio in Group (%)	22.5%	9.1%	31.1%
Average number of employees	89	95	92

*Any errors in additions are attributable to rounding of figures.*

### **Accounting and valuation principles**

As of January 1, 2005, the consolidated accounts have been prepared in accordance with International Financial Reporting Standards (IFRS). The company's interim report for the period January to June 2006 was prepared in accordance with the IFRS standards adopted by the EU and the interpretations of the applicable IFRIC standards also adopted by the EU. The interim report was prepared in accordance with IAS 34 Interim Financial Reporting. Information regarding the accounting principles applied to this interim report is presented in Active Biotech's 2005 Annual Report. The same accounting principles were applied to this interim report as were applied in 2005.

As of January 1, 2005, the Parent Company has applied RR 32, Reporting for Legal Entities. RR 32 essentially entails the application of IFRS, but with certain exceptions.

### **Legal disclaimer**

This financial report includes statements that are forward-looking, and actual results may differ materially from those anticipated. In addition to the factors discussed, other factors that can affect results are developments within research programs, including clinical trials, the impact of competing research programs, the effect of economic conditions, the effectiveness of the company's intellectual patent protection, obstacles due to technological development, exchange-rate and interest-rate fluctuations, and political risks.

## Financial calendar 2006

Interim report, January–September 2006: November 2

Year-end report, 2006: February 15, 2007

The reports will be available from this date at [www.activebiotech.com](http://www.activebiotech.com).

Lund, August 10, 2006  
Active Biotech AB (publ)

Sven Andréasson  
President and CEO

This report has not been reviewed by the company's auditors.

*Active Biotech AB is a biotechnology company focusing on research and development of pharmaceuticals. Active Biotech has a strong R&D portfolio with pipeline products focused on autoimmune/inflammatory diseases and cancer. Its most advanced projects are **laquinimod**, an orally administered small molecule with unique immunomodulatory properties for the treatment of multiple sclerosis, and **ANYARA**, for use in cancer immunotherapy, the primary indication being non-small cell lung cancer. Further key projects in clinical development comprise the three orally administered compounds – **TASQ** for prostate cancer, **57-57** for SLE and **RhuDex**® for RA. In addition, the **I-3D** project in preclinical development is being carried out jointly with Chelsea Therapeutics.*

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