

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

- **Teva's Phase II study with laquinimod against MS successfully concluded**
- **Milestone payment from Teva (SEK 51.2 million) received**
- **ANYARA Phase II/III renal cancer study to be initiated before year-end**
- **Positive interim data for TASQ prostate cancer project**
- **SLE project 57-57 proceeding according to plan**
- **Net sales: SEK 64.1 million (6.5)**
- **Operating loss: SEK 73.7 million (loss: 92.2)**
- **Loss after tax: SEK 82.9 million (loss: 91.9)**
- **Loss per share for the period: SEK 2.09 (loss: 2.58)**

**Phase II study of laquinimod successfully concluded**

The Phase IIb study performed by Active Biotech's partner Teva Pharmaceutical Industries Ltd met the primary endpoint and was successfully concluded. The aim of the study was to evaluate the safety and efficacy of laquinimod and to establish the dose for the following Phase III study.

Laquinimod treatment significantly reduced the rate of inflammatory disease activity, as measured by the cumulative number of Gadolinium-enhancing lesions on brain MRI scans after 36 weeks of treatment. Laquinimod treatment also demonstrated a considerable reduction in the number of clinical relapses compared to placebo.

The evaluation of safety and side-effect data confirmed the favorable safety profile that was seen in earlier clinical studies. Results from the study are scheduled to be presented at an upcoming scientific MS congress.

The majority of the patients who participated in the study are currently continuing treatment with laquinimod in an ongoing, randomized extension study in which the patients who had previously received placebo now are being treated with laquinimod.

Following the positive results of the study, Teva has decided to progress to the next development phase and is currently discussing laquinimod's development plan with the regulatory authorities in order to start the Phase III clinical program.

A milestone payment of USD 7 million has been paid to Active Biotech with October 6 as the liquidity date.

*Laquinimod is a novel oral agent for the treatment of relapsing remitting multiple sclerosis (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 (a once-daily tablet) represents a significant advantage over the products currently on the market, all of which must be injected.*

### **ANYARA cancer project initiates Phase II/III study for renal cancer**

An ANYARA phase II/III clinical study involving renal cancer patients is scheduled to start before year-end. The study will comprise approximately 500 patients, with prolonged survival being the primary endpoint, and is expected to be pivotal for registration. The study also comprises an interim analysis of the disease progression after 175 patients have been included.

The ongoing Phase I study with lung-, pancreas- and renal cancer patients is in the final stages, as is the combination study involving ANYARA and the cancer drug Taxotere® for the treatment of lung cancer. The monotherapy study is being performed in the US, Norway and the UK and involves a total of 40 patients. The combination study is being carried out at clinics in the US, Denmark and Russia and involves approximately 12 patients.

Important interim data regarding the dose level, safety profile, tumor localization and immune response were reported during 2005 and supplementary data for all ANYARA studies will be presented before year-end.

*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.*

### **Positive interim data for TASQ prostate cancer project**

An interim analysis of the ongoing TASQ Phase I study shows a treatment effect for all evaluated prostate cancer patients. The study comprises a total of 24 patients with so-called hormone-refractory prostate cancer. This is an advanced stage of prostate cancer where the tumor cells no longer respond to hormone treatment. All patients entering the study had rising serum levels of Prostate Specific Antigen (PSA), which is a surrogate marker for tumor progression.

The interim analysis was made after ten patients had passed four months of TASQ treatment. Daily treatment with 0.5 mg TASQ led to a reduced rate or lowered level of PSA increase for all ten patients. In nine out of ten patients, this decrease was larger than 50%. Four out of the ten patients showed a decreased serum level of PSA following four months TASQ treatment.

The results also showed that treatment with TASQ was well tolerated with only mild and transient side effects. All patients have now been recruited to the study and it is estimated that the last patient will conclude the one-year treatment by about mid-2007.

The study is being performed at the urological clinics at Sahlgrenska University Hospital in Gothenburg and the University Hospitals in Uppsala, Lund and Malmö.

Based on these positive results, Active Biotech has decided to continue the clinical development by initiating Phase II studies before year-end 2007.

*The objective for the 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 main indication Systemic Lupus Erythematosus (SLE) is continuing according to plan. The clinical study will primarily document the 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 comprises patients with SLE or rheumatoid arthritis (RA). The study is being conducted at three hospitals in Sweden – the Karolinska University Hospital in Stockholm, Uppsala University Hospital and Lund University Hospital. During the fourth quarter, new centers in Russia will also begin to include patients in the study.

Phase II/III studies for the project are scheduled to commence in 2007.

*SLE 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. Current treatment comprises anti-inflammatory drugs, so-called COX inhibitors, which are also called NSAID, anti-malaria drugs, cortisone, cell-inhibiting or anticoagulant drugs. 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. The market potential for the SLE indication is estimated at approximately USD 6 billion.*

### **RhuDex®**

In March 2006, Active Biotech’s partner Avidex Ltd., a subsidiary of MediGene AG, successfully concluded two Phase I studies in which it monitored the RhuDex® candidate drug’s safety, tolerability and pharmacokinetic properties in healthy volunteers.

In the fourth quarter of 2006, Avidex plans to commence a pilot Phase IIa dose-escalation study with RhuDex® comprising 35 RA patients. The objective 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 as much as 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.*

### **I-3D**

Active Biotech and Chelsea Therapeutics International Ltd. cooperate in the co-development and commercialization of I-3D, a group of orally active compounds that inhibit the enzyme dihydroorotate dehydrogenase (DHODH), for the treatment of rheumatoid arthritis (RA). The inhibition of DHODH interferes with DNA synthesis in T-lymphocytes.

The compounds have demonstrated “proof of concept” in models for the indication RA and pre-clinical optimization is currently being conducted. The aim is the selection of a candidate drug (CD) during the first quarter of 2007 and to commence clinical trials before mid 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 certain defined milestone payments related to clinical development and commercialization.*

### **Financial information**

#### **Comment on the Group’s results for January–September 2006**

Consolidated net sales for the period amounted to SEK 64.1 million (6.5). The increase in sales is mainly attributable to the initial milestone payment from Teva Pharmaceutical Industries Ltd (Teva) totaling SEK 51.2 M for the laquinimod project and to increased service and rental revenues.

The operations’ research and administration expenses totaled SEK 137.8 million (153.3), which corresponds to a 10% cost reduction mainly attributable to a lower purchase level of external research services. The clinical development program comprises a total of five projects – laquinimod, about to commence start Phase III studies, ANYARA, TASQ and 57-57, all of which are in the end stages of Phase I, and RhuDex®, in the planning phase ahead of the Phase IIa study. Laquinimod and RhuDex® are fully financed through partners, while the other three clinical projects are financed by Active Biotech. The preclinical I-3D project against RA is conducted in co-development with Chelsea Therapeutics.

The operating loss amounted to SEK 73.7 million (loss: 92.2), and the improvement in earnings is mainly attributable to increased revenues and a lower level of expenses. Earnings in the preceding year included a capital gain of SEK 54.7 million, with no effect on liquidity, when the property in which Active Biotech conducts operations was acquired.

The net financial expense for the period was SEK 12.7 million (14.1). The current year’s net financial expense includes interest expenses attributable to the convertible debenture issued in 2004 in an amount of SEK 8.8 million (9.6) and interest expenses related to the purchase of the property in which Active Biotech conducts operations in an amount of SEK 4.9 million (8.4).

The consolidated earnings after financial items amounted to a loss of SEK 86.4 million (loss: 105.8).

#### **Liquidity and financial position**

At the end of the period, the Group’s cash and cash equivalents amounted to SEK 89.3 million, excluding the milestone payment from Teva. Following receipt of the milestone payment from Teva on October 6, cash and cash equivalents totaled approximately SEK 137 million.

At the end of the period, unrestricted liquidity amounted to SEK 2.24 per share, compared with SEK 4.51 per share at year-end 2005.

Consolidated cash flow for the period, excluding the milestone payment from Teva SEK -89.2 million (5.4). In the corresponding period 2005, a preferential rights issue was conducted, which provided SEK 164.2 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 53.8 million (7.2).

Operating expenses during the period totaled SEK 23.5 million (21.5). Net financial expenses for the period amounted to SEK 29.3 million (3.4). Profit after financial items amounted to SEK 59.6 million (loss: 10.4).

Investments in fixed assets were less than SEK 0.1 million for both years.

Cash and cash equivalents, and financial investments, amounted to SEK 78.9 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 113.9 million, compared with SEK 176.8 million at year-end 2005. A total of 39,782,027 shares were outstanding at the end of the period, representing an increase of 189,803 shares following the conversion of convertible debentures since year-end 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 22.6%, compared with 31.1% at year-end 2005. The corresponding figures for the Parent Company, Active Biotech AB, were 49.8% 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. 73 (71) of the Group's employees work in research and development.

### **Board of Directors**

Maria Borelius has resigned and left her position on the Board of Active Biotech. Maria Borelius served as a Board member of Active Biotech AB since 2000.

### **Outlook**

The decision to focus operations on projects in clinical phases combined with previously signed partnership agreements will generate 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.–Sept.		Full-year 2005
	2006	2005	2006	2005	
<b>Net sales</b>	<b>52.7</b>	<b>0.6</b>	<b>64.1</b>	<b>6.5</b>	<b>9.2</b>
Administration expenses	-5.7	-6.3	-18.3	-21.7	-27.6
Research and development costs	-41.4	-40.3	-119.5	-131.6	-169.5
Other revenue	–	54.7	–	54.7	54.7
<b>Operating profit/loss</b>	<b>5.6</b>	<b>8.7</b>	<b>-73.7</b>	<b>-92.2</b>	<b>-133.2</b>
Profit/loss from participations in associated companies	0.0	1.4	0.0	0.4	-1.1
Net financial items	-3.8	-5.3	-12.7	-14.1	-15.1
<b>Profit/loss after financial items</b>	<b>1.8</b>	<b>4.9</b>	<b>-86.4</b>	<b>-105.8</b>	<b>-149.3</b>
Tax	-1.3	13.9	3.5	13.9	13.9
<b>Profit/loss for the period</b>	<b>0.5</b>	<b>18.8</b>	<b>-82.9</b>	<b>-91.9</b>	<b>-135.4</b>
Depreciation/amortization included in an amount of	6.2	4.9	14.7	15.2	20.1
Investment in tangible fixed assets	0.0	5.4	0.0	5.7	5.9
Earnings per share before dilution (SEK)	0.01	0.48	-2.09	-2.58	-3.70
Earnings per share after dilution (SEK)	0.01	0.48	-2.09	-2.58	-3.70
Weighted number of common shares before dilution (000s)	39,779	39,333	39,742	35,638	36,610
Weighted number of common shares after dilution (000s)	39,779	39,333	39,742	35,638	36,610
Number of shares at close of period (000s)	39,782	39,365	39,782	39,365	39,592
Number of shares at close of period, including warrants (000s)	41,112	40,695	41,112	40,695	40,922
<b>Balance sheet, condensed</b>			<b>Sept. 30,</b>		<b>Dec. 31,</b>
SEK M			<b>2006</b>	<b>2005</b>	<b>2005</b>
Tangible fixed assets			352.7	381.6	376.9
Financial assets			2.9	18.3	2.9
<b>Total fixed assets</b>			<b>355.6</b>	<b>399.9</b>	<b>379.8</b>
Current receivables			59.2	8.5	9.6
Cash and cash equivalents			89.3	220.3	178.4
<b>Total current assets</b>			<b>148.5</b>	<b>228.7</b>	<b>188.1</b>
<b>Total assets</b>			<b>504.1</b>	<b>628.6</b>	<b>567.9</b>
Shareholders' equity			113.9	213.6	176.8
Long-term liabilities			352.6	378.9	354.7
Current liabilities			37.6	36.1	36.3
<b>Total shareholders' equity and liabilities</b>			<b>504.1</b>	<b>628.6</b>	<b>567.9</b>
<b>Changes in shareholders' equity, condensed</b>					
Opening balance			176.8	104.1	104.1
Personnel options program			3.0	1.7	2.4
New share issue			–	164.2	164.2
Convertible issue			5.2	0.1	6.1
Revaluation reserve			7.2	35.8	35.8
Profit brought forward			4.5	–	–
Translation differences			0.0	-0.4	-0.5
Net loss for the period			-82.9	-91.9	-135.4
<b>Balance at close of period</b>			<b>113.9</b>	<b>213.6</b>	<b>176.8</b>

Cash-flow statement, condensed SEK M	Jan.–Sept.		Full-year
	2006	2005	2005
<b>Loss after financial items</b>	<b>-86.4</b>	<b>-105.8</b>	<b>-149.3</b>
Adjustments for items not included in the cash flow, etc.	17.8	-38.8	-31.8
Tax paid	0.0	0.0	0.0
<b>Cash flow from operating activities before changes in working capital</b>	<b>-68.6</b>	<b>-144.6</b>	<b>-181.1</b>
Changes in working capital	-41.5	-14.5	-11.4
<b>Cash flow from operating activities</b>	<b>-110.1</b>	<b>-159.2</b>	<b>-192.5</b>
Net investments in fixed assets	25.0	-13.7	-15.1
<b>Cash flow from investing activities</b>	<b>25.0</b>	<b>-13.7</b>	<b>-15.1</b>
New share issue	–	164.2	164.2
Borrowings/repayment of debt	-4.1	14.1	6.9
<b>Cash flow from financing activities</b>	<b>-4.1</b>	<b>178.3</b>	<b>171.2</b>
<b>Cash flow for the period</b>	<b>-89.2</b>	<b>5.4</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>89.3</b>	<b>220.3</b>	<b>178.4</b>
<b>Key figures</b>	<b>Sept. 30, 2006</b>	<b>Sept. 30, 2005</b>	<b>Dec. 31 2005</b>
Shareholders' equity (SEK)	113.9	213.6	176.8
Shareholders' equity per share (SEK)	2.86	5.43	4.47
Unrestricted liquidity (SEK)	89.3	216.4	178.4
Unrestricted liquidity/share (SEK)	2.24	5.50	4.51
Equity/assets ratio in Parent Company (%)	49.8%	48.5%	45.7%
Equity/assets ratio in Group (%)	22.6%	34.0%	31.1%
Average number of employees	89	93	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 September 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.

## **2007 Annual General Meeting**

The 2007 Annual General Meeting will be held on April 19, 2007 at the company's premises on Scheelevägen 22 in Lund, Sweden. A more detailed invitation to attend the Annual General Meeting will be issued closer to the time.

## **Financial calendar**

Year-end report, 2006: February 15, 2007

Interim report, January–March 2007: May 4, 2007

Interim report, January–June 2007: August 9, 2007

Interim report, January–September 2007: November 8, 2007

Year-end report, 2007: February 14, 2008

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

**Active Biotech will, from now on, not arrange a phone conference at each reporting date. Instead, this will be organized in connection with specific events and press releases.**

Lund, November 2, 2006

Active Biotech AB (publ)

Sven Andréasson  
President and CEO

## **Review report**

### **Introduction**

We have conducted a review of the interim report for Active Biotech AB for the period January 1, 2006 – September 30, 2006. The Board of Directors and the President are responsible for preparing and presenting this interim report in accordance with IAS 34 and the Annual Accounts Act. Our responsibility is to express an opinion on this interim report based on our review.

### **Focus and scope of the review**

We have conducted our review in accordance with the Standard on Review Engagements SÖG 2410, *Review of Interim Financial Information Performed by the Independent Auditor of the Entity* issued by FAR. A review consists of making inquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review has a different direction and is substantially more limited in scope than an audit conducted in accordance with Swedish GAAP and other generally accepted auditing practices. The procedures performed in a review do not enable us to obtain a level of assurance that would make us aware of all significant matters that might be identified in an audit. Therefore, the opinion expressed based on a review does not give the same level of assurance as a conclusion expressed based on an audit.

## Conclusion

Based on our review, nothing has come to our attention that causes us to believe that, in all material respects, the accompanying interim report has not been prepared in accordance with IAS 34 and the Annual Accounts Act.

Lund, November 2, 2006  
KPMG Bohlin AB

Stefan Holmström  
Authorized Public Accountant

*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. Most advanced projects are **laquinimod**, an orally administered small molecule with unique immunomodulatory properties for the treatment of multiple sclerosis, as well as **ANYARA** for use in cancer immunotherapy with the primary indication renal cancer. Further key projects comprise the three orally administered compounds in clinical development, **TASQ** for prostate cancer **57-57** for SLE and **RhuDex®** for RA as well as the **I-3D** project in pre-clinical co-development with Chelsea Therapeutics.*

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