

**Active Biotech  
Interim report  
January – March 2008**

- **Laquinimod — Pivotal Phase III program proceeding**
- **ANYARA — Phase II/III trial for treatment of renal cancer proceeding, new preclinical data presented**
- **TASQ — Phase II studies for treatment of prostate cancer in progress**
- **57-57 — Phase Ib study against SLE continues at highest dose level**
- **RhuDex<sup>®</sup> — Phase IIa study against RA at the end stage**
- **I-3D — Project concluded to focus on immunomodulatory compounds**
- **Net sales SEK 3.2 M (2.6)**
- **Operating loss SEK 52.2 M (loss: 52.5)**
- **Loss after tax SEK 52.7 M (loss: 55.8)**
- **Loss per share for the period amounted to SEK 1.11 (loss: 1.27)**

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This report is also available at [www.activebiotech.com](http://www.activebiotech.com)

## Operations

### **Pivotal Phase III program for laquinimod proceeding**

The **Allegro** study (*assessment of oral laquinimod in preventing progression of multiple sclerosis*), which is a global, pivotal, double-blind, Phase III study designed to evaluate the efficacy, safety and tolerability of laquinimod versus placebo in the treatment of RRMS, has been in progress since November 2007. The Allegro study will enroll approximately 1,000 patients and the treatment administered is a 0.6 mg tablet of laquinimod once a day or placebo. The study is scheduled to continue for 24 months with the possibility to extend to 30 months.

A second pivotal Phase III study, **Bravo** (*benefit-risk assessment of Avonex<sup>®</sup> and laquinimod*), which is a global, multi-center, randomized, placebo-controlled study with parallel groups encompassing approximately 1,200 patients who are to be studied for 24 months, was initiated. The study will compare the effect of once-daily orally administered laquinimod 0.6 mg with placebo and also provide risk-benefit data in relation to treatment with a product presently established in the market and administered by injection (Avonex<sup>®</sup>).

Information regarding the Phase III studies is published on [www.TevaClinicalTrials.com](http://www.TevaClinicalTrials.com) and [www.clinicaltrials.gov](http://www.clinicaltrials.gov).

Teva recently presented results from two preclinical studies for the MS project laquinimod at the conference 60th Annual Meeting of the American Academy of Neurology (AAN) held on April 12-19 in Chicago, in the US. Results from these preclinical studies can help enhance understanding of laquinimod's positive effects in patients with multiple sclerosis, MS. The complete posters are available for download at the company's website [www.activebiotech.com](http://www.activebiotech.com).

*Laquinimod is a novel oral immunomodulatory compound for the treatment of relapsing-remitting multiple sclerosis (RRMS). 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 adults, and more women than men; the average age of onset of the disease is about 30. Given that MS patients must take drugs over a period of decades, an oral treatment (one tablet once a day) represents a significant advantage over the products currently on the market, all of which must be injected. In 2007, the total market for MS pharmaceuticals was estimated at USD 7 billion (Cowen & Co, Therapeutic Categories Outlook, March 2008).*

### **ANYARA – new preclinical results strengthen clinical data**

Patient enrolment to the ongoing Phase II/III study of ANYARA in combination with interferon-alpha, compared with interferon-alpha alone, in patients with advanced renal cancer, is proceeding according to plan. The primary clinical efficacy parameter for this study is survival and it will include approximately 500 patients at about 50 clinics in Europe. Expected survival with conventional treatments for these patients is 10-15 months and the length of the study will depend on the patients' disease progression. An interim analysis based on data when approximately 200 patients have been enrolled is planned for mid-2008.

The company recently presented results from preclinical studies at the 99<sup>th</sup> Annual Meeting of the American Association for Cancer Research (AACR) in San Diego, in the US. The results demonstrate that TTS (Tumor Targeted Superantigens) technology is suitable for combination treatment agents, such as Taxotere®, and suggest a significant potential for such a combination in human cancer therapy. The complete poster is available for download at the company's website [www.activebiotech.com](http://www.activebiotech.com).

*Renal cancer affects approximately 36,000 people annually in the US and about 200,000 people worldwide. Half of patients are affected by metastases. If the disease has metastasized, average survival is one year. The survival rate of patients diagnosed with renal cancer is only 5-10% after five years (Cowen & Co, Therapeutic Categories Outlook, March 2008). ANYARA has been granted orphan-drug status by the European Medicines Agency for the renal cancer indication.*

### **Clinical Phase II study for TASQ prostate cancer project ongoing**

The ongoing Phase II study designed to document TASQ's ability to slow down disease progression in symptom-free patients with metastatic, hormone-resistant, prostate cancer is proceeding. This is a randomized, placebo-controlled, double-blind, Phase II study of 1 mg/day of TASQ versus placebo in 200 patients that is being conducted in the US, Canada and Sweden under an IND application (Investigational New Drug). Results are expected during the second half of 2009.

The primary endpoint of the study is to measure the proportion of patients that do not display disease progression after 6 months of TASQ therapy compared with placebo. Secondary clinical endpoints of importance for this group of patients include time to clinical progression and the effect on tumor growth. Documentation of such endpoints is of importance for future TASQ development and registration.

Treatment of all patients in the extension study of the preceding trial (Phase I) has been completed and a formal final report is being compiled. Patients that remained symptom-free during treatment in Phase I were invited to participate in a 12-month extension study. Results showed that TASQ was well-tolerated and that the favorable safety profile demonstrated earlier could now be documented over a period of more than 12 months of therapy. The study also showed that TASQ reduced the rate of PSA increase in the majority of the patients.

*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, in the US. Prostate cancer is the most common cancer form among men. Its occurrence is strongly age-related and it is very rare before the age of 50. In 2007, it is estimated that about 220,000 new cases were diagnosed in the US alone (Cowen & Co, Therapeutic Categories Outlook, March 2008). In 2006, the global market for pharmaceuticals for the treatment of prostate cancer amounted to USD 3.6 billion (IMS Health 2007).*

### **Clinical Phase I studies for the 57-57 project against SLE at the end stage with highest dose level**

The clinical Phase Ib trial for 57-57 is currently in progress and the company has decided to continue to the highest permitted dose level in the study protocol to ensure that the documentation concerning the compound is as comprehensive as possible ahead of continued clinical development.

This is a dose-escalation, multi-center study in which the compound's safety is studied in connection with step-wise dose increases. The study will principally document the candidate drug's safety and pharmacokinetic properties. In addition, various efficacy parameters will be studied in the form of so-called surrogate markers for disease activity. The study is being performed at three hospitals in Sweden – the Karolinska University Hospital in Stockholm, Uppsala University Hospital and Lund University Hospital, in addition to a number of clinics in Russia.

Preparations for the clinical Phase II/III program are being conducted in parallel and in consultation with the relevant pharmaceutical regulatory authorities. The next phase in the clinical development is now expected to commence at about year-end.

*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 with 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, anti-malaria drugs, cortisone, and cell-inhibiting or anticoagulant drugs. Active Biotech estimates the market at 1 million patients in the US and Europe. Accordingly, the market potential for the SLE indication is estimated at approximately USD 6 billion.*

### **Clinical Phase IIa study for RhuDex<sup>®</sup> at the end stage**

RhuDex<sup>®</sup> is a novel, orally available compound for the treatment of rheumatoid arthritis, originating from Active Biotech's patented CD80 antagonists, out-licensed to MediGene AG. RhuDex<sup>®</sup> is being developed as a disease-modifying drug for the treatment of rheumatic diseases and has a distinct competitive advantage in being the first orally available disease-modifying drug that blocks T-cell stimulation. RhuDex<sup>®</sup> inhibits the underlying disease process and blocks specific CD80 activation of inflammatory T cells, and inhibits the release of cytokines such as TNF.

In January 2007, Active Biotech's partner MediGene initiated a Phase IIa, double-blind, dose-escalation study with RhuDex<sup>®</sup> in about 30 RA patients to evaluate the compound's tolerability, to determine the appropriate dosage and to provide analysis results that demonstrate an anti-inflammatory effect of RhuDex<sup>®</sup>. Results from this study are scheduled to be presented during the first six months of 2008.

In 2007, the tablet formulation was improved and a Phase IIb study with the new formulation is scheduled to commence in 2008. MediGene is responsible for the clinical program and carries the related costs.

*RA - Rheumatoid Arthritis – is a chronic inflammatory disease that affects the body's joints and causes inflammations in synovial membranes and tendon sheaths. The inflammation can damage articular cartilage and surrounding skeletal areas, which means that the patient can eventually be affected by a physically debilitating handicap. Of those affected, approximately two of three are women. The disease affects more than 1% of the global*

population, can be found throughout the world and is equally as common on all continents. Medical treatment consists primarily of pain-alleviating and anti-inflammatory treatment. In 2007, the market for drugs against RA was estimated at close to USD 5.7 billion, distributed among Remicade, Enbrel, Humira, Orencia and Rituxan (Cowen & Co, Therapeutic Categories Outlook, March 2008).

### **The I-3D project**

The collaboration from 2006 with Chelsea Therapeutics International Ltd concerning the co-development and commercialization of the pre-clinical project I-3D, a group of orally active immunosuppressive compounds that inhibit the enzyme Dihydroorotate Dehydrogenase (DHODH), for the treatment of RA, has been concluded. The I-3D project is to be suspended to further focus resources on the company's immunomodulatory compounds.

## **Financial information**

### **Comments on the Group results for the period January – March 2008**

Consolidated net sales for the period amounted to SEK 3.2 M (2.6) and included service and rental revenues of SEK 2.4 M (1.8) as well as SEK 0.8 M (0.8) of a research grant from Vinnova.

The operation's research and administration expenses totaled SEK 55.5 M (55.0). The development is attributable to intensified clinical research activities and more extensive trials in later clinical phases, particularly the ongoing Phase II/III study for the ANYARA project and the recently initiated Phase II study for the TASQ project. In addition, Active Biotech conducted studies to explain the mode of action and target molecules that are behind the pharmacological effects of the quinoline compounds currently in clinical development.

Costs for Phase II studies with RhuDex<sup>®</sup> for the treatment of RA and current clinical Phase III studies with laquinimod are fully financed by the relevant partner.

The Group's operating loss amounted to SEK 52.2 M, a marginal improvement compared with the loss in the preceding year of SEK 52.5 M.

Net financial expense for the period totaled SEK 0.5 M (expense: 3.3). The improvement in net financial expense is attributable to the redemption of outstanding convertible debentures in early 2007. Loss after tax amounted to SEK 52.7 M (loss: 55.8).

### **Liquidity and financial position**

At the end of the period, cash and cash equivalents, including short-term investments with a duration less than 90 days, amounted to SEK 92.2 M, compared with SEK 138.6 M at the end of 2007.

The consolidated cash flow for the period amounted to a negative SEK 46.4 M (pos: 177.4). The difference between the years is primarily attributable to the implementation of the rights issue during the first quarter of 2007.

Cash flow from operating activities amounted to a negative SEK 44.9 M (neg: 53.8) and cash flow from investing activities was negative in the amount of SEK 0.3 M (0.0).

Cash flow from financing activities amounted to a negative SEK 1.2 M (pos: 231.1). The preceding year includes the proceeds from the implemented rights issue totaling SEK 234.4 M.

### **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 1.7 M (1.7).

Operating expenses during the period totaled SEK 6.8 M (8.2) and net financial income amounted to SEK 1.1 M (expense: 1.1). Loss after financial items amounted to SEK 4.0 M (loss: 7.5).

No investments in fixed assets were made during the period.

Cash and cash equivalents, including short-term investments, amounted to SEK 78.5 M at the end of the period, compared with SEK 122.9 M on January 1, 2008.

### **Share capital**

Consolidated shareholders' equity at the end of the period amounted to SEK 137.1 M, compared with SEK 189.6 M at year-end 2007. The equity trend is mainly attributable to the negative earnings during the period.

A total of 47,300,115 shares were outstanding at the end of the period. In the event of redemption of share warrants outstanding, the number of shares in Active Biotech would increase to a maximum of about 48.6 million shares.

At the end of the period, the equity/assets ratio for the Group was 31.9%, compared with 38.7% at year-end 2007. The corresponding figures for the Parent Company, Active Biotech AB, were 64.7% and 70.4%, respectively.

### **Organization**

At the end of the period, the Group had 89 employees (89), of which the number of employees in the research and development operation amounted to 72 (72).

Göran Forsberg was appointed VP Communication & Business Development. Göran was formerly project leader for the ANYARA cancer project and his most recent position was head of the Scientific Affairs department.

### **New share issue**

The Board of Directors proposes that the Annual General Meeting on May 7, 2008 resolves to implement a guaranteed preferential rights issue for approximately SEK 160 M to strengthen the company's financial position and drive development of the company's clinical project portfolio. It is proposed that the issue shall entitle existing shareholders with preferential rights to subscribe for one new share for each twelve shares held at an issue price of SEK 40 per share.

The principal owners, MGA Holding AB (30.01%) and Nordstjernan AB (14.98%), have undertaken to subscribe for the full amount of shares corresponding to their preferential rights. In addition, Nordstjernan AB has undertaken, if the issue is not fully subscribed, to subscribe for any additional shares that are not subscribed for with preferential rights. Accordingly, the issue is guaranteed in its entirety.

### **Outlook, including significant risks and uncertainties**

The Board of Directors' opinion is that available liquidity, revenues from existing partnership agreements, and liquidity from the rights issue proposed by the Board totaling a maximum of SEK 160 M provides sufficient financial resources to finance the company's operations in 2008.

In 2008, the company expects a strong news flow. Interim data will be reported for the ongoing Phase II/III study for ANYARA for the treatment of renal cancer and the launch of Phase II/III studies for the SLE project 57-57 is planned for the latter part of the year.

A research company such as Active Biotech is characterized by a high operational and financial risk, since the projects in which the company is involved are at the clinical phase, and there are a number of factors that have an impact on the likelihood of commercial success. In brief, the operation is associated with risks related to such factors as pharmaceutical development, competition, advances in technology, patents, official requirements, capital requirements, currencies and interest rates.

Since no significant changes took place with regard to risks and uncertainties during this period, refer to a detailed account of these in the directors' report in the 2007 annual report.

## Active Biotech - Group

Income statement, condensed SEK M	Jan-March		Full-year 2007
	2008	2007	
<b>Net sales</b>	<b>3.2</b>	<b>2.6</b>	<b>12.1</b>
Administration expenses	-5.7	-5.6	-25.0
Research and development costs	-49.8	-49.4	-189.7
<b>Operating profit/loss</b>	<b>-52.2</b>	<b>-52.5</b>	<b>-202.7</b>
Net financial items	-0.5	-3.3	-5.0
<b>Profit/loss after financial items</b>	<b>-52.7</b>	<b>-55.8</b>	<b>-207.7</b>
Tax	-	-	-
<b>Loss/profit for the year</b>	<b>-52.7</b>	<b>-55.8</b>	<b>-207.7</b>
Attributable to:			
Parent Company's shareholders	-52.7	-55.8	-207.7
Minority interests	-	-	-
Depreciation/amortization included in an amount of	4.6	4.8	18.9
Investment in tangible fixed assets	0.3	-	0.1
Earnings per share before dilution (SEK)	-1.11	-1.27	-4.47
Earnings per share after dilution (SEK)	-1.11	-1.27	-4.47
Weighted number of common shares before dilution (000s)	47 300	43 759	46 427
Weighted number of common shares after dilution (000s)	47 300	43 759	46 427
Number of shares at close of period (000s)	47 300	47 300	47 300
Number of shares at close of period, including warrants (000s)	48 630	48 630	48 630
<b>Balance sheet, condensed</b>	<b>Mar 31</b>		<b>Dec 31</b>
SEK M	<b>2008</b>	<b>2007</b>	<b>2007</b>
Tangible fixed assets	326.6	343.4	329.7
Financial assets	2.5	2.7	2.5
<b>Total fixed assets</b>	<b>329.0</b>	<b>346.1</b>	<b>332.2</b>
Current receivables	8.6	21.0	18.8
Cash and cash equivalents	92.2	275.3	138.6
<b>Total current assets</b>	<b>100.8</b>	<b>296.2</b>	<b>157.4</b>
<b>Total assets</b>	<b>429.8</b>	<b>642.3</b>	<b>489.5</b>
Shareholders' equity	137.1	338.8	189.6
Long-term liabilities	250.6	254.0	250.6
Current liabilities	42.2	49.6	49.3
<b>Total shareholders' equity and liabilities</b>	<b>429.8</b>	<b>642.3</b>	<b>489.5</b>
<b>Changes in shareholders' equity, condensed</b>			
Opening balance	189.6	60.4	60.4
Personnel options program	0.9	1.2	4.1
New share issue	-	234.4	234.4
Convertible issue	-	98.6	98.6
Translation differences	-0.6	-0.1	-0.2
Net loss for the period	-52.7	-55.8	-207.7
<b>Balance at close of period</b>	<b>137.1</b>	<b>338.8</b>	<b>189.6</b>

Cash flow statement, condensed SEK M	Jan-March		Full-year
	2008	2007	2007
Loss after financial items	-52.7	-55.8	-207.7
Adjustments for items not included in the cash flow, etc.	4.8	5.9	23.5
<b>Cash flow from operating activities before changes in working capital</b>	<b>-47.9</b>	<b>-49.9</b>	<b>-184.2</b>
Changes in working capital	3.1	-3.9	-2.5
<b>Cash flow from operating activities</b>	<b>-44.9</b>	<b>-53.8</b>	<b>-186.7</b>
Investments in tangible fixed assets	-0.3	–	-0.1
Decrease in financial assets	–	–	0.3
<b>Cash flow from investing activities</b>	<b>-0.3</b>	<b>–</b>	<b>0.2</b>
New share issue	–	234.4	234.4
Borrowings/repayment of debt	-1.2	-3.3	-7.2
<b>Cash flow from financing activities</b>	<b>-1.2</b>	<b>231.1</b>	<b>227.2</b>
<b>Cash flow for the period</b>	<b>-46.4</b>	<b>177.4</b>	<b>40.7</b>
<b>Cash and cash equivalents, beginning of the period</b>	<b>138.6</b>	<b>97.9</b>	<b>97.9</b>
<b>Exchange-rate differences in cash and cash equivalents</b>	<b>–</b>	<b>0.0</b>	<b>0.0</b>
<b>Cash and cash equivalents, end of the period</b>	<b>92.2</b>	<b>275.3</b>	<b>138.6</b>
<b>Key figures</b>	<b>2008</b>	<b>2007</b>	<b>2007</b>
Shareholders' equity (SEK M)	137.1	338.8	189.6
Shareholders' equity per share (SEK)	2.90	7.16	4.01
Equity/assets ratio in Parent Company	64.7%	78.1%	70.4%
Equity/assets ratio in Group	31.9%	52.7%	38.7%
Average number of employees	89	89	89

### Active Biotech - Parent Company

Income statement, condensed SEK M	Jan-March		Full-year
	2008	2007	2007
Net sales	1.7	1.7	6.8
Administration expenses	-6.8	-8.2	-30.7
<b>Operating profit/loss</b>	<b>-5.1</b>	<b>-6.5</b>	<b>-23.9</b>
<i>Profit/loss from financial items:</i>			
Profit/loss from shares in subsidiaries	–	–	-8.0
Interest income and similar items	1.1	1.3	6.3
Interest expenses and similar items	–	-2.4	-2.4
<b>Loss after financial items</b>	<b>-4.0</b>	<b>-7.5</b>	<b>-28.0</b>
Tax	–	–	–
<b>Loss for the year</b>	<b>-4.0</b>	<b>-7.5</b>	<b>-28.0</b>
<b>Balance sheet, condensed</b>	<b>Mar 31</b>		<b>Dec 31</b>
SEK M	<b>2008</b>	<b>2007</b>	<b>2007</b>
Tangible fixed assets	0.4	0.4	0.4
Financial assets	231.9	232.1	231.9
<b>Total fixed assets</b>	<b>232.2</b>	<b>232.5</b>	<b>232.2</b>
Current receivables	66.4	75.4	66.8
Short-term investments	59.8	–	99.5
Cash and bank balances	18.7	262.0	23.4
<b>Total current assets</b>	<b>144.9</b>	<b>337.4</b>	<b>189.6</b>
<b>Total assets</b>	<b>377.1</b>	<b>569.9</b>	<b>421.8</b>
Shareholders' equity	244.1	445.0	297.2
Current liabilities	133.1	124.9	124.7
<b>Total shareholders' equity and liabilities</b>	<b>377.1</b>	<b>569.9</b>	<b>421.8</b>

Any errors in additions are attributable to rounding of figures.

### **Accounting and valuation principles**

Active Biotech prepares the consolidated financial statements in accordance with International Financial Reporting Standards (IFRS). The Interim Report has been prepared in accordance with IAS 34 Interim Reporting. The new or amended standards and interpretations which came into effect as of the financial year 2008 do not influence Active Biotech's financial reports. The accounting principles described in the Annual Report for 2007 are also applied in this Interim Report.

The parent company's financial reports are prepared in accordance with the Annual Accounts Act and the Swedish Financial Reporting Board's recommendation RFR 2 Accounting for legal entities. The accounting principles for the parent company are unchanged compared to those provided in the Annual Report for 2007.

### **Segment reporting**

Active Biotech's operation comprises only one business segment, pharmaceutical development and, accordingly, the Group's income statement and balance sheet in their entirety comprise the primary segment.

### **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.

### **2008 Annual General Meeting and Annual Report**

The 2008 Annual General Meeting will be held on May 7, 2008 at 5:00 p.m. at the company's premises on Scheelevägen 22, Lund, Sweden.

For the Annual General Meeting in May 2008, the Election Committee consists of Johnny Sommarlund, MGA Holding, Tomas Billing, Nordstjerman, Ulf Strömsten, Catella funds and Mats Arnhög, Chairman of the Board. Individual shareholders not represented in the Election Committee can submit proposals to the Election Committee via the company by e-mail to [susanne.jonsson@activebiotech.com](mailto:susanne.jonsson@activebiotech.com).

Active Biotech's Annual Report for 2007 is now available at [www.activebiotech.com](http://www.activebiotech.com).

### **Financial calendar**

Interim report January-June: August 6, 2008

Interim report January-September: November 14, 2008

Year-end Report, 2008: February 12, 2009

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

Lund, April 24, 2008

Active Biotech AB (publ)

Sven Andréasson  
President and CEO

***This interim report has not been audited by the company's auditors.***

### **About Active Biotech**

*Active Biotech AB (OMX NORDIC: ACTI) 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 targeted therapy, primarily renal 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.*

The information included in this report is such information that Active Biotech AB (publ) is obligated to publish in accordance with the Swedish Securities Market Act and/or the Financial Instruments Trading Act. This information was provided to the media for publication on Thursday, April 24, 2008, at 8:30 a.m.