

Active Biotech AB

Interim report January – March 2015

Laquinimod

- The pivotal CONCERTO clinical study is continuing according to plan and results are expected in 2016
- Teva is holding a number of presentations of laquinimod at the AAN Annual Meeting on April 18-25

Tasquinimod

- Results from the Phase III study 10TASQ10 showed that treatment with tasquinimod reduced the risk of radiographic cancer progression or death compared to placebo (rPFS, HR=0.69, CI 95%: 0.60 - 0.80) in patients with metastatic castration resistant prostate cancer (mCRPC) who have not received chemotherapy, but did not extend overall survival (OS, HR=1.09, CI 95%: 0.94 - 1.28)
- Further development of tasquinimod for the treatment of prostate cancer has been discontinued. The collaboration agreement with Ipsen will accordingly cease.

ISI

- The project is currently focusing on building up a patent portfolio

Financial summary

MSEK	Jan. - Mar.		Jan. - Dec.
	2015	2014	2014
Net sales	2.9	2.1	10.4
Operating loss	-57.4	-59.2	-228.5
Loss for the period	-58.0	-60.2	-231.5
Loss per share (SEK)	-0.64	-0.80	-3.02
Cash and cash equivalents	270.5	298.5	328.5

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Laquinimod – a novel oral immunomodulatory compound for the treatment of neurodegenerative diseases

Laquinimod is a quinoline compound under development for the treatment of [multiple sclerosis](#) (MS). Active Biotech has an agreement with the Israeli company [Teva Pharmaceutical Industries Ltd](#) (June 2004) covering the development and commercialization of laquinimod. In December 2010, positive results from the Phase III [ALLEGRO](#) study were presented. Laquinimod met the primary endpoint of reducing the annualized relapse rate and significantly slowed progression of disability. On August 1, 2011, the initial results were announced from the second Phase III [BRAVO](#) study. The BRAVO findings supported the direct effect of laquinimod in the central nervous system (CNS) and were in line with the results of the first laquinimod Phase III trial, ALLEGRO, but did not achieve the primary clinical endpoint. The Phase III study CONCERTO is under way with the primary endpoint of measuring time to confirmed disability progression. In [November 2014](#), the first patient was screened for the LEGATO-HD clinical study, which will evaluate a daily dose (0.5, 1.0 or 1.5 mg) of laquinimod as a potential treatment for adult patients with Huntington's disease. Teva will also initiate a Phase II study called ARPEGGIO that will evaluate laquinimod in patients with primary progressive multiple sclerosis (PPMS).

– To confirm the benefits of laquinimod in relation to delaying further disability progression, Teva is conducting the CONCERTO trial, the largest MS trial with disability progression as the primary clinical endpoint. The ongoing CONCERTO trial is Teva's third Phase III study in relapsing remitting multiple sclerosis (RRMS) and explores daily doses of laquinimod 0.6 mg and 1.2 mg. This study will also examine the impact of laquinimod on endpoints such as percentage change in brain volume and other clinical and MRI markers of disease activity. The results from this study are expected in 2016.

Tasquinimod – an immunomodulatory, anti-metastatic substance for the treatment of prostate cancer

The development of tasquinimod is principally focused on the treatment of [prostate cancer](#). Tasquinimod is an immunomodulatory, anti-metastatic substance that indirectly affects the tumor's ability to grow and spread. In April 2011, [Active Biotech and Ipsen](#) (Euronext: IPN; ADR: IPSEY) entered a broad partnership for the co-development and commercialization of Active Biotech's compound, tasquinimod. Under the terms of the agreement, Active Biotech granted Ipsen exclusive rights to commercialize tasquinimod worldwide, except for North and South America and Japan, where Active Biotech has all commercial and marketing rights.

– The clinical Phase III trial 10TASQ10 is a global, randomized, double-blind, placebo-controlled study of mCRPC patients. The aim of the study is to confirm tasquinimod's efficacy on the disease, with radiological progression-free survival (PFS) as the primary clinical endpoint and overall survival (OS) as the secondary clinical endpoint. Refer to Events after the end of the period.

ISI (Inhibition of S100 interactions) – preclinical project based on the mode of action of quinoline compounds

Active Biotech is conducting a research project aimed at utilizing the company's own preclinical results that were generated with respect to a target molecule for the quinoline (Q) compounds and their biological mode of action. The [results](#) of a target molecule for the Q compounds were published in PLoS Biology ([Volume 7, Issue 4, pp. 800-812](#)) in April 2009. The study showed that Q compounds bind to a molecule called S100A9, which is expressed in white blood cells involved in the regulation of immune responses. Furthermore, it is shown that S100A9 interacts with two known pro-inflammatory receptors (Toll-like receptor 4 (TLR4) and Receptor of Advanced Glycation End products (RAGE)) and that this interaction is inhibited by Q compounds. The project aims at producing new, patentable chemical substances that interact with one of the target molecules of the Q compounds. This project is based on preclinical studies and has potential treatment applications in both degenerative diseases and cancer.

– Efforts have been focused on building up a patent portfolio around the substances that interact with S100 proteins and impede their interaction with their receptors. During 2014, the company submitted three priority applications for the purpose of obtaining patent protection for three, chemically unrelated, substance groups. As a result of the events in the tasquinimod project as detailed below, the selection of a first candidate drug for the ISI project has been moved forward.

Events after the end of the period

Laquinimod

Teva is holding a number of presentations of laquinimod at the ongoing 67th American Academy of Neurology (AAN) Annual Meeting on [April 18-25](#), 2015, addressing such aspects as the design of the clinical Phase II study ARPEGGIO, which will evaluate laquinimod's potential for treatment of primary progressive multiple sclerosis (PPMS).

Tasquinimod

The results of the 10TASQ10 study were presented on [April 16, 2015](#). The study showed that tasquinimod reduced the risk of radiographic cancer progression or death compared to placebo (rPFS, HR=0.69, CI 95%: 0.60 - 0.80) (primary endpoint) in patients with metastatic castration resistant prostate cancer (mCRPC) who have not received chemotherapy. However, tasquinimod did not extend overall survival (OS, HR=1.09, CI 95%: 0.94 - 1.28).

The weighted efficacy data, despite the favorable safety data, do not support a positive benefit risk balance in this population. Therefore the companies have decided to discontinue all studies and all further development for the treatment of prostate cancer. Full results will be presented at an upcoming scientific conference.

An additional consequence of these study results is that the collaboration agreement with Ipsen will cease. Also, all further development of tasquinimod in other indications by Ipsen will be discontinued.

Financial information

Comments on the Group's results for the period January – March 2015

Net sales amounted to SEK 2.9 M (2.1) and included service and rental revenues.

The operation's research and administrative expenses amounted to SEK 60.3 M (61.4), of which research expenses amounted to SEK 55.0 M (56.9). The decrease in expenses was attributable to planned lower costs for the clinical Phase III trial of tasquinimod for the treatment of prostate cancer. The other research projects – the ANYARA renal cell cancer project, 57-57 for the treatment of scleroderma and the preclinical research project ISI – only had a marginal impact on the cost development between the years. The out-licensed projects comprising laquinimod and RhuDex are financed by the relevant partners.

The operating loss for the period amounted to SEK 57.4 M (loss: 59.2). The change in earnings compared with the year-earlier period was attributable to lower research costs, given that patients in the Phase III tasquinimod trial were in the follow-up phase during the report period. Administrative expenses amounted to SEK 5.3 M (4.5), the net financial expense for the period to SEK 1.1 M (expense: 1.5) and the loss after tax to SEK 58.0 M (loss: 60.2).

Cash flow, liquidity and financial position, Group

Cash and cash equivalents at the end of the period amounted to SEK 270.5 M, compared with SEK 328.5 M at the end of 2014.

Cash flow for the period was a negative SEK 57.9 M (neg: 77.7), of which cash flow from operating activities accounted for a negative SEK 56.2 (neg: 80.5) and cash flow from financing activities for a negative SEK 1.7 M (pos: 2.9).

Investments

Investments in tangible fixed assets amounted to – (0.1).

Comments on the Parent Company's results and financial position for the period January – March 2015

Net sales for the period amounted to SEK 5.0 M (5.0) and operating expenses to SEK 67.9 M (69.5). The Parent Company's operating loss for the period was SEK 62.9 M (loss: 64.5). Net financial income amounted to SEK 0.6 M (0.7) and the loss after financial items was SEK 62.3 M (loss: 63.9). Cash and cash equivalents including short-term investments totaled SEK 259.8 M at the end of the period, compared with SEK 319.7 M on January 1, 2015.

Shareholders' equity

Consolidated shareholder's equity at the end of the period amounted to SEK 349.3 M, compared with SEK 405.3 M at year-end 2014. The number of shares outstanding at the end of the period totaled 89,908,298. At the end of the period, the equity/assets ratio for the Group was 52.9 percent, compared with 56.1 percent at year-end 2014. The corresponding figures for the Parent Company, Active Biotech AB, were 80.3 percent and 82.2 percent, respectively.

Organization

The average number of employees was 56 (59), of which the number of employees in the research and development organization accounted for 45 (48). At the end of the period, the Group had 56 employees.

Outlook, including significant risks and uncertainties

A vital factor for Active Biotech's long-term financial strength and stability is the company's ability to develop pharmaceutical projects to the point at which partnership agreements can be entered into and the partner can assume responsibility for future development and commercialization of the project. During this development phase, the value of projects is expected to increase. The development of partnership agreements already signed and the addition of new agreements are assumed to have a significant impact on future revenues and cash balances. Income from already signed agreements and existing cash and cash equivalents are expected to finance operations.

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, where a number of factors 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, regulatory requirements, capital requirements, currencies and interest rates. Since no significant changes took place with regard to risks and uncertainties during the period, we refer to the detailed account of these factors presented in the Directors' Report in the 2013 Annual Report. Since the Group's operations are primarily conducted in the Parent Company, risks and uncertainties refer to both the Group and the Parent Company.

Consolidated profit and loss SEK M	Jan. - Mar.		Jan. - Dec.
	2015	2014	2014
Net sales	2.9	2.1	10.4
Administrative expenses	-5.3	-4.5	-17.0
Research and development costs	-55.0	-56.9	-221.9
Operating profit/loss	-57.4	-59.2	-228.5
Net financial items	-1.1	-1.5	-5.3
Profit/loss before tax	-58.5	-60.8	-233.7
Tax	0.6	0.6	2.2
Net profit/loss for the period	-58.0	-60.2	-231.5
Comprehensive loss attributable to:			
Parent Company shareholders	-58.0	-60.2	-231.5
Non-controlling interests	—	—	—
Net profit/loss for the period	-58.0	-60.2	-231.5
Comprehensive profit/loss per share before dilution (SEK)	-0.64	-0.80	-3.02
Comprehensive profit/loss per share after dilution (SEK)	-0.64	-0.80	-3.02

Statement of profit and loss and consolidated comprehensive income SEK M	Jan. - Mar.		Jan. - Dec.
	2015	2014	2014
Net profit/loss for the period	-58.0	-60.2	-231.5
Other comprehensive income			
Items that can not be reclassified into profit or loss			
Change in revaluation reserve	1.8	1.8	7.2
Taxes attributable to other comprehensive income	-0.4	-0.4	-1.6
Total comprehensive profit/loss for the period	-56.6	-58.8	-225.9
Total other comprehensive profit/loss for the period attributable to:			
Parent Company shareholders	-56.6	-58.8	-225.9
Non-controlling interests	—	—	—
Total comprehensive profit/loss for the period	-56.6	-58.8	-225.9
Depreciation/amortization included in the amount of	3.0	3.1	12.3
Investments in tangible fixed assets	—	0.1	1.9
Weighted number of outstanding common shares before dilution (000s)	89 908	74 924	76 755
Weighted number of outstanding common shares after dilution (000s)	89 908	74 924	76 755
Number of shares at close of the period (000s)	89 908	74 924	74 924

Consolidated statement of financial position		Mar. 31	Dec. 31
SEK M		2015	2014
Tangible fixed assets		381.1	381.0
Long-term receivables		0.0	0.0
Total fixed assets		381.1	381.0
Current receivables		8.8	10.9
Cash and cash equivalents		270.5	298.5
Total current assets		279.4	309.5
Total assets		660.5	690.5
Shareholders equity		349.3	347.2
Long-term liabilities		221.0	227.4
Current liabilities		90.1	115.9
Total shareholders equity and liabilities		660.5	690.5
			722.5
Consolidated statement of changes in shareholders equity		Mar. 31	Dec. 31
SEK M		2015	2014
Opening balance		405.3	405.4
Transfer from revaluation reserve		0.6	0.6
New share issue		–	–
Net loss for the period		-56.6	-58.8
Balance at close of period		349.3	347.2
			405.3
Condensed consolidated cash-flow statement		Jan. - Mar.	Jan. - Dec.
SEK M		2015	2014
Loss after financial items		-58.5	-60.8
Adjustment for non-cash items, etc.		3.0	3.1
Cash flow from operating activities			
before changes in working capital		-55.5	-57.6
Changes in working capital		-0.8	-22.9
Cash flow from operating activities		-56.2	-80.5
Investments in tangible fixed assets		–	-0.1
Cash flow from investing activities		–	-0.1
New share issue		–	–
Loans raised/amortization of loan liabilities		-1.7	2.9
Cash flow from financing activities		-1.7	2.9
Cash flow for the period		-57.9	-77.7
Opening cash and cash equivalents		328.5	376.2
Closing cash and cash equivalents		270.5	298.5
			328.5

Key figures	Mar. 31				Dec. 31					
	2015	2014	2014							
Shareholders equity, SEK M	349.3				347.2					
Equity per share, SEK	3.89				4.63					
Equity/assets ratio in the Parent Company	80.3%				77.5%					
Equity/assets ratio in the Group	52.9%				50.3%					
Average number of annual employees	56				59					

Consolidated profit and loss by quarter																	
SEK M	2011				2012				2013				2014				2015
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	
Net sales	2.7	226.1	2.6	3.3	2.6	94.0	39.8	91.5	2.4	2.5	107.0	4.0	2.1	2.7	2.6	2.9	2.9
Administrative expenses	-5.3	-4.4	-3.2	-4.0	-3.8	-4.2	-3.2	-4.7	-4.2	-4.6	-3.8	-4.4	-4.5	-5.3	-3.7	-3.5	-5.3
Research and dev. costs	-68.3	-80.1	-76.2	-93.9	-99.4	-109.7	-84.8	-81.3	-75.2	-77.5	-75.3	-80.0	-56.9	-55.3	-54.6	-55.1	-55.0
Operating profit/loss	-70.9	141.5	-76.8	-94.7	-100.7	-19.9	-48.2	5.5	-77.0	-79.5	27.9	-80.4	-59.2	-57.9	-55.7	-55.6	-57.4
Net financial items	1.6	4.3	-2.8	-5.7	1.0	-5.3	-4.1	-0.4	-1.6	-2.2	0.8	-2.2	-1.5	-0.3	-1.5	-1.9	-1.1
Profit/loss before tax	-69.3	145.8	-79.6	-100.4	-99.6	-25.1	-52.3	5.1	-78.6	-81.7	28.7	-82.6	-60.8	-58.2	-57.2	-57.6	-58.5
Tax	-	1.2	0.6	7.2	0.6	0.6	0.6	-5.0	0.6	0.6	0.6	0.6	0.6	0.6	0.6	0.6	0.6
Net profit/loss for the period	-69.3	147.0	-79.0	-93.2	-99.0	-24.5	-51.6	0.1	-78.0	-81.2	29.2	-82.1	-60.2	-57.7	-56.6	-57.0	-58.0

Active Biotech Parent Company - Income Statement, condensed					Jan. - Mar.		Jan. - Dec	
SEK M					2015	2014	2014	
Net sales					5.0	5.0	18.0	
Administration expenses					-9.7	-8.9	-34.6	
Research and development costs					-58.2	-60.6	-235.5	
Operating profit/loss					-62.9	-64.5	-252.1	
<i>Profit/loss from financial items:</i>								
Interest income and similar income-statement items					0.2	0.9	2.4	
Interest expense and similar income-statement items					0.4	-0.2	-0.4	
Profit/loss after financial items					-62.3	-63.9	-250.0	
Tax					-	-	-	
Net profit/loss for the period					-62.3	-63.9	-250.0	
Statement of comprehensive income parent company								
Net profit/loss for the period					-62.3	-63.9	-250.0	
Other comprehensive income					-	-	-	
Total comprehensive profit/loss for the period					-62.3	-63.9	-250.0	

Active Biotech Parent Company - Balance sheet, condensed					Mar. 31		Dec. 31	
SEK M					2015	2014	2014	
Goodwill					92.9	109.0	96.9	
Tangible fixed assets					0.5	0.6	0.6	
Financial fixed assets					40.6	40.6	40.6	
Total fixed assets					134.0	150.2	138.0	
Current receivables					20.7	22.6	23.3	
Short-term investments					236.9	225.2	76.7	
Cash and bank balances					22.9	63.4	243.0	
Total current assets					280.4	311.2	343.0	
Total assets					414.3	461.4	481.0	
Shareholders equity					332.9	357.7	395.2	
Current liabilities					81.5	103.8	85.8	
Total equity and liabilities					414.3	461.4	481.0	

Any errors in additions are attributable to rounding of figures.

Note 1: Accounting policies

The interim report of the Group has been prepared in accordance with IAS 34, Interim Financial Reporting and applicable parts of the Annual Accounts Act. The interim report of the Parent Company has been prepared in accordance with Chapter 9 of the Annual Accounts Act. For the Group and the Parent Company, the same accounting policies and accounting estimates and assumptions were applied to this interim report as were used in the preparation of the most recent annual report.

Note 2: Fair value of financial instruments

SEK M	Mar 31, 2015		Dec 31, 2014	
	Level 2	Level 2	Level 2	Level 2
Short-term investments		236.9		76.7
Current liabilities, derivatives		-	-	-

The fair value of financial assets and liabilities essentially corresponds to the carrying amount in the balance sheet. The fair-value measurement of financial assets and liabilities has been conducted according to level 2 as defined in IFRS 7.27 A, with the exception of cash and cash equivalents, which is measured according to level 1. For more information, refer to Note 16 in the 2013 Annual Report. No significant changes have occurred in relation to the measurement made at December 31.

Annual General Meeting 2015

The Annual General Meeting of Active Biotech AB (publ) is to be held on Thursday, June 11, 2015 at 5:00 p.m. at Elite Hotel Ideon, Schelevägen 27, Lund, Sweden. The notice of the Annual General Meeting will be published no later than four weeks prior to the Meeting.

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 in 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

Interim reports 2015: August 7 and November 6

Year-end report 2015: February 18, 2016

The reports will be available from these dates at www.activebiotech.com.

Lund, April 23, 2015

Active Biotech AB (publ)

Tomas Leanderson

President and CEO

Active Biotech AB (publ) (Nasdaq Stockholm: ACTI) is a biotechnology company with focus on neurodegenerative/inflammatory diseases and cancer. Laquinimod, an orally administered small molecule with unique immunomodulatory properties, is in pivotal phase III development for the treatment of relapsing remitting multiple sclerosis. Also, laquinimod is in phase II development for the treatment of primary progressive multiple sclerosis and Huntington's disease. The project portfolio includes a preclinical project, ISI, with the objective to produce new, patentable chemical compounds for treatment of diseases within the company's focus areas. Please visit www.activebiotech.com for more information.

Active Biotech is obligated to publish the information contained in this interim report in accordance with the Swedish Securities Market Act. This information was provided to the media for publication on April 23, 2015 at 8:30 a.m.