

Active Biotech AB

Interim report January – March 2017

Laquinimod

- The clinical trials CONCERTO, ARPEGGIO and LEGATO-HD are progressing according to plan
- The study results from the pivotal clinical Phase 3 CONCERTO trial in relapsing remitting multiple sclerosis (RRMS) are expected in the first half of 2017
- The study results from the clinical Phase 2 ARPEGGIO trial, evaluating laquinimod for the treatment of primary progressive multiple sclerosis (PPMS), are expected in the second half of 2017
- Orphan Drug Designation granted for laquinimod for the treatment of Huntington's disease by the US Food and Drug Administration (FDA)

ANYARA

- Project proceeding according to plan

Tasquinimod, paquinimod and SILC

- Out-licensing activities are continuing
- The European Patent Office has granted a patent application covering tasquinimod for use in the treatment of multiple myeloma
- Orphan Drug Designation granted for tasquinimod for the treatment of multiple myeloma by the US Food and Drug Administration (FDA)
- Product patent for SILC substances granted by the European Patent Office

Financial summary

SEK M	Jan.-Mar.		Full-year
	2017	2016	2016
Net sales	4.7	3.9	19.0
Operating loss	-14.6	-16.1	-55.1
Loss after tax	-15.8	-16.8	-59.6
Loss per share, before and after dilution (SEK)	-0.16	-0.19	-0.65
Cash and cash equivalents (at close of period)	62.7	76.5	77.7

- Operations are progressing according to plan pending the Phase 3 results for laquinimod in the first half of 2017

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The report is also available at www.activebiotech.com.

Progress report from the CEO

The company's primary focus is the continued collaboration with our partners Teva in the development of the laquinimod project and NeoTX Therapeutics in the development of ANYARA. Regarding the tasquinimod, paquinimod and SILC projects, the necessary activities are underway for Active Biotech to identify a commercial partner for the further development of these projects. No comment will be provided concerning the status of these negotiations.

Projects in ongoing development

PROJECT	PRIMARY INDICATION	DISCOVERY PHASE	PRECLINICAL DEV.	CLINICAL PHASE I	CLINICAL PHASE II	CLINICAL PHASE III	PARTNER
Laquinimod	RRMS (Allegro/Bravo)						TEVA
	RRMS (Concerto)						
	PPMS (Arpeggio)						
	Huntingtons disease (Legato-HD)						
	Crohns disease						
	Lupus						
ANYARA	Oncology						NeoTX

Striped = Ongoing

Projects for licensing

PROJECT	PRIMARY INDICATION	DISCOVERY PHASE	PRECLINICAL DEV.	CLINICAL PHASE I	CLINICAL PHASE II	CLINICAL PHASE III
Tasquinimod	Prostate cancer					
	Multiple Myeloma					
Paquinimod	Systemic Sclerosis					
SILC	Oncology					

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

Laquinimod is a quinoline compound under development for the treatment of [multiple sclerosis](#) (MS) and Huntington's disease. Active Biotech has an agreement with the Israeli company [Teva Pharmaceutical Industries Ltd](#) since 2004 covering the development and commercialization of laquinimod.

In December 2010, positive results from the [Phase 3 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 3 study BRAVO](#). 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 3 trial, ALLEGRO, but did not achieve statistical significance regarding the primary clinical endpoint.

The ongoing CONCERTO trial is Teva's third Phase 3 study in relapsing remitting multiple sclerosis (RRMS), designed to evaluate daily doses of laquinimod 0.6 and 1.2 mg. The study is intended to confirm the benefits of laquinimod in delaying further disability progression (as measured by EDSS – Expanded Disability Status Scale), which is its primary endpoint. The 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. [On June 25, 2015](#), it was announced that enrollment to CONCERTO had been finalized and included 2,199 patients.

[In November 2014](#), the first patient was screened for the Phase 2 LEGATO-HD clinical study, which will evaluate a daily dose (0.5, 1.0 or 1.5 mg per day) of laquinimod as a potential treatment for adult patients with Huntington's disease. The primary endpoint for LEGATO-HD is change from baseline in the Unified Huntington's Disease Rating Scale-Total Motor Scale (UHDRS-TMS) as defined by the sum of the scores of all UHDRS-TMS sub-items after 12 months of treatment. The study is planned to include about 400 patients in the US, Canada and Europe.

It was announced [in April 2015](#) that the first patient had been enrolled in the study "A Randomized Placebo-controlled Trial Evaluating Laquinimod in PPMS, Gauging Gradations In MRI and Clinical Outcomes" (ARPEGGIO), which will evaluate laquinimod's potential for treatment of primary progressive multiple sclerosis (PPMS). ARPEGGIO is a multinational, multicenter, randomized, double-blind, placebo-controlled clinical Phase 2 study with parallel groups that will evaluate laquinimod (0.6 and 1.2 mg per day) compared with placebo in PPMS patients. The primary endpoint of the study is brain atrophy, defined as the percentage brain volume change (PBVC) as measured with MRI.

[On January 4, 2016](#), it was announced that the trial arms studying higher doses of laquinimod in two ongoing studies in multiple sclerosis (MS) (CONCERTO and ARPEGGIO) would be discontinued after the occurrence of cardiovascular events, none of which were fatal, in eight patients. The change came at the recommendation of the Data Monitoring Committee (DMC) overseeing the two active clinical studies in MS. The DMC identified an imbalance in the number of cardiovascular events in the studies. Further analysis of these events is ongoing. The studies are continuing according to plan with the treatment of patients with 0.6 mg per day. [On January 11, 2016](#), it was also announced that the trial design of a Phase 2 study (LEGATO-HD) of laquinimod in Huntington's disease would be amended. The amendment consists of dropping the highest of three doses (1.5 mg/day) in the trial while keeping two remaining active doses (0.5 and 1.0 mg/day) unchanged. This is a precautionary measure in the interest of patient safety being suggested by Teva to the DMC for the LEGATO-HD trial. Cardiovascular events have not been observed for any dose of the LEGATO-HD trial.

Extension studies involving patients from both the clinical Phase 2 and Phase 3 studies, ALLEGRO and BRAVO, are under way. These studies encompass more than 1,000 patients with a total exposure of more than 11,000 patient years.

- The clinical trials CONCERTO, ARPEGGIO and LEGATO-HD are progressing according to plan.
- Results from the pivotal Phase 3 CONCERTO trial are expected to be available in the first half of 2017.
- On January 31, 2017, the FDA announced that laquinimod had been granted Orphan Drug Designation in the US for the treatment of Huntington's disease.

ANYARA – fusion protein for immunological treatment of cancer

[ANYARA](#) (naptumomab estafenatox) is a TTS (Tumor Targeted Superantigen) compound that makes cancer treatment tumor-specific. The development of ANYARA is mainly focused on renal cell cancer. Positive data was reported in connection with the [interim analysis in Phase 2/3](#) and from clinical Phase 1 trials in lung cancer, renal cell cancer and pancreatic cancer. [In July 2009](#), the results from two Phase 1 studies of ANYARA were published in the *Journal of Clinical Oncology*, where ANYARA was studied both as a single agent (monotherapy) and in combination with an established tumor therapy – docetaxel (Taxotere®) – in patients with advanced cancer. The results showed that ANYARA was well tolerated both as monotherapy and in combination with docetaxel. Overall survival (OS) and progression-free survival (PFS) data from the ANYARA Phase 2/3 study in renal cell cancer was presented [in June 2013](#). The study encompassed 513 patients and was designed to evaluate the effect of ANYARA in combination with interferon-alpha, compared with interferon-alpha alone, in patients with advanced renal cell cancer. The primary endpoint was improved overall survival, which was not achieved in the overall ITT population, but was attained in a biomarker-defined subgroup of 130 patients. In this subgroup, the median OS for the ANYARA vs. placebo treatment arm was 63.3 vs. 31.1 months (HR: 0.59; p=0.020), respectively. The median PFS were 13.7 (ANYARA) vs. 5.8 (placebo) months (HR: 0.62; p=0.016). [On October 26, 2016](#), Active Biotech announced that it had entered into a licensing agreement with [NeoTX Therapeutics Ltd](#) (NeoTX) for Active Biotech's investigational compound Naptumumab estafenatox ("ANYARA") for cancer immunotherapy. NeoTX will be responsible for and finance the worldwide clinical development and commercialization of ANYARA. The total deal value amounts to USD 71 M and is contingent upon

achievement of clinical, regulatory and commercial milestones. Active Biotech will receive USD 250,000 as an initial payment. In addition, NeoTX will pay Active Biotech tiered, double-digit royalties on future market sales.

- The project is proceeding according to plan.

Events after the end of the period

[On April 12, 2017](#), it was announced that Active Biotech had been granted Orphan Drug Designation by the FDA for tasquinimod for the treatment of multiple myeloma.

Financial information

Comments on the Group's results for the period January – March 2017

Net sales amounted to SEK 4.7 M (3.9) and included service and rental revenues.

The operation's research and administration expenses amounted to SEK 19.3 M (20.0), of which research expenses amounted to SEK 15.2 M (15.6). In 2016 and the beginning of 2017, the company's research operations comprise solely activities aimed at supporting projects and patents for previously out-licensed projects, and commercial activities to identify partners for the paquinimod, tasquinimod and SILC projects.

The previously out-licensed projects, laquinimod, ANYARA and RhuDex, are financed in full by the relevant partners.

The operating loss for the period amounted to SEK 14.6 M (loss: 16.1). The year-on-year improvement in earnings was attributable to higher income and lower expenses. Administration expenses amounted to SEK 4.1 M (4.4), the net financial expense for the period to SEK 1.8 M (expense: 1.3) and the loss after tax to SEK 15.8 M (loss: 16.8).

Cash flow, liquidity and financial position, Group, for the period January – March 2017

Cash and cash equivalents at the end of the period amounted to SEK 62.7 M, compared with SEK 77.7 M at the end of 2016. Cash flow for the period was a negative SEK 15.0 M (neg: 27.1), of which cash flow from operating activities accounted for a negative SEK 13.6 M (neg: 14.4) and cash flow from financing activities for a negative SEK 1.6 M (neg: 1.6).

Investments

Investments in tangible fixed assets amounted to SEK 0.0 M (0.0).

Comments on the Parent Company's results and financial position for the period January – March 2017

Net sales for the period amounted to SEK 6.2 M (6.6) and operating expenses to SEK 24.2 M (25.0). The Parent Company's operating loss for the period was SEK 18.1 M (loss: 18.4). Net financial income amounted to SEK 0.0 M (0.4) and the loss after financial items was SEK 18.1 M (loss: 18.0). Cash and cash equivalents including short-term investments totaled SEK 57.7 M at the end of the period, compared with SEK 73.2 M on January 1, 2017.

The Board has calculated the Parent Company's equity in accordance with the rules in Chapter 25, Section 14, paragraphs 1 and 2 of the Swedish Companies Act and, it is evident according to this calculation that equity is not less than half of the registered share capital.

Shareholders' equity

Consolidated shareholder's equity at the end of the period amounted to SEK 168.7 M, compared with SEK 182.6 M at year-end 2016.

The number of shares outstanding at the end of the period totaled 96,824,320. At the end of the period, the equity/assets ratio for the Group was 42.4 percent, compared with 44.2 percent at year-end 2016. The corresponding figures for the Parent Company, Active Biotech AB, were 91.8 percent and 92.7 percent, respectively.

Organization

The average number of employees during the reporting period was 17 (43), of which the number of employees in the research and development organization accounted for 8 (34). At the end of the period, the Group had 17 employees.

Annual General Meeting

The Annual General Meeting will be held on June 15, 2017 at Elite Hotel Ideon, Scheelevägen 27, Lund, Sweden. Shareholders who wish to contact the Nomination Committee can do so by post to: Nomination Committee, Active Biotech AB, Box 724, SE-220 07 Lund, Sweden.

Annual Report

Active Biotech's Annual Report is expected to be published on the company's website www.activebiotech.com shortly.

Dividend

The Board of Directors proposes that no dividend be paid for the 2016 fiscal year.

Outlook, including significant risks and uncertainties

In the long term, the existing partnership agreements with Teva Pharmaceuticals and NeoTX have a decisive impact on the company's future revenues and financial position. Existing liquidity, financial and tangible assets will finance operations until a possible marketing authorization for laquinimod and ANYARA has been obtained. 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. A detailed account of these risks and uncertainties is presented in the Directors' Report in the 2015 Annual Report. The Group's operations are primarily conducted in the Parent Company, which is why risks and uncertainties refer to both the Group and the Parent Company.

Consolidated profit and loss SEK M	Jan. - Mar.		Full Year
	2017	2016	2016
Net sales	4,7	3,9	19,0
Administrative expenses	-4,1	-4,4	-15,9
Research and development costs	-15,2	-15,6	-58,2
Operating profit/loss	-14,6	-16,1	-55,1
Net financial items	-1,8	-1,3	-6,7
Profit/loss before tax	-16,4	-17,4	-61,8
Tax	0,6	0,6	2,2
Net profit/loss for the period	-15,8	-16,8	-59,6
Comprehensive loss attributable to:			
Parent Company shareholders	-15,8	-16,8	-59,6
Non-controlling interests	—	—	—
Net profit/loss for the period	-15,8	-16,8	-59,6
Comprehensive profit/loss per share before dilution (SEK)	-0,16	-0,19	-0,65
Comprehensive profit/loss per share after dilution (SEK)	-0,16	-0,19	-0,65

Statement of profit and loss and consolidated comprehensive income	Jan. - Mar.		Full Year
SEK M	2017	2016	2016
Net profit/loss for the period	-15,8	-16,8	-59,6
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	-14,4	-15,4	-54,0
Total other comprehensive profit/loss for the period attributable to:			
Parent Company shareholders	-14,4	-15,4	-54,0
Non-controlling interests	–	–	–
Total comprehensive profit/loss for the period	-14,4	-15,4	-54,0
Depreciation/amortization included in the amount of	2,8	3,0	11,8
Investments in tangible fixed assets	–	–	–
Weighted number of outstanding common shares before dilution (000s)	96824	89908	91041
Weighted number of outstanding common shares after dilution (000s)	96824	89908	91041
Number of shares at close of the period (000s)	96824	89908	96824

Consolidated statement of financial position	Mar. 31		Dec. 31
SEK M	2017	2016	2016
Tangible fixed assets	327,7	329,4	328,1
Long-term receivables	0,0	0,0	0,0
Total fixed assets	327,7	329,4	328,1
Current receivables	7,3	1,9	7,1
Cash and cash equivalents	62,7	76,5	77,7
Total current assets	70,0	78,4	84,8
Total assets	397,7	407,7	412,9
Shareholders equity	168,7	165,7	182,6
Long-term liabilities	208,6	214,6	207,0
Current liabilities	20,4	27,3	23,4
Total shareholders equity and liabilities	397,7	407,7	412,9

Consolidated statement of changes in shareholders equity	Mar. 31		Dec. 31
SEK M	2017	2016	2016
Opening balance	182,6	180,6	180,6
Transfer from revaluation reserve	0,6	0,6	2,2
New share issue	–	–	53,7
Net loss for the period	-14,4	-15,4	-54,0
Balance at close of period	168,7	165,7	182,6

Condensed consolidated cash-flow statement		Jan. - Mar.		Full Year
SEK M		2017	2016	2016
Loss after financial items		-16,4	-17,4	-61,8
Adjustment for non-cash items, etc.		2,8	3,0	11,8
Cash flow from operating activities before changes in working capital		-13,6	-14,4	-50,0
Changes in working capital		0,2	-11,1	-23,1
Cash flow from operating activities		-13,4	-25,5	-73,2
New share issue		-	-	53,7
Loans raised/amortization of loan liabilities		-1,6	-1,6	-6,5
Cash flow from financing activities		-1,6	-1,6	47,2
Cash flow for the period		-15,0	-27,1	-25,9
Opening cash and cash equivalents		77,7	103,6	103,6
Closing cash and cash equivalents		62,7	76,5	77,7

Key figures	Mar. 31		Dec. 31
	2017	2016	2016
Shareholders equity, SEK M	168,7	165,7	182,6
Equity per share, SEK	1,74	1,84	1,89
Equity/assets ratio in the Parent Company	91,8%	87,9%	92,7%
Equity/assets ratio in the Group	42,4%	40,7%	44,2%
Average number of annual employees	17	43	28

The equity/assets ratio is presented since this is a key figure that Active Biotech considers relevant for investors who wish to assess the company's capacity to meet its financial commitments. The key figure is calculated by dividing recognized shareholders' equity by recognized total assets.

Consolidated profit and loss																	
SEK M	2013				2014				2015				2016				2017
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1
Net sales	2,4	2,5	107,0	4,0	2,1	2,7	2,6	2,9	2,9	3,2	5,2	5,0	3,9	3,9	4,1	7,1	4,7
Administrative expenses	-4,2	-4,6	-3,8	-4,4	-4,5	-5,3	-3,7	-3,5	-5,3	-4,7	-3,8	-4,2	-4,4	-4,1	-3,5	-3,9	-4,1
Research and dev. costs	-75,2	-77,5	-75,3	-80,0	-56,9	-55,3	-54,6	-55,1	-55,0	-68,7	-23,6	-29,0	-15,6	-14,3	-11,7	-16,7	-15,2
Operating profit/loss	-77,0	-79,5	27,9	-80,4	-59,2	-57,9	-55,7	-55,6	-57,4	-70,1	-22,2	-28,2	-16,1	-14,5	-11,1	-13,5	-14,6
Net financial items	-1,6	-2,2	0,8	-2,2	-1,5	-0,3	-1,5	-1,9	-1,1	-1,8	-1,8	-2,1	-1,3	-1,6	-1,9	-1,9	-1,8
Profit/loss before tax	-78,6	-81,7	28,7	-82,6	-60,8	-58,2	-57,2	-57,6	-58,5	-71,9	-23,9	-30,3	-17,4	-16,1	-13,0	-15,4	-16,4
Tax	0,6	0,6	0,6	0,6	0,6	0,6	0,6	0,6	0,6	0,6	0,6	-10,4	0,6	0,6	0,6	0,6	0,6
Net profit/loss for the period	-78,0	-81,2	29,2	-82,1	-60,2	-57,7	-56,6	-57,0	-58,0	-71,4	-23,4	-40,8	-16,8	-15,5	-12,4	-14,8	-15,8

Active Biotech Parent Company - Income Statement, condensed		Jan. - Mar.	Full Year
SEK M		2017	2016
Net sales		6,2	6,6
Administration expenses		-8,2	-8,5
Research and development costs		-16,0	-16,5
Operating profit/loss		-18,1	-18,4
<i>Profit/loss from financial items:</i>			
Interest income and similar income-statement items		0,0	0,4
Interest expense and similar income-statement items		0,0	0,0
Profit/loss after financial items		-18,1	-18,0
Tax		–	–
Net profit/loss for the period		-18,1	-18,0
Statement of comprehensive income parent company			
Net profit/loss for the period		-18,1	-18,0
Other comprehensive income		–	–
Total comprehensive profit/loss for the period		-18,1	-18,0

Active Biotech Parent Company - Balance sheet, condensed		Mar. 31	Dec. 31
SEK M		2017	2016
Goodwill		60,6	76,7
Tangible fixed assets		0,5	0,5
Financial fixed assets		40,6	40,6
Total fixed assets		101,6	117,7
Current receivables		16,8	19,5
Short-term investments		48,7	56,6
Cash and bank balances		9,0	6,8
Total current assets		74,5	82,9
Total assets		176,0	200,7
Shareholders equity		161,5	176,5
Current liabilities		14,6	24,2
Total equity and liabilities		176,0	200,7

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

	Mar. 31, 2017	Dec. 31, 2016
SEK M	Level 2	Level 2
Short-term investments	48,7	68,7

The fair value of financial assets and liabilities essentially corresponds to the carrying amount in the balance sheet. For more information, refer to Note 17 in the 2015 Annual Report. No significant changes have occurred in relation to the measurement made at December 31, 2016.

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 2017: August 10 and November 9

Annual General Meeting 2017: June 15

Year-end report 2017: February 15, 2018

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

Lund, April 27, 2017

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 3 development for the treatment of relapsing remitting multiple sclerosis. Also, laquinimod is in Phase 2 development for the treatment of primary progressive multiple sclerosis and Huntington's disease. Furthermore, commercial activities are conducted for the tasquinimod, SILC and paquinimod projects. Please visit www.activebiotech.com for more information.

Active Biotech is obligated to make public the information contained in this interim report pursuant to the EU Market Abuse Regulation and the Securities Markets Act. This information was provided to the media, through the agency of the contact person set out above, for publication on April 27, 2017 at 8:30 a.m. CET.