

Active Biotech AB Interim report January – March 2020

First quarter in brief

- Active Biotech announces new direction
- Patent regarding use of tasquinimod in the treatment of multiple myeloma granted in Japan

Events after the end of the period

 Due to the current situation with the COVID-19 pandemic the Investment day planned to be held in connection with the Annual general meeting will be postponed to a later timepoint

Financial summary

SEK M	Jan	-Mar	Full-year
	2020	2019	2019
Net sales	0.5	5.5	8.4
Operating loss	-9.7	-6.4	-32.3
Loss after tax	-10.1	-8.1	-34.1
Loss per share (SEK)	-0.07	-0.06	-0.24
Cash and cash equivalents (at close of the period)	47.9	16.4	59.7

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

Active Biotech is obligated to make public the information contained in this report pursuant to the EU Market Abuse Regulation. This information was provided to the media, through the agency of the contact person set out above, for publication on April 23, 2020, at 08.30 a.m. CET.

Comments from the CEO

We started the first quarter of this year by communicating a new direction for the company. In the beginning of February, we announced our new focus, where we are taking advantage of the comprehensive clinical data package generated for tasquinimod and laquinimod during late stage product development and launch a partly new project portfolio with new disease indications.

We will advance **tasquinimod** in a clinical phase 1b/2a study in an academic partnership with Perelman's School of Medicine in Philadelphia. The final preparation for starting the clinical study is underway and we are expecting the first patient to be dosed during the third quarter this year. In the beginning of the year a patent for the use of tasquinimod in multiple myeloma was granted in Japan. With this patent in place we have a global patent protection for tasquinimod in this indication until 2035.

For **laquinimod** we are focusing on the two eye-disorders, wetAMD and uveitis and currently we are investigating options for a topical formulation to be used in these indications. We will also, in order to increase our understanding of the potential of laquinimod, carry out complementary preclinical studies. These activities are ongoing, and we expect to be able to provide updates during the year as the work progresses. In parallel, we evaluate possible paths forward for laquinimod in Crohn's disease and we plan for a new advice procedure with the regulatory authorities based on the previously performed Phase 2a study in this inflammatory bowel disease indication.

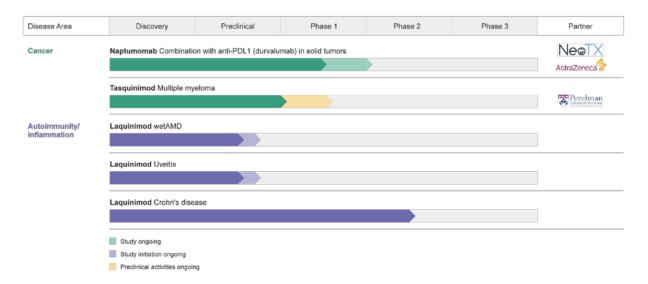
The clinical 1b/2 study with **naptumomab** in combination with the checkpoint inhibitor durvalumab in patients with advanced solid tumors is proceeding according to plan. We expect the first part of the study, that investigates the maximum tolerated dose of the combination, to be completed late 2020.

We, like everyone else, are affected by the COVID-19 epidemic. There is still a great uncertainty about the spread of the virus and its effects and the authorities in Sweden and in most other countries have imposed restrictions on events, travel and business activities. Active Biotech's priority in the current situation is to ensure the well-being and safety of our employees, patients and partners. Therefore, we take the necessary precautions and we will continue to monitor the spread of COVID-19 and subsequent actions carefully. We, together with business partners, have ongoing clinical trials and clinical trials planned to start. Global measures against COVID-19 and the need to prioritize health care resources are likely to affect the timelines of these studies. This means that the timing of the initial results of the ongoing clinical study with naptumomab in patients with solid tumors and the onset of the planned clinical study with tasquinimod in multiple myeloma may be affected and we will provide updates as needed. We were looking forward to presenting our project plans and the new focus of the company at a capital markets day in connection to the AGM. Due to the current situation with COVID-19, this is however not feasible and we will revert with a new date once the situation has normalized.

Helén Tuvesson, CEO

Projects

<u>Active Biotech's project portfolio</u> includes projects for the development of drugs for the treatment of cancer and autoimmune/inflammatory diseases.



Naptumomab Estafenatox

<u>Naptumomab</u> estafenatox, (naptumomab) is a tumor targeting immunotherapy that enhances the ability of the immune system to recognize and kill the tumor. Since October 2016, Active Biotech has a licensing agreement with <u>NeoTX Therapeutics Ltd (NeoTX)</u>. for the worldwide development and commercialization of naptumomab for cancer therapy.

Naptumomab increases tumor recognition and redirect specific T cells to trigger tumor killing. So-called "programmed death 1/ligand 1" (PD-1/L1) antibodies are a new group of cancer drugs, checkpoint inhibitors, which function by unleashing the immune system to attack the tumor. Despite the successes of recent years with these immunotherapies, it remains a challenge for the immune system to recognize tumor cells and there is a need to optimize the therapeutic effect of checkpoint inhibitors. Naptumomab increases the immune system's ability to recognize and attack the tumor and preclinical data from several different pre-clinical studies show synergistic anti-tumor effects and prolonged overall survival when naptumomab is combined with checkpoint inhibitors.

Currently, an open-label, multicenter, dose-finding clinical phase 1b study with naptumomab in combination with durvalumab, a PD-L1 checkpoint inhibitor, is ongoing. The clinical trial will enroll patients with previously treated advanced or metastatic, 5T4-positive solid tumors and aims to establish the maximum tolerated dose in the phase 1b study before advancing to a phase 2 cohort expansion study. The trial was initiated in the second half of 2019 and is performed under an agreement with AstraZeneca. More information about the study is available at clinicaltrials.gov (NCT03983954).

Tasquinimod

<u>Tasquinimod</u> is a once-daily, oral immunomodulatory compound that affects the tumor's ability to grow and spread. Tasquinimod has been studied in both healthy subjects and cancer patients. Clinical effects and an overall good tolerability have been demonstrated in 1500 patients, representing more than 650 patient-years of exposure to tasquinimod.

Today, tasquinimod is in development for treatment of multiple myeloma, a rare form of blood cancer with a high medical need. Extensive preclinical studies performed in collaboration with the Wistar Institute in Philadelphia, during the past years, provide clear support for the advancement of tasquinimod in multiple myeloma. An academic partnership with The Perelman School of Medicine, University of Pennsylvania for the development of tasquinimod as a new immunomodulatory product for the treatment of multiple myeloma has been formed. We are now supporting the preparation of a phase 1b/2a study in multiple myeloma patients. We expect that the first patient will be treated in Q3-2020. This program has also received funding from the Leukemia & Lymphoma Society in United States.

Patents in key markets have been granted, most recently in Japan, providing protection for the use of tasquinimod in malignant blood disorders, specifically acute forms of leukemia and multiple myeloma, until 2035. Furthermore, the FDA has granted orphan drug designation for tasquinimod for the treatment of multiple myeloma, which provides for seven years of market exclusivity in the event of future registration.

Events during the first quarter

Patent regarding use of tasquinimod in the treatment of multiple myeloma granted in Japan

Laquinimod

<u>Laquinimod</u> is an orally administered small molecule with unique immunomodulatory properties that previously has been developed primarily within neurodegenerative diseases. During its years of advanced product development, clinical efficacy and safety data on laquinimod was established in more than 5000 patients, representing more than 14000 patient-years of exposure.

Laquinimod as a new product for use in eye disorders

Our analyses have revealed an exciting pre-clinical evidence base supporting use of laquinimod for treatment of the two eye disorders Wet AMD and Uveitis. Our focus the coming 12 months will be, to define how best to develop laquinimod as a topical agent within these diseases and to increase our understanding of the therapeutic potential of laquinimod through additional pre-clinical studies.

Laquinimod as a new product in Crohn's disease

We have also decided to advance laquinimod for use in Crohn's disease, as an immunomodulatory agent with a novel mechanism of action, an indication for which a prior clinical Phase 2a study provides compelling data. Our review of the extensive preclinical scientific profiling of laquinimod in models of gastro-intestinal disorders, further supports a potential role in treatment of Crohn's disease. We will during the coming 12 months refresh the prior regulatory advice received from the FDA, and explore possible partnership modalities, including academic partnerships, to advance the evaluation of laquinimod in this indication.

Financial information

Comments on the Group's results for the period January - March, 2020

Net sales amounted to SEK 0.5 M (5.5) and includes real estate services according to the agreement signed with the buyer of the facility in April 2019. All services provided by Active Biotech cease from the beginning of April, 2020.

The operation's research and administration expenses amounted to SEK 10.2 M (11.9), of which research expenses totaled SEK 6.8 M (9.1), equivalent to a 25-percent reduction in expenses. During the reporting period, the company's research operations have been focused on supporting NeoTX in the clinical development of naptumomab in solid tumors and our academic partnership at Penn University in initiating clinical activities for tasquinimod in multiple myeloma. The pre-clinical activities with laquinimod in the eye diseases, uveitis and wetAMD, as outlined in the new direction of the company has also been initiated.

The operating loss for the period amounted to SEK 9.7 M (loss: 6.4). Administrative expenses amounted to SEK 3.4 M (2.8), the net financial expense for the period amounted to SEK 0.4 M (expense: 1.7) and the loss after tax to SEK 10.1 M (loss: 8.1).

Cash flow, liquidity and financial position, Group, for the period January – March, 2020

Cash and cash equivalents at the end of the period amounted to SEK 47.9 M, compared with SEK 59.7 M at the end of 2019. Cash flow for the period amounted to a negative SEK 11.8 M (neg: 9.1). The cash flow from operating activities amounted to a negative SEK 11.5 M (neg: 7.7) whereof the first quarter 2020 includes a one-time payment of approx. SEK 4 M related to the clinical and commercial evaluation of the company's lead assets undertaken in Q3 and Q4 of 2019. Cash flow from investments amounted to SEK 0 M (0). Cash flow from financing activities amounted to a negative SEK 0.3 M (neg: 1.4).

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, 2020 Net sales for the period amounted to SEK 0.5 M (4.8) and operating expenses to SEK 10.2 M (12.2). The Parent Company's operating loss for the period was SEK 9.7 M (loss: 7.4). Net financial expense amounted to SEK 0.4 M (0.0) and the loss after financial items was SEK 10.1 M (loss: 7.4). Cash and cash equivalents including short-term investments totaled SEK 47.1 M at the end of the period, compared with SEK 59.4 M on January 1, 2020.

Shareholders' equity

Consolidated shareholders' equity at the end of the period amounted to SEK 43.7 M, compared with SEK 53.8 M at year-end 2019.

The number of shares outstanding at the end of the period totaled 145,236,480. At the end of the period, the equity/assets ratio for the Group was 80.6 percent, compared with 80.3 percent at year-end 2019. The corresponding figures for the Parent Company, Active Biotech AB, were 24.6 percent and 31.4 percent, respectively.

Organization

The average number of employees during the reporting period was 11 (13), of which the number of employees in the research and development organization accounted for 5 (5). At the end of the period the number of employees related to the new direction of the company amounted to 8 whereof 5 in research and development.

Outlook, including significant risks and uncertainties

Active Biotech's ability to develop pharmaceutical projects to the point at which partnership agreements can be secured, and the partner assumes responsibility for the future development and commercialization of the project, is decisive for the company's long-term financial strength and stability.

The partnership agreement entered into with NeoTX in 2016 will have an impact on the company's future revenues and financial position if naptumomab progress in development. NeoTX initiated the clinical development of naptumomab in combination with a checkpoint inhibitor during 2019, and results are expected during 2021.

Available liquidity in combination with income from existing and anticipated partner agreements are, according to current plans, assumed to be sufficient to finance operations into 2021.

A research company such as Active Biotech is characterized by high operational and financial risk, since the projects in which the company is involved have both development, regulatory and commercialization risks. In addition, the ability of the company to attract and retain key people with both insights to the field of research, and relevant product development experiences is a significant risk.

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 Annual Report 2019. With regards to the prevailing situation for COVID-19, the ongoing and planned preclinical and clinical activities might be delayed with possible implications on the financing risks. 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	Jaı	n-Mar	Full Year
SEK M	2020	2019	2019
Net sales	0,5	5,5	8,4
Administrative expenses	-3,4	-2,8	-12,2
Research and development costs	-6,8	-9,1	-28,5
Other operating expenses/income	_	_	
Operating profit/loss	-9,7	-6,4	-32,3
Net financial items	-0,4	-1,7	-1,8
Profit/loss before tax	-10,1	-8,1	-34,1
Tax		_	
Net profit/loss for the period	-10,1	-8,1	-34,1
Comprehensive profit/loss attributable to:			
Parent Company shareholders	-10,1	-8,1	-34,1
Non-controlling interest			
Net profit/loss for the period	-10,1	-8,1	-34,1
Comprehensive profit/loss per share before dilution (SEK)	-0,07	-0,06	-0,24
Comprehensive profit/loss per share after dilution (SEK)	-0,07	-0,06	-0,24
Statement of profit and loss and consolidated comprehensive income	la	n-Mar	Full Year
SEK M	2020	2019	2019
Net profit/loss for the period Other comprehensive income	-10,1 —	-8,1 _	-34,1
Total comprehensive profit/loss for the period	-10,1	-8,1	-34,1
Total other comprehensive profit/loss for the period attributable to:	40.4	0.4	0.1.1
Parent Company shareholders Non-controlling interest	-10,1	-8,1	-34,1
Total comprehensive profit/loss for the period	-10,1	-8,1	-34,1
	•	•	•
Depreciation/amortization included in the amount of Investments in tangible fixed assets	0,3	0,0	0,9
investments in tangible liked assets			
Weighted number of outstanding common shares before dilution (000s)	145 236	145 236	145 236
Weighted number of outstanding common shares after dilution (000s)	145 236	145 236	145 236
Number of shares at close of the period (000s)	145 236	145 236	145 236
Consolidated statement of financial marking	B.O.	- 24	Dec 24
Consolidated statement of financial position		ar 31	Dec 31
SEK M	2020	2019	2019
Tangible fixed assets	2,9	2,2	3,2
Long-term receivables	0,0	0,0	0,0
Total fixed assets Current receivables	2,9 3,4	2,2 3,4	3,2
Assets held for sale	3,4	3,4 271,8	4,1
Cash and cash equivalents	47,9	16,4	59,7
Total current assets	51,3	291,5	63,8
Total assets	54,2	293,7	67,0
Shareholders equity	43,7	79,8	53,8
Long-term liabilities	1,7	1,1	2,0
Current liabilities	8,8	212,9	11,2
Total shareholders equity and liabilities	54,2	293,7	67,0
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Consolidated statement of changes in shareholders equity	Mai	Mar 31	
SEKM	2020	2019	2019
Opening balance	53,8	87,9	87,9
Loss for the period	-10,1	-8,1	-34,1
Other comprehensive income for the period	-	-	_
Comprehensive profit/loss for the period	-10,1	-8,1	-34,1
Transfer from revaluation reserve	_	_	-88,9
Transfer to profit/loss brought forward	_	_	88,9
Balance at close of period	43,7	79,8	53,8

Condensed consolidated cash-flow statement	Jan-Mar		Full Year
SEK M	2020	2019	2019
Loss after financial items	-10,1	-8,1	-34,1
Adjustment for non-cash items, etc.	0,3	0,0	0,9
Cash flow from operating activities before changes in working capital	-9,8	-8,1	-33,3
Changes in working capital	-1,7	0,3	-2,5
Cash flow from operating activities	-11,5	-7,7	-35,8
Sale of property, plant and equipment	_	_	275,0
Cash flow from investments	-	-	275,0
Loans raised/amortization of loan liabilities	-0,3	-1,4	-205,1
Cash flow from financing activities	-0,3	-1,4	-205,1
Cash flow for the period	-11,8	-9,1	34,1
Opening cash and cash equivalents	59,7	25,6	25,6
Closing cash and cash equivalents	47,9	16,4	59,7

	Ma	Mar 31	
Key figures	2020	2019	2019
Shareholders equity, SEK M	43,7	79,8	53,8
Equity per share, SEK	0,30	0,55	0,37
Equity/assets ratio in the Parent Company	24,6%	86,1%	31,4%
Equity/assets ratio in the Group	80,6%	27,2%	80,3%
Average number of annual employees	11	13	12

The equity/assets ratio and equity per share are presented since these are performance measures that Active Biotech considers relevant for investors who wish to assess the company's capacity to meets its financial commitments. The equity/assets ratio is calculated by dividing recognized shareholders equity by recognizes total assets. Equity per share is calculated by dividing recognized shareholders equity by the number of shares.

Consolidated profit and loss		20	16			20 ⁻	17			201	18			20	19		2020
SEK M	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1
Net Sales	3,9	3,9	4,1	7,1	4,7	5,1	5,1	5,4	4,8	5,7	4,7	4,8	5,5	1,1	0,9	0,9	0,5
Administration expenses	-4,4	-4,1	-3,5	-3,9	-4,1	-10,2	-2,5	-3,3	-2,9	-2,6	-2,5	-2,5	-2,8	-3,6	-2,7	-3,2	-3,4
Research and development costs	-15,6	-14,3	-11,7	-16,7	-15,2	-14,6	-9,1	-10,4	-10,5	-10,4	-9,1	-9,4	-9,1	-5,2	-5,3	-8,8	-6,8
Other operating expenses/income		_	_	_	_	-3,3	_	-50,0	_	_	_	_	_	2,2	-2,2		_
Operating profit/loss	-16,1	-14,5	-11,1	-13,5	-14,6	-23,1	-6,5	-58,4	-8,5	-7,3	-6,9	-7,1	-6,4	-5,4	-9,3	-11,2	-9,7
Net financial items	-1,3	-1,6	-1,9	-1,9	-1,8	-1,8	-1,9	-1,8	-1,7	-1,7	-1,8	-1,8	-1,7	0,0	0,0	-0,1	-0,4
Profit/loss before tax	-17,4	-16,1	-13,0	-15,4	-16,4	-24,9	-8,4	-60,1	-10,2	-9,1	-8,7	-8,9	-8,1	-5,5	-9,3	-11,2	-10,1
Tax	0,6	0,6	0,6	0,6	0,6	0,6	-	_	_	_	-	-	-	-	-	-	-
Net profit/loss for the period	-16,8	-15,5	-12,4	-14,8	-15,8	-24,4	-8,4	-60,1	-10,2	-9,1	-8,7	-8,9	-8,1	-5,5	-9,3	-11,2	-10,1

Active Biotech Parent Company - Income Statement, condensed	Jan	Jan-Mar		Jan-Mar	
SEK M	2020	2019	2019		
Net Sales	0,5	4,8	8,3		
Administration expenses	-3,4	-2,8	-12,3		
Research and development costs	-6,8	-9,4	-28,7		
Operating profit/loss	-9,7	-7,4	-32,7		
Profit/loss from financial items:					
Interest income and similar income-statement items	_	0,0	0,0		
Interest expense and similar income-statement items	-0,4	0,0	0,1		
Profit/loss after financial items	-10,1	-7,4	-32,6		
Tax	_	_	_		
Net profit/loss for the period	-10,1	-7,4	-32,6		
Statement of comprehensive income parent company					
Net profit/loss for the period	-10,1	-7,4	-32,6		
Other comprehensive income	_	-	_		
Total comprehensive profit/loss for the period	-10,1	-7,4	-32,6		

Active Biotech Parent Company - Balance sheet, condensed	Ma	Mar 31		Mar 31	
SEK M	2020	2019	2019		
Financial fixed assets	40,5	40,5	40,5		
Total fixed assets	40,5	40,5	40,5		
Current receivables	3,2	10,3	3,3		
Short-term investments	42,3	12,7	55,6		
Cash and bank balances	4,8	3,5	3,8		
Total current assets	50,3	26,4	62,8		
Total assets	90,8	66,9	103,3		
Shareholders equity	22,3	57,7	32,4		
Current liabilities	68,5	9,3	70,8		
Total equity and liabilities	90,8	66,9	103,3		
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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 in this interim report as were used in the preparation of the most recent annual report.

Not 2: Distribution of sales	Jar	Jan-Mar		
SEK M	2020	2019	2019	
Rental revenues	_	4,7	4,9	
Service revenues	0,5	0,7	3,3	
Other	_	0,1	0,2	
Total	0,5	5,5	8,4	

Not 3: Fair value of financial instruments	Mar 31, 2020	Dec 31, 2019
SEK M	Level 2	Level 2
Short-term investments	42,3	55,6

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 2020: August 6 and November 5, 2020

Year-end report 2020: February 11, 2021 Annual General Meeting: May 19, 2020

Investor Meeting: Will be announced at a later date

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

Lund, April 23, 2020

Active Biotech AB (publ)

Helén Tuvesson

President and CEO

This interim report is unaudited.

Active Biotech AB (publ) (NASDAQ Stockholm: ACTI) is a biotechnology company with focus on autoimmune /inflammatory diseases and cancer. Naptumomab, an immunotherapy licensed to NeoTX Therapeutics Ltd., is in clinical phase 1b/2 development for treatment of solid tumors. Tasquinimod, an immunomodulator, is in development for treatment of multiple myeloma. Laquinimod, an immunomodulator, is evaluated as a potential treatment of the eye disorders wet AMD and uveitis and the inflammatory bowels disease, Crohn's disease. Please visit www.activebiotech.com for more information.