

Active Biotech AB

Year-end report January – December 2019

Fourth quarter in brief

- The first patient in the Phase 1b/2 study of naptumomab estafenatox in combination with a checkpoint inhibitor in solid tumors was dosed
- Preclinical data on naptumomab estafenatox were presented at the Society for Immunotherapy of Cancer's 34th Annual Meeting

Other significant events during the January-December period

- Active Biotech's partner NeoTX entered into a clinical collaboration with AstraZeneca to evaluate naptumomab estafenatox in combination with IMFINZI® (durvalumab) in the Phase 1b/2 study
- A patent regarding tasquinimod treatment of acute leukemia was granted in the US
- Active Biotech completed the sale of the property, Forskaren 1, to Estea AB on April 5, 2019. The purchase price amounted to SEK 275 M, equal to its book value and generated an approx. SEK 70 M liquidity injection.
- Michael Shalmi was elected Chairman of the Board and Uli Hacksell as Board member at the Annual General Meeting on May 23, 2019
- An evaluation of the company's clinical and commercial assets was initiated

Events after the end of the period

- A new direction for Active Biotech was approved by the Board ([see separate press release from February 5, 2020](#))

Financial summary

SEK M	Oct-Dec		Jan-Dec	
	2019	2018	2019	2018
Net sales	0,9	4,8	8.4	20.1
Operating loss	-11.2	-7.1	-32.3	-29.8
Loss after tax	-11.2	-8.9	-34.1	-36.9
Earnings per share (SEK)	-0,08	-0,06	-0,24	-0,27
Cash and cash equivalents (at close of period)			59.7	25.6

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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 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 February 6, 2020, at 8:30 a.m. CET.

Comments from the CEO

Naptumomab clinical study proceeding according to plan

In late October, we reported dosing of the first patient in the Phase 1b/2 combination study with naptumomab and the checkpoint inhibitor durvalumab. The initial stage of the study involves a dose escalation aimed at defining the optimal dose of the combination before continuing to a Phase 2 cohort expansion. The study is proceeding according to plan and we expect this first part to be completed during 2020. The study is sponsored by our partner NeoTX and is performed under an agreement with AstraZeneca. Based on the preclinical data demonstrating impressive combination effects of naptumomab and checkpoint inhibitors in treatment of solid tumors, most recently presented in November at the SITC conference in US, there is a strong rationale for use of this combination in patients not having clinical response when receiving a checkpoint inhibitor alone.

During the fourth quarter, our collaboration with Wistar Institute and Penn University hospital was intensified to support the planning of the clinical development of tasquinimod in multiple myeloma. Furthermore, a patent on use of tasquinimod treatment of acute leukemia was granted in the US and we now have issued patents for the use of tasquinimod in hematological malignances in key markets up until 2035.

Results from exploratory analysis of the Phase 2 study of laquinimod in Huntington Disease were presented at scientific meetings in the past year. Altogether, the results suggest that laquinimod has an effect on neuroinflammation in the disease but the clinical relevance remains to be proven. With these results, the preplanned analysis of the study has now been completed.

Summary and way forward

Looking back, 2019 has been a year focused on establishing a new base from where Active Biotech can advance. In early 2019, we sold our facility in Lund to a newly formed investor collective lead by Estea AB. The property was sold at a book value of SEK 275 million and provided us with a cash injection of approximately SEK 70 million as well as the opportunity to focus on our core business of being a biotech company. At the Annual General Meeting in May, two new board members with significant experience in drug development were elected to the Board of Directors: Michael Shalmi as Chairman and Uli Hacksell as board member. During the autumn, Board and Management worked together with external international specialists and advisors to analyze the value potential our portfolio of projects entails, in order to identify potential relevant and value-enhancing clinical indications for the company to explore. Concurrently with this analysis, the financial assets of Active Biotech were reviewed. The conclusions drawn from these parallel evaluations forms the basis for a new direction for the company. Information about the new way forward [was presented in a separate press release on February 5, 2020](#).

Executing on a new direction

The overall goals for 2019 have been met: our research facility has been sold, the clinical combination study with naptumomab is proceeding and a new direction for the company has been established.

I'm looking forward to an exciting 2020, when we move from evaluation to execution of the new direction for Active Biotech. In conclusion, I would like to thank the entire Active Biotech team and shareholders for your loyal support over the past year.

Helén Tuveon, CEO

Projects

Active Biotech focuses on development of pharmaceuticals in therapeutic areas in which the immune system is of central importance.

Over the past 6 months, a detailed evaluation of the unpartnered projects from a technical as well as a commercial perspective to assess potential value-enhancing paths forward for the company in developing these assets, has been undertaken. The evaluation has been focused on tasquinimod and laquinimod. These projects have been in late stage product development, generated extensive clinical efficacy and safety data as well as datasets spanning full-scale manufacturing and pre-clinical safety data, in support of regulatory filings of advanced prostate cancer for tasquinimod and multiple sclerosis for laquinimod.

Naptumomab

Naptumomab (naptumomab estafenatox, previously ANYARA) is a tumor-targeting superantigen (TTS) compound that increases the immune system's capacity to identify and kill tumors. Active Biotech has since 2016 an agreement with [NeoTX Therapeutics Ltd](#) (NeoTX) covering the development and commercialization of naptumomab.

Clinically, the development of naptumomab has mainly focused on solid cancer forms with a high unmet medical need. Positive data were reported from Phase 1 studies relating to lung cancer, renal cell cancer and pancreatic cancer, where naptumomab 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 naptumomab was well tolerated both as monotherapy and in combination with docetaxel, and increased the immune system's capability to recognize tumors. A Phase 2/3 trial of naptumomab in combination with interferon alpha in renal cell cancer that was completed 2013 demonstrated a favorable safety profile, but did not achieve its primary endpoint of showing prolonged overall survival (OS) in the intention to treat (ITT) population.

In April 2018, NeoTX presented new preclinical data at the American Association for Cancer Research (AACR) scientific conference. The data presented demonstrates a synergistic anti-tumor effect when naptumomab is combined with a PD-1 checkpoint inhibitor in several different tumor models that normally respond poorly or not at all to PD-1 inhibition. A clinical trial will be carried out in combination with a checkpoint inhibitor, a combination strategy in line with naptumomab's mode of action and supported by preclinical data. Active Biotech's partner NeoTX has entered a clinical collaboration with AstraZeneca to evaluate naptumomab in combination with the checkpoint inhibitor durvalumab in the Phase 1b/2 study started in October 2019.

Events during the fourth quarter

- The first patient in the Phase 1b/2 trial of naptumomab estafenatox in combination with durvalumab in solid tumors was dosed
- Preclinical data on naptumomab estafenatox were presented at the Society for Immunotherapy of Cancer's 34th Annual Meeting

Financial information

Comments on the Group's results for the period January - December, 2019

Net sales amounted to SEK 8.4 M (20.1) and included service and rental revenues, of which rental revenues totaled SEK 4.9 M (16.0). The company's property was sold to the property company Estea AB on April 5, which explains the lower rental revenues during the period.

The operation's research and administration expenses amounted to SEK 40.7 M (49.9), of which research expenses totaled SEK 28.5 M (39.3), equivalent to a 27-percent reduction in expenses. During the reporting period, the company's research operations has been focused on the scientific and commercial evaluation of laquinimod and tasquinimod to identify the way forward but also activities to support the out-licensed naptumomab project and the technology transfer of laquinimod from Teva. The period includes approximately SEK 4 M in one-time costs related to the scientific and commercial evaluation of the laquinimod and tasquinimod assets and the new direction of the company.

The operating loss for the period amounted to SEK 32.3 M (loss: 29.8). Administrative expenses amounted to SEK 12.2 M (10.6), the net financial expense for the period to SEK 1.8 M (expense: 7.0) and the loss after tax to SEK 34.1 M (loss: 36.9).

Comments on the Group's results for the period October - December, 2019

Net sales amounted to SEK 0.9 M (4.8) and included service and rental revenues, with the lower levels of income explained by the sale of the property in the second quarter of 2019 .

The operation's research and administration expenses amounted to SEK 12.0 (11.9), of which research expenses amounted to SEK 8.8 (9.4), the latter has been focused on the scientific and commercial evaluation of laquinimod and tasquinimod. The fourth quarter includes approximately 4 MSEK in one-time costs related to the scientific and commercial evaluation of the laquinimod and tasquinimod assets and the new direction of the company.

The operating loss for the period amounted to SEK 11.2 M (loss: 7.1). Administrative expenses totaled SEK 3.2 M (2.5), the net financial expense for the period to SEK 0.1 M (expense: 1.8) and the loss after tax to SEK 11.2 M (loss: 8.9).

Cash flow, liquidity and financial position, Group, for the period January – December, 2019

Cash and cash equivalents at the end of the period amounted to SEK 59.7 M, compared with SEK 25.6 M at the end of 2018. The sale of the property generated a liquidity injection of around SEK 70.0 M and reduced the company's total assets by approximately SEK 210 M after the outstanding property loan was repaid.

Cash flow for the period was SEK 34.1 M (0.4), of which cash flow from operating activities amounted to a negative SEK 35.8 M (neg: 40.6). Cash flow from investments amounted to SEK 275.0 M (0.0) as a result of the completed property sale. Cash flow from financing activities amounted to a negative SEK 205.1 M (41.0), which is a result of the repayment of the outstanding property loan in connection with the completion of the transaction.

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 – December, 2019

Net sales for the period amounted to SEK 8.3 M (23.2) and operating expenses to SEK 41.0 M (58.1). The Parent Company's operating loss for the period was SEK 32.7 M (loss: 34.8). Net financial income amounted to SEK 0.1 M (loss: 0.1) and the loss after financial items was SEK 32.6 M (loss: 34.9). Cash and cash equivalents including short-term investments totaled SEK 59.4 M at the end of the period, compared with SEK 24.2 M on January 1, 2019.

Comments on the Parent Company's results and financial position for the period October – December, 2019

Net sales for the period amounted to SEK 0.9 M (5.7) and operating expenses to SEK 12.0 M (12.2). The Parent Company's operating loss for the period was SEK 11.2 M (loss: 6.5). Net financial income amounted to SEK 0.0 M (loss: 0.1) and the loss after financial items was SEK 11.2 M (loss: 6.5).

Shareholders' equity

Consolidated shareholders' equity at the end of the period amounted to SEK 53.8 M, compared with SEK 87.9 M at year-end 2018.

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 80.3 percent, compared with 29.1 percent at year-end 2018. The corresponding figures for the Parent Company, Active Biotech AB, were 31.4 percent and 87.3 percent, respectively.

Organization

The average number of employees during the reporting period was 12 (16), of which the number of employees in the research and development organization accounted for 5 (7). At the end of the period, the Group had 11 employees whereof 3 employees provided paid services to Estea AB, purchaser of Active Biotech's property, and will end their employment with Active Biotech during 2020.

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 and the capital infusion generated by the sale of the property in April 2019, 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 2018 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	Oct-Dec		Jan-Dec	
SEK M	2019	2018	2019	2018
Net sales	0,9	4,8	8,4	20,1
Administrative expenses	-3,2	-2,5	-12,2	-10,6
Research and development costs	-8,8	-9,4	-28,5	-39,3
Operating profit/loss	-11,2	-7,1	-32,3	-29,8
Net financial items	-0,1	-1,8	-1,8	-7,0
Profit/loss before tax	-11,2	-8,9	-34,1	-36,9
Tax	-	-	-	-
Net profit/loss for the period	-11,2	-8,9	-34,1	-36,9
Comprehensive profit/loss attributable to:				
Parent Company shareholders	-11,2	-8,9	-34,1	-36,9
Non-controlling interest	-	-	-	-
Net profit/loss for the period	-11,2	-8,9	-34,1	-36,9
Comprehensive profit/loss per share before dilution (SEK)	-0,08	-0,06	-0,24	-0,27
Comprehensive profit/loss per share after dilution (SEK)	-0,08	-0,06	-0,24	-0,27

Statement of profit and loss and consolidated comprehensive income		Oct-Dec		Jan-Dec	
		2019	2018	2019	2018
SEK M					
Net profit/loss for the period		-11,2	-8,9	-34,1	-36,9
Other comprehensive income		–	–	–	–
Total comprehensive profit/loss for the period		-11,2	-8,9	-34,1	-36,9
Total other comprehensive profit/loss for the period attributable to:					
Parent Company shareholders		-11,2	-8,9	-34,1	-36,9
Non-controlling interest		–	–	–	–
Total comprehensive profit/loss for the period		-11,2	-8,9	-34,1	-36,9
Depreciation/amortization included in the amount of		0,3	0,1	0,9	0,4
Investments in tangible fixed assets		–	–	–	–
Weighted number of outstanding common shares before dilution (000s)		145 236	145 236	145 236	137 492
Weighted number of outstanding common shares after dilution (000s)		145 236	145 236	145 236	137 492
Number of shares at close of the period (000s)		145 236	145 236	145 236	145 236

Consolidated statement of financial position		Dec 31	
		2019	2018
SEK M			
Tangible fixed assets		3,2	1,3
Long-term receivables		0,0	0,0
Total fixed assets		3,2	1,3
Current receivables		4,1	3,9
Assets held for sale		–	271,8
Cash and cash equivalents		59,7	25,6
Total current assets		63,8	301,2
Total assets		67,0	302,4
Shareholders equity		53,8	87,9
Long-term liabilities		2,0	0,1
Current liabilities		11,2	214,4
Total shareholders equity and liabilities		67,0	302,4

Consolidated statement of changes in shareholders equity		Dec 31	
		2019	2018
SEK M			
Opening balance		87,9	77,7
Loss for the period		-34,1	-36,9
Other comprehensive income for the period		–	–
<i>Comprehensive profit/loss for the period</i>		<i>-34,1</i>	<i>-36,9</i>
Transfer from revaluation reserve		-88,9	–
Transfer to profit/loss brought forward		88,9	–
New share issue		–	47,1
Balance at close of period		53,8	87,9

Condensed consolidated cash-flow statement		Jan-Dec	
		2019	2018
SEK M			
Loss after financial items		-34,1	-36,9
Adjustment for non-cash items, etc.		0,9	0,4
Cash flow from operating activities before changes in working capital		-33,3	-36,4
Changes in working capital		-2,5	-4,2
Cash flow from operating activities		-35,8	-40,6
Sale of property, plant and equipment		275,0	–
Cash flow from investments		275,0	–
New share issue		–	47,1
Loans raised/amortization of loan liabilities		-205,1	-6,1
Cash flow from financing activities		-205,1	41,0
Cash flow for the period		34,1	0,4
Opening cash and cash equivalents		25,6	25,2
Closing cash and cash equivalents		59,7	25,6

Key figures	Dec 31	
	2019	2018
Shareholders equity, SEK M	53,8	87,9
Equity per share, SEK	0,37	0,61
Equity/assets ratio in the Parent Company	31,4%	87,3%
Equity/assets ratio in the Group	80,3%	29,1%
Average number of annual employees	12	16

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 meet its financial commitments. The equity/assets ratio is calculated by dividing recognized shareholders' equity by recognized total assets. Equity per share is calculated by dividing recognized shareholders' equity by the number of shares.

Consolidated profit and loss	2015				2016				2017				2018				2019			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
SEK M																				
Net Sales	2,9	3,2	5,2	5,0	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
Administration expenses	-5,3	-4,7	-3,8	-4,2	-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
Research and development costs	-55,0	-68,7	-23,6	-29,0	-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
Other operating expenses/income	–	–	–	–	–	–	–	–	–	-3,3	–	-50,0	–	–	–	–	–	2,2	-2,2	–
Operating profit/loss	-57,4	-70,1	-22,2	-28,2	-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
Net financial items	-1,1	-1,8	-1,8	-2,1	-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
Profit/loss before tax	-58,5	-71,9	-23,9	-30,3	-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
Tax	0,6	0,6	0,6	-10,4	0,6	0,6	0,6	0,6	0,6	0,6	–	–	–	–	–	–	–	–	–	–
Net profit/loss for the period	-58,0	-71,4	-23,4	-40,8	-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

Active Biotech Parent Company - Income Statement, condensed		Oct-Dec		Jan-Dec	
SEK M		2019	2018	2019	2018
Net Sales		0,9	5,7	8,3	23,2
Administration expenses		-3,2	-2,6	-12,3	-10,9
Research and development costs		-8,8	-9,6	-28,7	-47,2
Operating profit/loss		-11,2	-6,5	-32,7	-34,8
<i>Profit/loss from financial items:</i>					
Interest income and similar income-statement items		-0,1	0,0	0,0	-
Interest expense and similar income-statement items		0,1	-0,1	0,1	-0,1
Profit/loss after financial items		-11,2	-6,5	-32,6	-34,9
Tax		-	-	-	-
Net profit/loss for the period		-11,2	-6,5	-32,6	-34,9
Statement of comprehensive income parent company					
Net profit/loss for the period		-11,2	-6,5	-32,6	-34,9
Other comprehensive income		-	-	-	-
Total comprehensive profit/loss for the period		-11,2	-6,5	-32,6	-34,9

Active Biotech Parent Company - Balance sheet, condensed		Dec 31	
SEK M		2019	2018
Financial fixed assets		40,5	40,5
Total fixed assets		40,5	40,5
Current receivables		3,3	9,8
Short-term investments		55,6	20,6
Cash and bank balances		3,8	3,6
Total current assets		62,8	34,0
Total assets		103,3	74,5
Shareholders equity		32,4	65,0
Current liabilities		70,8	9,5
Total equity and liabilities		103,3	74,5

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, except regarding IFRS 16, see below.

The company applies IFRS 16 Leases as of January 1, 2019. At the transition to IFRS 16, the Group reported rights of use of SEK 890 thousand and leasing liabilities of SEK 1,091 thousand. The leasing agreements concern passenger cars and office equipment. Reconciliation for leasing in the annual report 2018 compared to leasing liabilities in accordance with IFRS 16 is shown in the table below:

Operational leasing as of 31 December 2018 according to note in the annual report	960
Discounted with the margin rate as of 1 Jan 2019	<u>854</u>
Deductible item: Short term leases	-60
Additional item: Reported financial leasing liabilities as of 31 Dec 2018	<u>297</u>
Total lease liabilities as of 1 Jan 2019	<u>1,091</u>

The company's property was classified as "Assets held for sale" at the beginning of the financial year, which meant that its carrying amount was expected to be recovered mainly through sales and not through use. The property was sold on April 5 2019 to the Real Estate Company Estea AB. From July 1, Active Biotech rents premises in the divested property. The Group's new leases are reported as of the third quarter in accordance with IFRS 16, which increased the right of use rights by SEK 3,297 thousand and the lease liability by SEK 3,297 thousand.

In the balance sheet as of December 31, 2019, rights of use were reported amounting to SEK 3,190 thousand and leasing debt of SEK 3,253 thousand, of which SEK 1,252 thousand is short-term lease liabilities. The introduction of IFRS 16 has not had any significant impact on the reported results for the period.

Not 2: Distribution of sales	Oct-Dec		Jan-Dec	
	2019	2018	2019	2018
SEK M				
Research services	–	0,1	–	1,1
Rental revenues	–	3,8	4,9	16,0
Service revenues	0,9	0,9	3,3	2,9
Other	–	–	0,2	–
Total	0,9	4,8	8,4	20,1

Not 3: Fair value of financial instruments	Dec 31, 2019	Dec 31, 2018
	Level 2	Level 2
SEK M		
Short-term investments	55,6	20,6

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: April 23, August 6 and November 5, 2020

Year-end report 2020: February 11, 2021

Annual General Meeting May 19, 2020

Investor Meeting May 19, 2020

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

The interim report for the January – December period 2019 provides a true and fair view of the Parent Company's and the Group's operations, position and results, and describes significant risks and uncertainties that the Parent Company and Group companies face.

Lund, February 6, 2020

Active Biotech AB (publ)

Helén Tuve

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 Please visit www.activebiotech.com for more information.