

Q1 Q2 Q3 Q4

INTERIM REPORT Q3 2021 | ACTIVE BIOTECH AB

“We have seen the first encouraging results from the ongoing tasquinimod trial in multiple myeloma and started a new combination study with naptumomab and docetaxel in lung cancer”

THIRD QUARTER IN BRIEF

- Active Biotech provided status update of its clinical naptumomab project on July 5
- Active Biotech’s partner NeoTX hosted KOL webinar on overcoming checkpoint inhibitor resistance on July 8

EVENTS AFTER THE END OF THE PERIOD

- Tasquinimod clinical development in multiple myeloma advanced into combination therapy following completion of the initial phase of the ongoing trial in the US (Oct 3)
- Active Biotech and NeoTX announced that the first patient had been enrolled in the phase IIa clinical trial of naptumomab estafenatox in combination with docetaxel in patients with advanced non-small cell lung cancer (NSCLC) (Oct 20)

FINANCIAL SUMMARY

SEK M	Jul-Sep		Jan-Sep		Full Year 2020
	2021	2020	2021	2020	
Net sales	-	-	-	0.5	6.7
Operating profit/loss	-11.3	-8.3	-33.6	-28.2	-32.3
Profit/loss after tax	-11.2	-8.2	-33.7	-28.2	-32.2
Earnings per share (SEK)	-0.05	-0.05	-0.16	-0.17	-0.19
Cash and cash equivalents (at close of period)			68.4	30.9	26.2

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 persons set out above, for publication on November 4, 2021 at 08.30 a.m. CET.



Helén Tuveesson
CEO



I am enthusiastic with the current progress in our projects

COMMENTS FROM THE CEO

During the third quarter, our internal focus was on preparing for the start of the clinical study of the newly developed eye drop formulation of laquinimod. In the beginning of October, we announced the first results from the ongoing study with tasquinimod in multiple myeloma, and shortly thereafter the first patient was enrolled in the combination study with naptumomab and docetaxel in lung cancer.

In the third quarter, we prepared for the start of the clinical phase I study with laquinimod eye drop formulation in healthy subjects. A preclinical program to bridge between the existing documentation for oral treatment and the treatment with the newly developed eye drop formulation is now finalized and the study documentation has been completed. Preparations are ongoing to start the study at the end of this year. To restart the clinical development of laquinimod is an important step for us.

In the beginning of October, we determined the safety of *tasquinimod* monotherapy in the ongoing phase Ib/IIa study in multiple myeloma. The optimal dose and dosing schedule was defined at 1 mg tasquinimod per day after a 1-week run in period at 0.5 mg daily. This is similar to the previously schedule used in solid tumors except for a shorter run-in period. Tasquinimod was well tolerated in myeloma patients and the previously documented safety profile was confirmed. The patients included in this part of the study were heavily pretreated, and the majority was triple refractory to Imids, proteasome inhibitors and anti-CD38 antibodies.

Although no formal response was confirmed according to the International Myeloma Working Group (IMWG) criteria, significant periods of stable disease were documented in 2 of the 10 patients included in this portion of the study. Based on the good safety and encouraging signals of anti-myeloma activity in these late-stage, heavily pretreated and refractory patients, the study will now continue into the combination part where tasquinimod will be combined with oral anti-myeloma agents, i.e., ixazomib, lenalidomide and dexamethasone. The use of tasquinimod, as a novel type of treatment for multiple myeloma, in combination with treatments used for earlier stage patients, is aligned with our current understanding of the mechanism of action of tasquinimod in these patients.

We recently announced that the first patient was enrolled in the phase IIa study with *naptumomab*, which is developed together with our partner NeoTX, in combination with docetaxel in patients with non-small cell lung cancer (NSCLC). The study, which enrolls patients with progressive disease that are previously treated with checkpoint inhibitor will be conducted at several clinical sites in the US. The primary endpoint is objective response rate, with secondary endpoints including response duration and survival. For detailed information about the study, see [clinicaltrials.gov: NCT04880863T](https://clinicaltrials.gov/ct2/show/study/NCT04880863). NSCLC is one of the deadliest cancers, and there is a high need for an effective treatment. We are following the trial progress with great interest.

In parallel, the first part of the phase Ib/II study in combination with the checkpoint inhibitor durvalumab in patients with selected advanced solid tumors is being completed. Importantly, results

of the initial phase indicate that the concept of pre-treatment with obinutuzumab successfully lowers the levels of anti-drug antibodies (ADA) to naptumomab. When the safety and tolerability has been defined, the study will continue into phase II cohort studies. For more information about the study, see [clinicaltrials.gov: NCT03983954](https://clinicaltrials.gov/ct2/show/study/NCT03983954).

Synergistic effects of naptumomab together with checkpoint inhibitors or chemotherapy have previously been demonstrated. At the prestigious SITC meeting in Washington D.C. (November 10-14), preclinical data for the combination of naptumomab and CAR-T cells will be presented at a poster session. The title of the presentation is *Tumor Targeted Superantigen (TTS), Naptumomab Estafenatox (NAP), enhances CAR-T cells potency and can boost CAR-T efficacy against solid tumors*.






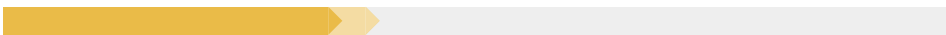
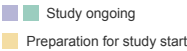
I am enthusiastic with the current progress in our projects. Since we announced our new direction in 2020, we have prepared and initiated activities according to the new plan. I'm very pleased that we are now beginning to see results, and I'm looking forward to continuing to execute on the new direction outlined. We have reported the first encouraging results from the ongoing tasquinimod trial in multiple myeloma and the start of a new combination with naptumomab and docetaxel in lung cancer – two cancer diseases where the medical need remains high despite new treatments being made available.



Helén Tuvešson, CEO

PROJECTS

Active Biotech’s project portfolio includes projects for the development of drugs for the treatment of cancer and inflammatory diseases.

Disease Area	Discovery	Preclinical	Phase I	Phase II	Phase III	Partner
Cancer	Naptumomab Combination with anti-PDL1 (durvalumab) in solid tumors 					
	Naptumomab Combination with docetaxel in non-small cell lung cancer 					
	Tasquinimod Multiple myeloma* 					
Inflammation	Laquinimod Uveitis 					
						
<small>* In an academic partnership with the Abramson Cancer Center, Philadelphia, University of Pennsylvania</small>						

Naptumomab

Naptumomab estafenatox (naptumomab) is a tumor targeting immunotherapy that enhances the ability of the immune system to recognize and kill the tumor. Naptumomab is developed for treatment of solid tumors by Active Biotech’s partner NeoTX.

This is naptumomab

Naptumomab, a Tumor Targeting Superantigen (TTS), is a fusion protein containing the Fab-fragment of an antibody that targets the tumor-associated 5T4 antigen which is expressed in a high number of solid tumors.

The antibody part of naptumomab is fused with an engineered bacterial superantigen that activates specific T cells expressing a particular set of T cell receptors. In short, naptumomab functions by activating T cells and re-direct them to 5T4-expressing tumors. This leads to a massive infiltration of effector T cells into the tumor and tumor cell killing.

Solid tumors

Cancer is a collective name for a large group of diseases characterized by the growth of abnormal cells, which can invade adjacent parts of the body or spread to other organs. Cancer is the second most common cause of death in the world. Solid tumors like lung, prostate, rectal, stomach and liver cancer are the most common types of cancer among men, while breast, rectal, lung, cervical and thyroid cancer are the most common types among women.

Current treatments

Treatment of solid tumors generally combines several types of therapy, which traditionally may include surgery, chemotherapy, and radiation therapy. Immunotherapy has been of decisive importance for solid tumors treatment in recent years and therapies aimed at targeting immune suppression are dominated by biological drugs classified as checkpoint inhibitors. Several new checkpoint inhibitors have been approved for various types of solid tumors.

Naptumomab in solid tumors

Naptumomab increases the immune system's ability to recognize and attack the tumor and preclinical data from various experimental models show synergistic anti-tumor effects and prolonged overall survival when naptumomab is combined with checkpoint inhibitors.

Checkpoint inhibitors are a group of cancer drugs, which function by unleashing the immune system to attack the tumor. Despite the successes over recent years with these immunotherapies in the treatment of solid tumors, 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.

Ongoing clinical development

An open-label, multicenter, dose-finding clinical phase Ib/II study is ongoing with naptumomab in combination with the checkpoint inhibitor durvalumab. 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 Ib study before advancing to a phase II 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) and at neotx.com.

An open label clinical phase IIa study, in US, will assess naptumomab in combination with docetaxel in patients who had been previously treated with checkpoint inhibitors and have advanced or metastatic non-small cell lung cancer (NSCLC). On October 20, 2021, it was announced that the first patient was enrolled. The primary endpoint is objective response rate as measured by RECIST 1.1 criteria. The trial will also evaluate safety, duration of response, progression free survival, overall survival, pharmacokinetics, and pharmacodynamics. For more information about the trial, visit clinicaltrials.gov (NCT04880863) and neotx.com.

Previous clinical experience with naptumomab

In clinical phase I trials, naptumomab was studied both as a single agent and in combination with docetaxel in patients with advanced lung cancer, renal cell cancer or pancreatic cancer (Borghaei et al, 2009). The results showed that naptumomab was well tolerated both as monotherapy and in combination with docetaxel. The phase I results also showed proof-of-concept in terms of increased immunologic activity, including systemic increase of inflammatory cytokines, expansion of naptumomab reactive T cells and induction of infiltrating T cells.

Based on the results of the phase I studies, a phase II/III trial was conducted with naptumomab combined with interferon-alpha treatment in renal cell cancer. The study encompassed 513 patients and was designed to evaluate the efficacy of naptumomab in combination with interferon-alpha. The study did not achieve its primary endpoint to show a prolonged overall survival in the intention-to-treat population. However, a retrospective sub-group analysis demonstrated a statistically significant advantage in terms of prolonged OS and length of progression-free survival for 25% of the patient population (Elkord et al, 2015).

EVENTS DURING THE THIRD QUARTER

- Active Biotech provided status update of its clinical naptumomab project on July 5
- Active Biotech's partner NeoTX hosted KOL webinar on overcoming checkpoint inhibitor resistance on July 8

EVENTS AFTER THE THIRD QUARTER

- On October 20, 2021 it was announced that the first patient had been enrolled in the phase IIa clinical trial of naptumomab estafenatox in combination with docetaxel in patients with advanced non-small cell lung cancer (NSCLC)

Tasquinimod

Tasquinimod is a small molecule immunomodulator and represents a new drug class with a mode of action that is complementary to current multiple myeloma therapies. Tasquinimod is being developed for treatment of multiple myeloma, which is an incurable blood cancer.

This is tasquinimod

The immunosuppressed tumor microenvironment in the bone marrow is essential for developing multiple myeloma and a contributing factor of disease relapses and development of resistance to the treatment. Tasquinimod affects special immune cells in the tumor microenvironment, specifically immunosuppressive myeloid cells, which makes it easier for the body's immune system to attack the cancer cells. Tasquinimod also disrupts the formation of new blood vessels in the tumor microenvironment, which results in reduced supply of oxygen and nutrients to the tumor.

With this novel mode of action, tasquinimod has the potential as a monotherapy and in combination with other anti-myeloma drugs to overcome resistance and increase survival in patients that have progressed on standard therapy.

Multiple myeloma

Multiple myeloma is an incurable blood cancer in which abnormal plasma cells in the bone marrow grow uncontrollably while other blood forming cells such as white and red blood cells and blood platelets are suppressed. This leads to anemia, infections, destruction of bone tissue and progressive loss of renal function. Despite new treatments having greatly improved survival of multiple myeloma patients, the biological heterogeneity of the disease and the emergence of drug resistance is a major challenge, and the medical need of innovative treatment modalities remains high.

Current treatments

Multiple myeloma patients undergo several lines of treatment. In early as well as relapse treatment, the goal is to stabilize the patient's disease and thereby achieve as long as possible period of effective disease control. To support deeper and durable responses and overcome treatment resistance, patients are as standard treated with combinations of drugs from available product classes. Currently, the market is dominated by drugs that can be divided into four different classes: immunomodulatory imides (IMiDs), proteasome inhibitors (PI), monoclonal antibodies and alkylating agents.

Tasquinimod in multiple myeloma

Tasquinimod will be developed as a new product class with a novel mechanism of action that differs from the others and thus has the potential to overcome the problem of drug resistance. The clinical safety profile of tasquinimod is well known. Given the good tolerability and the possibility to combine with the available product classes, tasquinimod has the potential to expand over time from an initial position as late-stage treatment, like the patient population in the ongoing clinical study, to earlier lines of treatment. There is a significant market opportunity for a novel drug in a new product class in multiple myeloma.

Ongoing clinical development

Based on preclinical data and the previous clinical experience with tasquinimod, a clinical study was initiated, and the first patient was dosed in August 2020. The study recruits relapsed refractory multiple myeloma patients after at least one prior anti-myeloma therapy and is conducted in two parts:

- First part (A) evaluation of tasquinimod as a monotherapy
- Second part (B) evaluation of the combination of tasquinimod and an oral standard anti-myeloma regimen (IRd; ixazomib, lenalidomide, dexamethasone)

Primary endpoint in both parts is safety and tolerability, and a key secondary endpoint is preliminary efficacy by objective response rate.

An important milestone was reached in October 2021:

- Ten patients in part A have been treated with increasing doses of tasquinimod and the safety read-out showed that tasquinimod was generally well tolerated
- The optimal dose and schedule of tasquinimod, when used as a single agent in patients with multiple myeloma has been established at 1 mg per day after a one-week run in of 0.5 mg daily. This is similar to the treatment schedule used in previous studies of tasquinimod.

The trial will now advance to a previously planned combination part, in which treatment with tasquinimod will be tested in patients with multiple myeloma together with the orally administered anti-myeloma agents ixazomib, lenalidomide, and dexamethasone (IRd). Once an optimal dose and schedule of tasquinimod for the IRd combination is established, an expansion cohort will be recruited to further document the biological activity of tasquinimod in myeloma patients. Key secondary endpoints will include anti-myeloma activity using the response criteria of the International Myeloma Working Group.

The study is carried out in an academic partnership with Abramson Cancer Center in Philadelphia, US, with Dr. Dan Vogl as principal investigator. More information about the study design is available at clinicaltrials.gov (NCT04405167).

Previous clinical experience of tasquinimod

Tasquinimod has been in development for the treatment of prostate cancer and has completed a phase I-III clinical development program. Tasquinimod was studied in both healthy volunteers and cancer patients. While the results from the phase III trial in prostate cancer showed that tasquinimod prolonged progression-free survival (PFS) compared to placebo, tasquinimod did not extend overall survival (OS) in this patient population and development for prostate cancer was discontinued. (Sternberg et al, 2016). Clinical effects and a favorable safety profile have been demonstrated in more than 1,500 patients, equivalent to more than 650 patient-years of exposure to tasquinimod.

EVENTS AFTER THE THIRD QUARTER

- Tasquinimod clinical development in multiple myeloma advanced into combination therapy following completion of the initial phase of the ongoing trial in the US (Oct 3)

Laquinimod

Laquinimod is a first-in-class immunomodulator with a novel mode of action for the treatment of severe inflammatory eye diseases such as uveitis.

This is laquinimod

It has been shown in experimental models of autoimmune/ inflammatory diseases that laquinimod targets the aryl hydrocarbon receptor (AhR) that is present in antigen presenting cells and involved in the regulation of these cells. By targeting the AhR, antigen presenting cells are re-programmed to become tolerogenic, meaning that instead of activating pro-inflammatory T cells, regulatory T cells with anti-inflammatory properties are activated leading to dampening of the inflammation in the eye.

Uveitis

Uveitis is the inflammation of the uveal tract (iris, ciliary body, and choroid), but can also lead to inflammation of nearby tissues, such as the retina, the optic nerve and the vitreous humor. The uvea is crucial for the delivery of oxygen and nutrients to the eye tissues, and inflammation of uvea can cause serious tissue damage to the eye with symptoms including general vision problems and a risk of blindness. Furthermore, floater spots in the eye, eye pain and redness, photophobia, headache, small pupil and alteration of iris color are common symptoms. If left untreated, uveitis can lead to severe eye problems, including blindness, cataracts, glaucoma, damage to the optic nerve, and detachment of the retina.

Current treatments

The treatment standards today for patients with non-infectious non-anterior uveitis are high-dose oral corticosteroids or injections of corticosteroid in or around the eye. Immunosuppressants, such as methotrexate or cyclosporin, are used in 2nd line of treatment, whereas anti-TNF antibodies (Humira) are used as a 2nd or 3rd line of treatment.

There is a high unmet medical need for new effective and safe therapies for non-infectious non-anterior uveitis:

- approximately 35 percent of patients suffer from severe visual impairment with risk of blindness
- approximately 40 percent of patients fail on steroid therapy
- long-term treatment of corticosteroid in high doses is associated with severe side effects
- currently no topical treatment options are available

Therefore, there is a need for new treatments with complimentary effects to corticosteroids to limit failures in the 1st line of treatment. Furthermore, there is a need for safer therapies that can reduce or replace long-term use of steroids and a treatment that could be administered topically and reach to the back of the eye to minimize systemic adverse effects and to reduce injection-related risks.

Laquinimod in uveitis

Laquinimod will be developed as a new treatment for non-infectious non-anterior uveitis and has the potential to be used in the 1st line of treatment as an add on to steroids as well as in the 2nd line of treatment for patients that have failed steroid treatment.

Clinical development

An eye drop formulation of laquinimod has been developed and a preclinical safety-bridging program for topical treatment has been completed to study the eye drop formulation in clinical studies.

Preparations are ongoing for the start of a phase I study of laquinimod eye drops in healthy subjects. The study will include up to 42 subjects treated in part 1 with an increasing dose of laquinimod eye drops and in part 2 with repeated doses of laquinimod eye drops.

The primary objective of the study is safety and tolerance to laquinimod eye drops and the secondary readings include ocular toxicity, pharmacokinetics and exposure.

In parallel, planning is ongoing for a phase II clinical study of oral and eye drop formulations of laquinimod in patients with uveitis.

Previous clinical experience of laquinimod

During its years of advanced product development, clinical efficacy and safety data on laquinimod was established in more than 5,000 patients, primarily in multiple sclerosis (MS) patients, representing more than 14,000 patient-years of exposure. In addition, extensive datasets spanning full-scale manufacturing and preclinical safety data, in support of regulatory filings of multiple sclerosis for laquinimod, have also been generated.

FINANCIAL INFORMATION

Comments on the Group's results for the period January – September 2021

No sales were recorded during the period, the corresponding period previous year included SEK 0.5 M income related to real estate services.

The total operational costs for the period amounted to SEK 33.6 M (28.7) whereof research and development expenses totaled SEK 23.4 M (18.6), representing an increased activity level which is reflected in the 26-percent cost increase.

The company's research efforts have been focused on complementing existing and generating new preclinical results data for tasquinimod and laquinimod, support NeoTX in the development of naptumomab, initiate clinical development of laquinimod and establishing clinical partnerships for continued development of the ongoing programs:

- the phase Ib/IIa clinical study with tasquinimod for treatment of multiple myeloma that was initiated in August 2020 in collaboration with Penn University, USA. The study is progressing according to plan
- laquinimod as a new product class for treatment of inflammatory eye diseases. A topical ophthalmic formulation has been developed. A phase I clinical study scheduled to be initiated during H2 2021

Administrative expenses amounted to SEK 10.3 M (10.1).

The operating loss for the period amounted to SEK 33.6 M (loss: 28.2), the net financial income for the period amounted to SEK 0.0 M (0.0) and the loss after tax to SEK 33.7 M (loss: 28.2).

Comments on the Group's results for the period July – September 2021

No sales were recorded during the third quarter 2021. Total operating costs for the period amounted to SEK 11,3 M (8,3) whereof research and development expenses totaled SEK 7.8 M (5.5), which is explained by increased pre-clinical and clinical activities ahead of the planned initiation of the clinical development program with laquinimod.

The operating loss for the period amounted to SEK 11,3 M (loss: 8.3). Administrative costs amounted to SEK 3.5 M (2.9), the net financial income for the period amounted to SEK 0.0 M (income: 0.1) and the loss after tax to SEK 11.2 M (loss: 8.2).

Cash flow, liquidity and financial position, Group, for the period January – September 2021

Cash and cash equivalents at the end of the period amounted to SEK 68.4 M, compared with SEK 26.2 M at the end of 2020. Cash flow for the period amounted to SEK 42.2 M (negative: 28.8). The cash flow from operating activities amounted to a negative SEK 31.0 M (neg: 27.9). Cash flow from investments amounted to SEK 0 M (0) and cash flow from financing activities amounted to a positive SEK 73.1 M (negative: 0.9) following the rights issue concluded in the period. The share issue added SEK 74.1 M to liquidity after issue costs.

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 – September 2021

Net sales for the period amounted to SEK 0 M (0.5) and operating expenses to SEK 33.6 M (28.7).

The Parent Company's operating loss for the period was SEK 33.6 M (loss: 28.2). Net financial income amounted to SEK 0.1 M (income: 0.1) and the loss after financial items was SEK 33.6 M (loss: 28.1).

Cash and cash equivalents including short-term investments totaled SEK 68.2 M at the end of the period, compared with SEK 26.1 M on January 1, 2021.

Comments on the Parent Company's results and financial position for the period July – September 2021

Net sales for the period amounted to SEK 0.0 M (0.0) and operating expenses to SEK 11.3 M (8.3). The Parent Company's operating loss for the period was SEK 11.3 M (loss: 8.3). Net financial income amounted to SEK 0.0 M (income: 0.1) and the loss after financial items was SEK 11.2 M (loss: 8.2).

Shareholders' equity

Consolidated shareholders' equity at the end of the period amounted to SEK 62.8 M, compared with SEK 22.1 M at year-end 2020.

The number of shares outstanding at the end of the period totaled 217,971,720. At the end of the period, the equity/assets ratio for the Group was 86.3 percent, compared with 68.8 percent at year-end 2020. The corresponding figures for the Parent Company, Active Biotech AB, were 37.1 percent and 1.2 percent, respectively.

Long Term Incentive Programs

The Annual General Meeting on May 19, 2020, resolved to adopt two Long Term Incentive Programs (LTIPs), Plan 2020/2024 to include the employees within the Active Biotech Group and the Board Plan 2020/2023 to include all Board members of Active Biotech.

Employees and Board members acquired in total 659,756 shares (Savings shares) in the market during the applicable time period in the respective incentive programs. Total costs, including social contributions, as of September 30, 2021 YTD, amounted to SEK 832 K, whereof SEK 118 K refers to the period January – September, 2021.

Detailed terms and conditions for each of the programs are available on the company homepage.

Organization

The average number of employees during the reporting period was 8 (10), of which the number of employees in the research and development organization accounted for 5 (5). The number of employees at the end of the period amounted to 8 whereof 5 in the research and development organization.

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.

Following a portfolio refocus during 2020, Active Biotech currently holds three projects in its portfolio:

- naptumomab, a targeted anti-cancer immunotherapy, partnered to NeoTX, is in phase Ib/II clinical development in patients with advanced solid tumors and in phase IIa development in combination with docetaxel in NSCL
- tasquinimod, targeted towards hematological malignancies is in clinical phase Ib/IIa treatment of multiple myeloma
- laquinimod, targeted towards inflammatory eye disorders is advancing to a clinical phase I trial with a topical ophthalmic formulation estimated to start late 2021

The partnership agreement entered 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 2019, a phase Ib/II study is ongoing and an additional phase II study in NSCLC was initiated in October 2021.

In 2020, Active Biotech entered an academic collaboration with Penn University for the development of tasquinimod in multiple myeloma, a phase Ib/IIa study was initiated in August 2020. The optimal

dose and schedule of tasquinimod, when used as a single agent in patients with multiple myeloma has been established in the initial phase of the study. The trial will advance to a previously planned combination part together with the orally administered antimyeloma agents ixazomib, lenalidomide, and dexamethasone.

Active Biotech focuses its activities to secure value growth and conduct commercial activities aimed at entering new partnerships for tasquinimod in multiple myeloma and laquinimod in uveitis.

A rights issue was successfully concluded in January 2021 when SEK 74.1 M after issue costs was secured. The rights issue aimed at providing Active Biotech with the financial stability required to await the outcome of the ongoing clinical studies and to conduct negotiations with partners.

The available liquidity together with revenues from existing and anticipated partnership agreements are expected to finance the operations, including the three ongoing clinical trials described above, thru 2022.

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 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 2020. With regards to the prevailing situation for COVID-19, it is uncertain how global measures against COVID-19, and prioritization of health care resources, may affect timelines of project and 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

SEK M	Jul-Sep		Jan-Sep		Full Year
	2021	2020	2021	2020	2020
Net sales	-	-	-	0.5	6.7
Administrative expenses	-3.5	-2.9	-10.3	-10.1	-13.5
Research and development costs	-7.8	-5.5	-23.4	-18.6	-25.5
Operating profit/loss	-11.3	-8.3	-33.6	-28.2	-32.3
Net financial items	0.0	0.1	0.0	0.0	0.1
Profit/loss before tax	-11.2	-8.2	-33.7	-28.2	-32.2
Tax	-	-	-	-	-
Net profit/loss for the period	-11.2	-8.2	-33.7	-28.2	-32.2
Comprehensive profit/loss attributable to:					
Parent Company shareholders	-11.2	-8.2	-33.7	-28.2	-32.2
Non-controlling interest	-	-	-	-	-
Net profit/loss for the period	-11.2	-8.2	-33.7	-28.2	-32.2
Comprehensive profit/loss per share before dilution (SEK)	-0.05	-0.05	-0.16	-0.17	-0.19
Comprehensive profit/loss per share after dilution (SEK)	-0.05	-0.05	-0.16	-0.17	-0.19

STATEMENT OF PROFIT AND LOSS AND CONSOLIDATED COMPREHENSIVE INCOME

SEK M	Jul-Sep		Jan-Sep		Full Year
	2021	2020	2021	2020	2020
Net profit/loss for the period	-11.2	-8.2	-33.7	-28.2	-32.2
Other comprehensive income	-	-	-	-	-
Total comprehensive profit/loss for the period	-11.2	-8.2	-33.7	-28.2	-32.2
Total other comprehensive profit/loss for the period attributable to:					
Parent Company shareholders	-11.2	-8.2	-33.7	-28.2	-32.2
Non-controlling interest	-	-	-	-	-
Total comprehensive profit/loss for the period	-11.2	-8.2	-33.7	-28.2	-32.2
Depreciation/amortization included in the amount of	0.3	0.3	1.0	1.0	1.3
Investments in tangible fixed assets	-	-	-	-	-
Weighted number of outstanding common shares before dilution (000s)	217,972	168,606	209,877	168,606	168,606
Weighted number of outstanding common shares after dilution (000s)	217,972	168,606	209,877	168,606	168,606
Number of shares at close of the period (000s)	217,972	145,236	217,972	145,236	145,236

CONSOLIDATED STATEMENT OF FINANCIAL POSITION

SEK M	Sep 30		Dec 31
	2021	2020	2020
Tangible fixed assets	0.9	2.2	1.9
Long-term receivables	0.0	0.0	0.0
Total fixed assets	0.9	2.2	1.9
Current receivables	3.4	3.0	4.1
Cash and cash equivalents	68.4	30.9	26.2
Total current assets	71.8	33.8	30.3
Total assets	72.7	36.0	32.2
Shareholders equity	62.8	25.9	22.1
Long-term liabilities	0.1	1.0	0.7
Current liabilities	9.8	9.1	9.4
Total shareholders equity and liabilities	72.7	36.0	32.2

CONSOLIDATED STATEMENT OF CHANGES IN SHAREHOLDERS EQUITY

SEK M	Sep 30		Dec 31
	2021	2020	2020
Opening balance	22.1	53.8	53.8
Loss for the period	-33.7	-28.2	-32.2
Other comprehensive income for the period	-	-	-
<i>Comprehensive profit/loss for the period</i>	<i>-33.7</i>	<i>-28.2</i>	<i>-32.2</i>
Share-based payments that are settled with equity instruments, IFRS2	0.2	0.3	0.6
New share issue	74.1	-	-
Balance at close of period	62.8	25.9	22.1

CONDENSED CONSOLIDATED CASH-FLOW STATEMENT

SEK M	Jan-Sep		Full Year
	2021	2020	2020
Loss after financial items	-33.7	-28.2	-32.2
Adjustment for non-cash items, etc.	1.2	1.3	1.9
Cash flow from operating activities before changes in working capital	-32.5	-26.8	-30.3
Changes in working capital	1.5	-1.0	-1.9
Cash flow from operating activities	-31.0	-27.9	-32.2
New share issue	74.1	-	-
Loans raised/amortization of loan liabilities	-1.0	-0.9	-1.3
Cash flow from financing activities	73.1	-0.9	-1.3
Cash flow for the period	42.2	-28.8	-33.5
Opening cash and cash equivalents	26.2	59.7	59.7
Closing cash and cash equivalents	68.4	30.9	26.2

KEY FIGURES

	Sep 30		Dec 31
	2021	2020	2020
Shareholders equity, SEK M	62.8	25.9	22.1
Equity per share, SEK	0.29	0.18	0.15
Equity/assets ratio in the Parent Company	37.1%	6.3%	1.2%
Equity/assets ratio in the Group	86.3%	72.0%	68.8%
Average number of annual employees	8	10	10

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

SEK M	2017				2018				2019				2020				2021		
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3
Net Sales	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	-	-	6.2	-	-	-
Administration expenses	-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	-3.8	-2.9	-3.4	-3.3	-3.5	-3.5
Research and development costs	-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	-6.3	-5.5	-7.0	-6.4	-9.2	-7.8
Other operating expenses/income	-	-3.3	-	-50.0	-	-	-	-	-	2.2	-2.2	-	-	-	-	-	-	-	-
Operating profit/loss	-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	-10.1	-8.3	-4.1	-9.7	-12.6	-11.3
Net financial items	-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	0.3	0.1	0.0	0.0	0.0	0.0
Profit/loss before tax	-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	-9.8	-8.2	-4.1	-9.8	-12.6	-11.2
Tax	0.6	0.6	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Net profit/loss for the period	-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	-9.8	-8.2	-4.1	-9.8	-12.6	-11.2

ACTIVE BIOTECH PARENT COMPANY – INCOME STATEMENT, CONDENSED

SEK M	Jul-Sep		Jan-Sep		Full Year 2020
	2021	2020	2021	2020	
Net Sales	-	-	-	0.5	6.7
Administration expenses	-3.5	-2.9	-10.3	-10.1	-13.5
Research and development costs	-7.8	-5.5	-23.4	-18.6	-25.5
Operating profit/loss	-11.3	-8.3	-33.6	-28.2	-32.3
<i>Profit/loss from financial items:</i>					
Interest income and similar income-statement items	0.0	0.1	0.1	0.2	0.2
Interest expense and similar income-statement items	0.0	0.0	0.0	-0.1	-0.1
Profit/loss after financial items	-11.2	-8.2	-33.6	-28.1	-32.1
Tax	-	-	-	-	-
Net profit/loss for the period	-11.2	-8.2	-33.6	-28.1	-32.1
Statement of comprehensive income parent company					
Net profit/loss for the period	-11.2	-8.2	-33.6	-28.1	-32.1
Other comprehensive income	-	-	-	-	-
Total comprehensive profit/loss for the period	-11.2	-8.2	-33.6	-28.1	-32.1

ACTIVE BIOTECH PARENT COMPANY – BALANCE SHEET, CONDENSED

SEK M	Sep 30		Dec 31 2020
	2021	2020	
Financial fixed assets	40.5	40.5	40.5
Total fixed assets	40.5	40.5	40.5
Current receivables	3.4	2.8	3.9
Short-term investments	66.9	26.8	22.8
Cash and bank balances	1.3	4.0	3.3
Total current assets	71.6	33.6	30.1
Total assets	112.1	74.1	70.6
Shareholders equity	41.6	4.7	0.9
Current liabilities	70.6	69.4	69.7
Total equity and liabilities	112.1	74.1	70.6

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.

NOTE 2: DISTRIBUTION OF SALES

SEK M	Jul-Sep		Jan-Sep		Full Year
	2021	2020	2021	2020	2020
Licence revenues	-	-	-	-	6.2
Service revenues	-	-	-	0.5	0.5
Other	-	-	-	-	-
Total	-	-	-	0.5	6.7

NOTE 3: FAIR VALUE OF FINANCIAL INSTRUMENTS

SEK M	Sep 30, 2021 Level 2	Dec 31, 2020 Level 2
Short-term investments	66.9	22.8

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

- Year-end report 2021: February 9, 2022
- Interim reports 2022: April 21 (Q1), August 4 (Q2), November 3 (Q3)
- Annual General Meeting: May 19, 2022

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

The interim report for the January – September period 2021 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 November 4, 2021
Active Biotech AB (publ)

Helén Tuve
President and CEO

REVIEW REPORT

To the Board of Directors of Active Biotech AB (publ.)
Corp. id. 556223-9227

Introduction

We have reviewed the condensed interim financial information (interim report) of Active Biotech AB (publ.) as of 30 September 2021 and the nine-month period then ended. The Board of Directors and the Managing Director are responsible for the preparation and presentation of this interim report in accordance with IAS 34 and the Annual Accounts Act. Our responsibility is to express a conclusion on this interim report based on our review.

Scope of review

We conducted our review in accordance with International Standard on Review Engagements ISRE 2410 Review of Interim Financial Information Performed by the Independent Auditor of the Entity. A review of interim financial information consists of making inquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with International Standards on Auditing and other generally accepted auditing practices and consequently does not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion.

Conclusion

Based on our review, nothing has come to our attention that causes us to believe that the interim report is not prepared, in all material respects, for the Group in accordance with IAS 34 and the Annual Accounts Act, and for the Parent Company in accordance with the Annual Accounts Act.

Malmö November 4, 2021
KPMG AB

Linda Bengtsson
Authorized Public Accountant

About Active Biotech

Active Biotech AB (publ) (NASDAQ Stockholm: ACTI) is a biotechnology company that deploys its extensive knowledge base and portfolio of compounds to develop first-in-class immunomodulatory treatments for specialist oncology and immunology indications with a high unmet medical need and significant commercial potential. Following a portfolio refocus, the business model of Active Biotech aims to advance projects to the clinical development phase and then further develop the programs internally or pursue in partnership. Active Biotech currently holds three projects in its portfolio: Naptumomab, a targeted anti-cancer immunotherapy, partnered to NeoTX Therapeutics, is in a phase Ib/II clinical program in patients with advanced solid tumors. The small molecule immunomodulators, tasquinimod and laquinimod, both having a mode of actions that includes modulation of myeloid immune cell function, are targeted towards hematological malignancies and inflammatory eye disorders, respectively. Tasquinimod, is in clinical phase Ib/IIa for treatment of multiple myeloma. Laquinimod is advancing to a clinical phase I study with a topical ophthalmic formulation, to be followed by phase II for treatment of non-infectious uveitis. Please visit www.activebiotech.com for more information.