

# Q1 Q2 Q3 Q4

## YEAR END REPORT 2023 | ACTIVE BIOTECH AB

“We are working towards start of two studies in myelofibrosis in 2024”

### FOURTH QUARTER IN BRIEF

- Lead Principal Investigator Rebekka Schneider-Kramann presents the clinical plan and positioning of tasquinimod in myelofibrosis (December 1)
- Active Biotech enters into collaboration agreement for clinical ocular biodistribution study with laquinimod (December 5)
- Active Biotech announces outcome of the Company's rights issue (December 6)
- Preclinical data of tasquinimod presented at ASH (December 14)
- Active Biotech provides update on the scheduled clinical program for 2024 (December 22)

### OTHER SIGNIFICANT EVENTS JAN – DEC 2023

- Active Biotech confirmed positive clinical safety profile of laquinimod eye drops (January 30)
- Safety and preliminary efficacy of naptumomab in combination with durvalumab presented at AACR 2023 (April 19)
- Positive interim data from the ongoing study of tasquinimod in heavily pre-treated patients with relapsed and refractory multiple myeloma presented at ASCO 2023 (May 26)

- Positive safety and tolerability in clinical phase I study and preclinical ocular biodistribution data supporting the further development of laquinimod eye drops for inflammatory eye diseases were established (May 30)
- New preclinical data regarding tasquinimod's anti-fibrotic effects in myelofibrosis were presented at EHA 2023 (June 10)
- Collaboration agreement for clinical study with tasquinimod in myelofibrosis signed (July 31)
- Tasquinimod successfully completed dose optimization in patients with multiple myeloma and advances into the pre-planned expansion cohort (September 11)
- Clinical safety and preclinical ocular biodistribution for laquinimod eye drops presented at the IOIS meeting is made available on Active Biotech's website (September 13)

### FINANCIAL SUMMARY

SEK M	Oct-Dec		Jan-Dec	
	2023	2022	2023	2022
Net sales	-	-	-	-
Operating profit/loss	-12.8	-15.2	-46.5	-57.9
Profit/loss after tax	-12.5	-15.0	-45.8	-58.4
Earnings per share (SEK)	-0.04	-0.06	-0.17	-0.25
Cash and cash equivalents (at close of period)			36.2	41.8

The report is also available at [www.activebiotech.com](http://www.activebiotech.com)

This information was provided to the media, through the agency of the contact persons set out below, for publication on February 8, 2024 at 08.30 am CET.



*During the year, we refined our strategy and decided to focus our main activities to tasquinimod in myelofibrosis*

## COMMENTS FROM THE CEO

**Our wholly owned projects tasquinimod and laquinimod within hematological cancers and inflammatory eye disorders respectively made significant progress in 2023. During the year, we refined our strategy and decided to focus our main activities to tasquinimod in myelofibrosis. Preparations are ongoing for the start of two clinical studies in myelofibrosis in 2024. In the laquinimod project a good safety profile of the newly developed eye drop formulation was confirmed in healthy subjects. The next step is a clinical biodistribution study to evaluate the ocular distribution following administration of laquinimod eye drops. Beyond that, our focus will be on finding a partner for the continued clinical development of laquinimod. A rights issue to finance planned clinical programs was successfully concluded in December and added 43.5 MSEK to liquidity before issue expenses.**

In the fourth quarter, preclinical data of tasquinimod from our collaboration with MD Anderson was presented as an oral presentation at the prestigious scientific conference ASH. The data demonstrate that tasquinimod administered in models of myelofibrosis, given either as monotherapy or in combination with front-line therapy for advanced myelofibrosis, has a clear therapeutic effect and thereby a clinical potential in this indication. We also reported that we entered a collaboration with Stanford University for the clinical ocular biodistribution study with laquinimod. Also, in December, we reported the successful outcome of the company's rights issue.

With exiting clinical programs ongoing, and the financial position established to pursue planned clinical milestones, we are looking ahead with excitement.

### **Tasquinimod – Focus on Myelofibrosis**

Following a strategic review of our potential clinical programs and their financing, we decided to focus our main activities to the clinical programs for tasquinimod in myelofibrosis.

Myelofibrosis is a rare form of blood cancer characterized by abnormal production of blood-forming cells replacing the healthy bone marrow with fibrous tissue. Symptoms of the disease include anemia, splenomegaly, and other complications. Today, patients are treated with varying protocols, including bone marrow transplantations in some cases. JAK-inhibitors are the only drug class approved for the treatment of myelofibrosis. There is a high medical need for a treatment that affects the underlying disease processes and provides a broad impact on disease progression.

Results from preclinical models of myelofibrosis indicate that tasquinimod has the potential to modify the disease in broad sense, i.e., by reducing fibrosis, and by normalizing spleen size and hematopoiesis, which are the key manifestations of the disease. In December 2023, Professor Rebekka Schneider-Kramann, the lead Principal investigator for the upcoming clinical study in Europe with tasquinimod in

myelofibrosis, presented the clinical plan for tasquinimod in myelofibrosis and discussed the positioning of tasquinimod in the disease. A short summary of the audiocast is presented on page 12 in this report and the full audiocast including a discussion with our CMO Erik Vahtola and Rebekka Schneider-Kramann, is available on Active Biotech's website. Our plan is to start two clinical proof of concept studies in myelofibrosis in 2024. The clinical study currently being prepared in Europe has external funding from the Oncode Institute and will be conducted in the HOVON research network at clinics in the Netherlands and Germany. A clinical trial agreement was signed in July 2023, and the study is planned to start in Q3 2024. Preparations for the clinical study in myelofibrosis in the US in collaboration with MD Anderson is advancing, and we currently expect it could commence in H1, 2024.

In the beginning of the autumn, we reported that the enrollment to the preplanned expansion cohort of the ongoing myeloma study with tasquinimod in combination with ixazomib, lenalidomide and dexamethasone (IRd) is ongoing. We are encouraged by the good safety and preliminary response to tasquinimod treatment in this heavily pretreated group of patients and look forward to review the final data of the study towards end of 2024. From a safety and efficacy perspective, the data for tasquinimod already established in the treatment of patients with multiple myeloma provides a bridge towards the trial program within myelofibrosis, and thereby contributes to documentation of tasquinimod's therapeutic potential in hematological cancers.

#### **Laquinimod – Commercial Activities to Establish a Partnership**

For laquinimod, the results of the clinical phase I study of the novel eye drop formulation were presented and well received at the International Ocular Inflammation Society (IOIS) 2023 meeting in Berlin, Germany, in September. A clean safety profile was shown at repeat doses where we expect therapeutic concentrations of laquinimod. We also presented distribution data suggesting ocular distribution of laquinimod in the rabbit eye upon application of the eye drops. To support the further development of this formulation in patients with uveitis, a clinical ocular biodistribution study of the eye drop formulation will be conducted at the Byers Eye Institute at Stanford University, US. A clinical collaboration agreement was signed in December and the study preparations are progressing towards a planned start in Q1, 2024. In parallel, commercial activities will be initiated to establish a partnership for the continued development of laquinimod in patients with uveitis.

#### **Naptumomab – Upcoming Results in Lung Cancer**

With respect to naptumomab, which is developed in collaboration with our partner NeoTX, the clinical phase IIa trial in patients with lung cancer is progressing towards results in 2024. Furthermore, naptumomab was reported to be safe in combination with durvalumab, in patients with selected solid tumors. The preliminary efficacy of the combination was encouraging, and in the next step, an expansion cohort in esophageal cancer is planned. A new phase I study is also being planned with naptumomab combined with the checkpoint inhibitor pembrolizumab in patients with urothelial cancer. NeoTX's start of these studies is subject to new financing and the timing of the start is uncertain due to the current geopolitical situation.

#### **Rights Issue 2023**

The board of directors resolved in November to carry out a rights issue to secure financing of the ongoing wholly owned prioritized development programs until the end of 2024. The right issue added 43.5 MSEK to liquidity before deduction of issue expenses and will provide the company with the financial stability required to reach clinically important milestones and enable continued discussions with potential partners.

**In Summary**

I am very pleased with the progress of our projects in the past year. We are strengthened in our conviction that our projects have the potential to treat diseases of great medical need. In 2024, our goals comprise the start of two clinical proof-of-concept studies with tasquinimod in myelofibrosis and to obtain results from the ongoing study in multiple myeloma. Furthermore, we will conduct a biodistribution study of laquinimod eye drops and initiate commercial activities to secure a partnership for the continued clinical development of laquinimod in uveitis. With finances secured to reach important goals in the planned clinical programs, I look forward to an exciting 2024. I will keep you updated as we advance in our projects.

Finally, I wish to thank the entire Active Biotech team and our shareholders for your loyal support.



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	
Hematological malignancies	Tasquinimod Multiple myeloma*						
	Tasquinimod Myelofibrosis**						
Inflammatory eye disorders	Laquinimod Eye drops, safety and tolerability						
	Laquinimod Eye drops, ocular biodistribution**						
Solid tumors	Naptumomab Combination with docetaxel in non-small cell lung cancer						NeoTX
	Naptumomab Combination with anti-PDL1 (durvalumab) in solid tumors						NeoTX AstraZeneca
Study ongoing * In an academic partnership with the Abramson Cancer Center, Philadelphia, University of Pennsylvania ** Study preparations ongoing							

## Tasquinimod

Tasquinimod is an orally active small molecule immunomodulator with a novel mode of action, blocking tumor supporting pathways in the bone marrow microenvironment. Tasquinimod is being developed for the treatment of blood cancers, such as multiple myeloma and myelofibrosis.

### This is Tasquinimod

The tumor microenvironment in the bone marrow is essential for development of blood cancers and a key driver of disease recurrency as well as resistance to treatment.

Tasquinimod targets cells in the microenvironment of the bone marrow, immunosuppressive myeloid cells, endothelial cells, and mesenchymal cells, which play a central role in the development of blood cancers. Tasquinimod affects the function of these cells, leading to reduced tumor growth, reduced fibrosis, and restored hematopoiesis.

### Multiple Myeloma

Multiple myeloma is an incurable blood cancer where 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 which have 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.

### The Market for Treatment of Multiple Myeloma

The expected annual incidence of new diagnosed cases of multiple myeloma in the US alone is approximately 30,000 patients. In Europe and Japan approx. 40,000 and 8,000 new patients, respectively, are

expected to be diagnosed each year (Global Data Report March 2019, Multiple Myeloma – Global Drug Forecast and Market Analysis to 2027).

The global sales of drugs for the treatment of multiple myeloma is projected at USD 21.6 billion in 2027 (Global Data Report March 2019, Multiple Myeloma – Global Drug Forecast and Market Analysis to 2027).

The market for drugs used in the treatment of multiple myeloma experiences strong growth and is expected to continue to grow strongly due to the greater incidence in an elderly population, longer progression-free and overall survival, and thanks to more treatments and combination options are made available. The US accounts for around 60 percent of the market, the EU for approximately 23 percent and Japan and China for 17 percent of the total market sales (Global Data Report March 2019, Multiple Myeloma – Global Drug Forecast and Market Analysis to 2027).

### **Current Treatments**

Multiple myeloma patients undergo several lines of treatment. In both early and later treatment lines, the goal is to reduce tumor burden, improve symptoms and thereby achieve as long a period of effective disease control as possible. 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 the following classes: immunomodulatory imides (IMiDs), proteasome inhibitors (PI), monoclonal antibodies, bispecific antibodies, Chimeric Antigen Receptor T- cells (CAR-T) and alkylating agents.

### **Tasquinimod in Multiple Myeloma**

Tasquinimod is being developed as a new product class with a distinct and novel mechanism of action and thus has the potential to overcome the problem of drug resistance. The clinical safety profile of tasquinimod is well known from previous clinical phase I-III trials. Given the good tolerability and the possibility to combine with available product classes, tasquinimod has the potential to expand over time from an initial position as the 3rd line treatment to earlier lines of treatment, similar to the patient population in the ongoing clinical study. 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) studying of tasquinimod as a monotherapy
- Second part (B) studying 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 key secondary endpoint is preliminary efficacy by objective response rate.

Important milestones were reached in October 2021, February 2022, and May 2023, respectively. Ten patients in part A had been treated with increasing doses of tasquinimod and the safety read-out showed that tasquinimod was generally well tolerated. The optimal dosing 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 patients included in this study phase were heavily pretreated, and 8 of the 10 patients were triple refractory to IMiDs, proteasome inhibitors, and anti-CD-38 monoclonal antibodies.

While none of the patients formally achieved a partial response, 3 patients with documented progressive myeloma at study entry achieved significant periods of stable disease on single agent tasquinimod therapy.

This suggests that tasquinimod has anti-myeloma activity in patients with advanced disease that is resistant to established therapies.

In February 2022, the trial subsequently advanced to the previously planned combination part of the phase Ib/IIa study in which treatment with tasquinimod is tested in patients with multiple myeloma together with the orally administered anti-myeloma agents ixazomib, lenalidomide, and dexamethasone (IRd).

In May 2023, Active Biotech announced that tasquinimod as monotherapy, or in combination with IRd, has a favorable safety profile in heavily pretreated patients with a median of eight previous treatments. All 15 patients who were part of this interim assessment were previously refractory against IMiDs, proteasome inhibitors (PI) and CD38 mAbs. One patient who had been resistant to previous Pi+IMiD combination had a durable partial response ongoing for over a year.

The results were presented at the annual meeting of American Society of Clinical Oncology (ASCO) 2023. In September 2023, Active Biotech announced that the dose optimization of tasquinimod + IRd was completed, and the expansion part of the study was started to further document the biological activity of tasquinimod + IRd in patients with multiple myeloma. These results will yield important information also for the new hematological indications with tasquinimod.

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

### **Myelofibrosis**

Myelofibrosis is a rare (orphan) blood cancer belonging to a group of disorders called myeloproliferative neoplasms (MPN) with an estimated annual incidence of 0.4-1.3 cases per 100 000 people in Europe.

The underlying cause of myelofibrosis is unknown. Patients with myelofibrosis have an abnormal production of blood-forming cells leading to the replacement of healthy bone marrow with scar tissue (fibrosis). Due to the lack of normal blood cell production, patients typically show laboratory value abnormalities, such as anemia and changes in white blood cell counts, and blood cell-differentiation. Later symptoms include enlargement of the spleen, an increased risk for infections, night sweats and fever. Myelofibrosis is associated with shortened survival, due to for instance bone marrow failure and transformation into acute leukemia.

### **Current Treatments and Market**

Myelofibrosis can be treated with bone marrow transplantation for eligible individuals, erythropoietin to manage anemia and JAK inhibitors to reduce spleen size. Today the following drugs are approved for these patients as symptom-directed therapy: Hydroxy-urea, ruxolitinib, momelotinib, fedratinib and pacritinib (the latter four are JAK inhibitors, JAKi). At present there are no approved therapies that would reverse bone marrow fibrosis in myelofibrosis, and there are only limited treatment options available for myelofibrosis patients whose disease progress during JAKi treatment or cannot tolerate JAKi.

The projected sales in the 8 major markets (US, 5EU, Japan and China) is USD 2,9 billion by 2031 (Global Data Report May 2023 – Myelofibrosis – Market Forecast 2021-2031).

### **Tasquinimod in Myelofibrosis**

In collaboration with a research group at Erasmus MC, the Netherlands, Active Biotech will explore myelofibrosis as a new high value orphan indication for tasquinimod within blood cancers. In February 2022, a global patent license agreement was signed with Oncode Institute, acting on behalf of Erasmus MC, for tasquinimod in myelofibrosis. Under the agreement, Oncode Institute grants to Active Biotech a global exclusive license to develop and commercialize tasquinimod in myelofibrosis. Proof-of-concept studies with tasquinimod in myelofibrosis patients are planned to start in Europe and at MD Anderson, TX, USA. The study in Europe will be conducted by the HOVON (Stichting Hemato-Oncologie voor Volwassenen Nederland) research network at clinics in The Netherlands and Germany. The study is funded by Oncode Institute. Active Biotech also has a preclinical collaboration with a research group at MD Anderson. Preclinical results from this collaboration were presented in December 2023 at an oral session at the annual meeting of the American Society of Hematology (ASH) in San Diego, USA. The results demonstrated tasquinimod's efficacy as monotherapy and in combination with approved

and investigational therapies in models of advanced MPN. The positive results create a rationale for a clinical study in patients with myelofibrosis for which the preparations are ongoing.

Tasquinimod was granted orphan designation in myelofibrosis by the FDA in May 2022.

### **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. 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 the development for prostate cancer was discontinued. Tasquinimod was studied in both healthy subjects and cancer patients.

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. Extensive datasets including a regulatory package of preclinical and clinical safety and full commercial scale CMC documentation has been generated.

### **EVENTS DURING THE FOURTH QUARTER**

- Lead Principal Investigator Rebekka Schneider-Kramann presents the clinical plan and positioning of tasquinimod in myelofibrosis (December 1)
- Preclinical data of tasquinimod presented at ASH (December 14)

## **Laquinimod**

Laquinimod is a first-in-class immunomodulator with a novel mode of action for the treatment of severe inflammatory eye diseases such as non-infectious 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, so that instead of activating pro-inflammatory T cells, regulatory T cells with anti-inflammatory properties are activated leading to a dampening of the inflammation.

### **Non-Infectious Uveitis**

Non-infectious uveitis (NIU) is the inflammation of the uveal tract (iris, ciliary body, and choroid), but can also lead to an inflammation of nearby tissues, such as the retina, the optic nerve, and the vitreous humor, in the absence of an infectious cause. The uvea is crucial for the delivery of oxygen and nutrients to the eye tissues, and an inflammation of the 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 pupils, and alteration of iris color are common symptoms.

If left untreated, uveitis can lead to severe eye problems, including blindness, cataract, glaucoma, damage to the optic nerve, and detachment of the retina. Non-infectious uveitis often occurs in connection with systemic autoimmune diseases such as sarcoidosis, multiple sclerosis and Crohn's disease. Uveitis can be divided into subtypes depending on the location of the inflammation. Intermediate, posterior and panuveitis (non-anterior non-infectious uveitis, NA-NIU) are the most severe and highly recurrent forms which can cause blindness if left untreated. Laquinimod will be developed as a new treatment option for non-infectious uveitis.



## The Market

There are limited treatment options for patients with NA-NIU. The drug of choice for most patients remains long term high dose corticosteroid therapy. Still, about 40 percent of patients fail in achieving disease control, or cannot continue with high dose corticosteroids due to side effects (Rosenbaum JT. Uveitis: treatment. In: Post TW, ed. UpToDate. Waltham (MA): UpToDate; 2021).

Recently, intra-ocular corticosteroid injections have been introduced with a benefit for some patients and may limit the systemic corticosteroid-related side effects. However, the procedure of injecting a sustained release depot directly in the eye is associated with risks such as cataract and increased intraocular pressure.

Approximately 1.7 million patients in the nine major markets were diagnosed with uveitis 2020, whereof approx. 600,000 patients received treatment. Of these about 205,000 will fail corticosteroids and are candidates for the 2nd line of treatment (Global Data Report June 2021, Uveitis – Market Forecast 2019-2029).

The global sales of drugs for uveitis totaled approx. USD 300 million in 2020, and sales are expected to reach approximately USD 0.8 billion by 2029 (Global Data Report June 2021, Uveitis – Market Forecast 2019-2029).

## Current Treatments

The current standard treatment for patients with non-infectious uveitis is high-dose oral corticosteroids or injections of corticosteroids in or around the eye. Immunosuppressants, such as methotrexate or cyclosporin, are used as corticosteroid-sparing regimen in the 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 the risk of blindness
- approximately 40 percent of patients fail on corticosteroids therapy
- long-term treatment of corticosteroids 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 additive 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 Non-infectious Uveitis

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

## Clinical development

An eye drop formulation of laquinimod has been developed, and a preclinical safety and toxicity bridging program for topical treatment has been completed. A phase I study of laquinimod eye drops in healthy subjects started in December 2021, and the study was completed in January 2023. The study enrolled a total of 54 healthy subjects. Subjects received laquinimod eye drops as a single ascending dose in part 1 and as repeated doses up to 21 days in part 2.

The primary objective of the study was safety and tolerability of laquinimod eye drops and the secondary readouts included ocular toxicity, pharmacokinetics, and plasma exposure. More information about the study design is available at [clinicaltrials.gov](https://clinicaltrials.gov) (NCT05187403). The eye drop formulation of laquinimod was well tolerated showing a beneficial safety and tolerability profile at dose levels where we expect to achieve therapeutic concentrations. No serious adverse events were reported. Data from the

recently completed phase I study together with preclinical data showing the distribution of laquinimod to the back of the eye after administration of the eye drop formulation to rabbits were presented at a poster session at the International Ocular Inflammation Society (IOIS) 2023 meeting in Berlin, Germany, 6-9 September 2023. To ensure that laquinimod reaches the posterior chamber of the eye to support further development in patients with non-anterior uveitis, a clinical ocular biodistribution study of the eye drop formulation will be conducted in collaboration with researchers at the Byers Eye Institute, Stanford University (Palo Alto, CA, USA) with the Principal Investigator Quan Dong Nguyen, MD, MSc, FAAO, FARVO, FASRS, Professor of Ophthalmology, Medicine, and Pediatrics, Stanford University School of Medicine.

A phase II clinical study of oral and eye drop formulations of laquinimod in patients with non-infectious uveitis is prepared. The start of the study is subjected to collaboration with a partner.

#### **Previous Clinical Experience with Laquinimod**

During its years of advanced product development, clinical efficacy, and safety data on oral laquinimod was established in more than 5,000 patients, primarily in multiple sclerosis (MS) patients, representing more than 14,000 patient-years of exposure. Extensive datasets have also been generated, including regulatory package of preclinical and clinical safety and full commercial scale CMC documentation.

#### **EVENTS DURING THE FOURTH QUARTER**

- Active Biotech enters into collaboration agreement for clinical ocular biodistribution study with laquinimod (December 5)

## **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. 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 ([www.who.int/health-topics/cancer](http://www.who.int/health-topics/cancer)).

#### **The Market**

Immunotherapy is one of the major breakthroughs of recent years in cancer therapy, which is reflected in the checkpoint inhibitors Keytruda, Opdivo, Imfinzi and Tecentriq achieving combined global sales of USD 30.7 billion in 2021 (Global Data report 2022). The strong sales development for checkpoint inhibitors is expected to continue and sales are forecasted at USD 60.0 billion in 2028 (Global Data report 2022).

### **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 cancer care in recent years, and the immuno-oncology market has demonstrated strong growth. 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 in 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 clinical phase IIa study in US testing naptumomab in combination with docetaxel in patients with advanced or metastatic non-small cell lung cancer (NSCLC) previously treated with checkpoint inhibitors has finished recruitment and results will be presented in 2024. The primary endpoint is objective response rate. In October, 2021, it was announced that the first patient was enrolled. In June 2022, it was announced that the trial will start enrolling into the second stage, after successful completion of the first stage. To move the study from the first to the second stage, a minimum of two responses out of ten patients was required. For more information about the trial, visit [clinicaltrials.gov](https://clinicaltrials.gov) (NCT04880863) and [neotx.com](https://neotx.com).

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 enrolls patients with previously treated advanced or metastatic, 5T4-positive solid tumors. The phase Ib part of the study is completed and the recommended phase II dose (RP2D) established. The trial was initiated in H2 2019 and is performed under an agreement with AstraZeneca. Interim safety and preliminary efficacy data from the study were presented at the American Association for Cancer Research (AACR) annual meeting in Orlando, Florida in April 2023. Data based on 59 patients with previously treated advanced or metastatic disease demonstrate that naptumomab in combination with durvalumab is well tolerated with limited toxicity at the RP2D. Durable, including complete, treatment responses were seen in patients where response to checkpoint inhibitor alone was not expected. In addition, the results indicate that pretreatment with obinutuzumab, a B-cell therapy, reduces the formation of anti-drug antibodies against naptumomab. A cohort expansion of this trial with patients suffering from esophageal cancer is planned. More information about the study is available at [clinicaltrials.gov](https://clinicaltrials.gov) (NCT03983954) and at [neotx.com](https://neotx.com). A new phase I study is also planned with naptumomab in combination with the checkpoint inhibitor pembrolizumab in patients with urothelial cancer. More information about the study is available at [clinicaltrials.gov](https://clinicaltrials.gov) (NCT05894447) and at [neotx.com](https://neotx.com).

In both ongoing studies patients are pre-treated with obinutuzumab, a B-cell therapy, to lower the levels of anti-drug antibodies (ADA) to naptumomab.

### **Previous Clinical Experience with Naptumomab**

Safety and tolerability of naptumomab as monotherapy and in combination with standard treatment have been established in clinical studies that include more than 300 patients.

Clinical development of naptumomab includes phase I studies in patients suffering from advanced non-small cell lung cancer, renal cell cancer and pancreatic cancer and a phase II/III study in combination with interferon alpha in patients with renal cell cancer.

Combining checkpoint inhibitors with the unique mode of action of naptumomab could be a useful strategy to treat multiple types of cancers, not responding to checkpoint inhibitors alone.

## Clinical Plan and Positioning of Tasquinimod in Myelofibrosis

*Summary of Presentation by Univ.-Prof. Dr. med. Rebekka Schneider-Kramann, PhD*

**Rebekka Schneider-Kramann is the Director at the Institute of Cell and Tumor Biology at the University Hospital in Aachen, Germany, Oncode Principal Investigator at Oncode Institute and Associate Professor, Cancer Center Erasmus MC, Rotterdam, The Netherlands. Professor Schneider-Kramann shares her preclinical research results with tasquinimod in animal models of myelofibrosis. The results provide a strong rationale to initiate a proof of concept clinical trial in patients with myelofibrosis who are ineligible to JAK inhibitor therapy.**

### **Tasquinimod in Myelofibrosis**

The tumor microenvironment is a key driver of bone marrow fibrosis in myelofibrosis and at present no approved therapies that target the tumor cell microenvironment exist. A preclinical animal model carrying the same mutation as in humans was developed to identify fibrosis driving cells in the tumor microenvironment and to test the effect of tasquinimod which targets the tumor micro environment on the disease. The animals develop the basic characteristics of myelofibrosis including spleen enlargement, changes in blood cell counts and bone marrow fibrosis. Mesenchymal stromal cells 1 and 2 were identified as fibrosis-driving cells in the tumor microenvironment. Treating the animals with tasquinimod resulted in normalization of spleen size and white blood cell counts and inhibition of bone marrow fibrosis. Furthermore, blood samples from patients with myelofibrosis showed that certain markers of inflammation named alarmins (S100A8/A9) are increased with grade of disease, with higher degree of alarmins in patients with more fibrotic bone marrow. Importantly, these alarmins were not increased in non-diseased i.e. normal bone marrows. Alarmins present a promising novel target in myelofibrosis. Tasquinimod blocks alarmin signaling and may therefore have potential as a disease modifying treatment in patients. A clinical proof of concept trial, TasqForce, will start recruiting patients in 2024 to evaluate tasquinimod as a new treatment option in patients who are ineligible for JAK inhibitor therapy. The study will investigate the effect of tasquinimod on spleen volume and bone marrow fibrosis in patients with primary or secondary myelofibrosis. Further, the study will test the possibility to use alarmins as an actionable biomarker to predict treatment response to tasquinimod.

See [www.activebiotech.com](http://www.activebiotech.com) for the audiocast between Univ.-Prof. Dr. med. Rebekka Schneider-Kramann, PhD and Chief Medical Officer Erik Vahtola, MD, PhD, Active Biotech.



# FINANCIAL INFORMATION

## Comments on the Group's results for the period January – December 2023

No sales were recorded during the period. The operational costs totaled SEK 46.5 M (57.9) whereof research and development expenses amounted to SEK 32.5 M (42.8), a 24% decrease in costs reflecting the concluded phase I laquinimod clinical trial and decreased costs for clinical drug.

The company's research efforts during 2023 have been focused on the clinical development of tasquinimod in multiple myeloma, the planning for start of clinical proof of concept studies in myelofibrosis and the finalization of the phase I study with laquinimod in eye diseases. Collaborations to expand the preclinical and clinical development of tasquinimod are ongoing.

The financial resources have been allocated to the development of the wholly owned projects tasquinimod and laquinimod. The clinical development programs include:

- the ongoing phase Ib/IIa clinical study with tasquinimod for treatment of multiple myeloma initiated in August 2020 in collaboration with Penn University, USA. Results are expected in the second half of 2024.
- the planning for start of proof of concept studies with tasquinimod in myelofibrosis scheduled to be initiated in 2024.
- the development of laquinimod as a new product class for treatment of inflammatory eye diseases. The topical ophthalmic formulation of laquinimod was tested in a phase I clinical study, that was concluded 2023, the positive study results supports the further development of laquinimod for inflammatory eye diseases. A phase I bio-distribution study is planned to start 1H 2024.

Administrative expenses amounted to SEK 13.9 M (15.1). The operating loss for the period amounted to SEK 46.5 M (loss: 57.9), the net financial income for the period amounted to SEK 0.7 M (loss: 0.5) and the loss after tax to SEK 45.8 M (loss: 58.4).

## Comments on the Group's results for the period October – December 2023

No sales were recorded during the period. The operational costs totaled SEK 12.8 M (15.2) whereof research and development expenses amounted to SEK 9.6 M (10.3), the decrease in costs is mainly explained by the finalization of the laquinimod phase I study.

Administrative expenses amounted to SEK 3.2 M (5.0). The operating loss for the period amounted to SEK 12.8 M (loss: 15.2), the net financial income for the period amounted to SEK 0.3 M (income: 0.3) and the loss after tax to SEK 12.5 M (loss: 15.0).

## Cash flow, liquidity and financial position, Group, for the period January – December 2023

Cash and cash equivalents at the end of the period amounted to SEK 36.2 M, compared with SEK 41.8 M at the end of 2022. Cash flow for the period amounted to a negative SEK 5.6 M (neg: 11.3). The cash flow from operating activities amounted to a negative SEK 45.7 M (neg: 54.8) and cash flow from financing activities amounted to a positive SEK 40.2 M (pos: 43.8) reflecting a rights issue concluded in the fourth quarter of 2023.

## 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 2023

No sales were recorded during the period. Operating expenses amounted to SEK 46.7 M (57.9).

The Parent Company's operating loss for the period was SEK 46.7 M (loss: 57.9). Net financial income amounted to a SEK 1.7 M (19.7) and the loss after financial items was SEK 45.0 M (loss: 38.2). Cash and bank balances totaled SEK 36.2 M at the end of the period, compared with SEK 41.6 M on January 1, 2023.

### **Comments on the Parent Company's results and financial position for the period October – December 2023**

No sales were recorded during the period. Operating expenses amounted to SEK 12.9 M (14.9). The Parent Company's operating loss for the period was SEK 12.9 M (loss: 14.9). Net financial income amounted to a SEK 1.1 M (0.3) and the loss after financial items was SEK 11.7 M (loss: 14.5).

### **Shareholders' equity**

Consolidated shareholders' equity at the end of the period amounted to SEK 30.7 M, compared with SEK 34,5 M at year-end 2022.

The number of shares outstanding at the end of the period totaled 361,739,047. At the end of the period, the equity/assets ratio for the Group was 69.6 percent, compared with 67.7 percent at year-end 2022. The corresponding figures for the Parent Company, Active Biotech AB, were 75.5 percent and 39.0 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 940,827 shares (Savings shares) in the market during the period 2020 to December 2023 in the respective incentive programs. Total costs, including social contributions, as of December 31, 2023, amounted to SEK 1877 K.

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 (9), of which the number of employees in the research and development organization accounted for 5 (6). 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. Active Biotech has currently three projects in its portfolio:

- tasquinimod, targeted towards hematological malignancies is in clinical phase Ib/IIa treatment of multiple myeloma and preparations are ongoing for start of proof of concept studies in Myelofibrosis in Europe and US. The study in Europe will mainly be funded by Oncode Institute
- laquinimod, targeted towards inflammatory eye disorders. A clinical phase I trial with a topical ophthalmic formulation was concluded in 2023. The planning of a phase I bio-distribution study is ongoing, study start is scheduled the first half of 2024.
- naptumomab, which is developed in collaboration with our partner NeoTX, the clinical phase IIa trial in patients with lung cancer is progressing towards results in 2024. Furthermore, a phase Ib/II study is ongoing with naptumomab in combination with the checkpoint inhibitor durvalumab, in patients with selected solid tumors. The preliminary efficacy of the combination was encouraging, and in the next step, an expansion cohort in esophageal cancer is planned. A new phase I study is also being planned with naptumomab combined with the checkpoint inhibitor pembrolizumab in patients with urothelial cancer. NeoTX start of these studies is subject to new financing and the timing of the start is uncertain due to the current geopolitical situation.

The ongoing preclinical and clinical programs are advancing positively. The company regularly receive inbound approaches from scientists who wish to explore the potential of tasquinimod or laquinimod

in different disease areas. Active Biotech will maintain focus for tasquinimod within hematological malignancies and laquinimod within inflammatory eye disorders.

Active Biotech focuses its activities to secure long-term value growth and conduct commercial activities aimed at entering new partnerships for the wholly owned clinical assets tasquinimod and laquinimod.

#### **Financing and financial position:**

The Board and the management team continuously assess the Groups financial viability and access to cash.

The available liquidity on December 31, 2023 will fund continued operations through 2024, and Active Biotech will therefore require access to further growth capital to maintain progress of its unpartnered project portfolio. Various sources of financing are explored, including partnering the company's development programs and broadening the shareholder base by directed share issuances to new investors. Given the current macro-economic uncertainties and the projected developments of the company's project portfolio, the Board has decided to keep all options open for the time being.

As the company within the next 12 months has additional financing needs that has not yet been secured, the Board is continuously working on evaluating various financing options to ensure continued operation. It is the Board's assessment that the company has good prospects at securing future financing, however the absence of secured financing at the time of submission of this report means that there is an uncertainty factor regarding the company's ability to continue operation on a longer term.

As a research company, 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.

In addition to the industry-specific risk factors described above, there is also an increased political uncertainty in the world which has led to financial instability with rising inflation and general macro-economic uncertainty. A more detailed description of the exposure to risk, and of the ways in which Active Biotech manages it, is provided in the 2022 Annual Report, see pages 44-46 and 49 and in Note 18 on pages 84-85. The Annual Report is available on the company's website: [www.activebiotech.com](http://www.activebiotech.com).

#### **EVENTS DURING THE FOURTH QUARTER**

- Lead Principal Investigator Rebekka Schneider-Kramann presents the clinical plan and positioning of tasquinimod in myelofibrosis (December 1)
- Active Biotech enters into collaboration agreement for clinical ocular biodistribution study with laquinimod (December 5)
- Active Biotech announces outcome of the Company's rights issue (December 6)
- Preclinical data of tasquinimod presented at ASH (December 14)
- Active Biotech provides update on the scheduled clinical program for 2024 (December 22)

## CONSOLIDATED PROFIT AND LOSS

SEK M	Oct-Dec		Jan-Dec	
	2023	2022	2023	2022
<b>Net sales</b>	-	-	-	-
Administrative expenses	-3.2	-5.0	-13.9	-15.1
Research and development costs	-9.6	-10.3	-32.5	-42.8
<b>Operating profit/loss</b>	<b>-12.8</b>	<b>-15.2</b>	<b>-46.5</b>	<b>-57.9</b>
Net financial items	0.3	0.3	0.7	-0.5
<b>Profit/loss before tax</b>	<b>-12.5</b>	<b>-15.0</b>	<b>-45.8</b>	<b>-58.4</b>
Tax	-	-	-	-
<b>Net profit/loss for the period</b>	<b>-12.5</b>	<b>-15.0</b>	<b>-45.8</b>	<b>-58.4</b>
Comprehensive profit/loss attributable to:				
Parent Company shareholders	-12.5	-15.0	-45.8	-58.4
Non-controlling interest	-	-	-	-
<b>Net profit/loss for the period</b>	<b>-12.5</b>	<b>-15.0</b>	<b>-45.8</b>	<b>-58.4</b>
Comprehensive profit/loss per share before dilution (SEK)	-0.04	-0.06	-0.17	-0.25
Comprehensive profit/loss per share after dilution (SEK)	-0.04	-0.06	-0.17	-0.25

## STATEMENT OF PROFIT AND LOSS AND CONSOLIDATED COMPREHENSIVE INCOME

SEK M	Oct-Dec		Jan-Dec	
	2023	2022	2023	2022
Net profit/loss for the period	-12.5	-15.0	-45.8	-58.4
Other comprehensive income	-	-	-	-
<b>Total comprehensive profit/loss for the period</b>	<b>-12.5</b>	<b>-15.0</b>	<b>-45.8</b>	<b>-58.4</b>
Total other comprehensive profit/loss for the period attributable to:				
Parent Company shareholders	-12.5	-15.0	-45.8	-58.4
Non-controlling interest	-	-	-	-
<b>Total comprehensive profit/loss for the period</b>	<b>-12.5</b>	<b>-15.0</b>	<b>-45.8</b>	<b>-58.4</b>
Depreciation/amortization included in the amount of	0.4	0.2	1.7	1.5
Investments in tangible fixed assets	-	-	-	-
Weighted number of outstanding common shares before dilution (000s)	285,411	266,585	271,525	235,150
Weighted number of outstanding common shares after dilution (000s)	285,411	266,585	271,525	235,150
Number of shares at close of the period (000s)	361,739	264,887	361,739	264,887



## CONSOLIDATED STATEMENT OF FINANCIAL POSITION

SEK M	Dec 31	
	2023	2022
Intangible fixed assets	0.2	0.2
Tangible fixed assets	4.7	6.3
Long-term receivables	0.4	0.4
<b>Total fixed assets</b>	<b>5.3</b>	<b>6.9</b>
Current receivables	2.5	2.3
Cash and cash equivalents	36.2	41.8
<b>Total current assets</b>	<b>38.7</b>	<b>44.1</b>
<b>Total assets</b>	<b>44.0</b>	<b>51.0</b>
Shareholders equity	30.7	34.5
Long-term liabilities	3.0	4.4
Current liabilities	10.4	12.1
<b>Total shareholders equity and liabilities</b>	<b>44.0</b>	<b>51.0</b>

## CONSOLIDATED STATEMENT OF CHANGES IN SHAREHOLDERS EQUITY

SEK M	Dec 31	
	2023	2022
Opening balance	34.5	46.7
Loss for the period	-45.8	-58.4
Other comprehensive income for the period	-	-
<i>Comprehensive profit/loss for the period</i>	<i>-45.8</i>	<i>-58.4</i>
Share-based payments that are settled with equity instruments, IFRS2	0.2	0.7
New share issue	41.8	45.5
<b>Balance at close of period</b>	<b>30.7</b>	<b>34.5</b>

## CONDENSED CONSOLIDATED CASH-FLOW STATEMENT

SEK M	Jan-Dec	
	2023	2022
<b>Loss after financial items</b>	<b>-45.8</b>	<b>-58.4</b>
Adjustment for non-cash items, etc.	1.8	2.2
<b>Cash flow from operating activities before changes in working capital</b>	<b>-44.0</b>	<b>-56.2</b>
Changes in working capital	-1.8	1.3
<b>Cash flow from operating activities</b>	<b>-45.7</b>	<b>-54.8</b>
Investments in intangible assets	-	-0.2
<b>Cash flow from investments</b>	<b>-</b>	<b>-0.2</b>
New share issue	41.8	45.5
Loans raised/amortization of loan liabilities	-1.6	-1.8
<b>Cash flow from financing activities</b>	<b>40.2</b>	<b>43.8</b>
<b>Cash flow for the period</b>	<b>-5.6</b>	<b>-11.3</b>
<b>Opening cash and cash equivalents</b>	<b>41.8</b>	<b>53.1</b>
<b>Closing cash and cash equivalents</b>	<b>36.2</b>	<b>41.8</b>

## KEY FIGURES

	Dec 31	
	2023	2022
Shareholders equity, SEK M	30.7	34.5
Equity per share, SEK	0.08	0.13
Equity/assets ratio in the Parent Company	75.5 %	39.0 %
Equity/assets ratio in the Group	69.6 %	67.7 %
Average number of annual employees	8	9

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	2019				2020				2021				2022				2023			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
<b>Net Sales</b>	<b>5.5</b>	<b>1.1</b>	<b>0.9</b>	<b>0.9</b>	<b>0.5</b>	-	-	<b>6.2</b>	-	-	-	-	-	-	-	-	-	-	-	-
Administration expenses	-2.8	-3.6	-2.7	-3.2	-3.4	-3.8	-2.9	-3.4	-3.3	-3.5	-3.5	-5.0	-3.6	-3.4	-3.0	-5.0	-3.8	-4.0	-3.0	-3.2
Research and development costs	-9.1	-5.2	-5.3	-8.8	-6.8	-6.3	-5.5	-7.0	-6.4	-9.2	-7.8	-11.2	-11.7	-10.5	-10.3	-10.3	-8.1	-7.3	-7.6	-9.6
Other operating expenses/income	-	2.2	-2.2	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
<b>Operating profit/loss</b>	<b>-6.4</b>	<b>-5.4</b>	<b>-9.3</b>	<b>-11.2</b>	<b>-9.7</b>	<b>-10.1</b>	<b>-8.3</b>	<b>-4.1</b>	<b>-9.7</b>	<b>-12.6</b>	<b>-11.3</b>	<b>-16.1</b>	<b>-15.3</b>	<b>-14.0</b>	<b>-13.4</b>	<b>-15.2</b>	<b>-11.8</b>	<b>-11.3</b>	<b>-10.6</b>	<b>-12.8</b>
Net financial items	-1.7	-0.0	-0.0	-0.1	-0.4	0.3	0.1	0.0	-0.0	-0.0	0.0	-0.0	-0.4	-0.3	-0.0	0.3	0.3	0.1	0.0	0.3
<b>Profit/loss before tax</b>	<b>-8.1</b>	<b>-5.5</b>	<b>-9.3</b>	<b>-11.2</b>	<b>-10.1</b>	<b>-9.8</b>	<b>-8.2</b>	<b>-4.1</b>	<b>-9.8</b>	<b>-12.6</b>	<b>-11.2</b>	<b>-16.2</b>	<b>-15.7</b>	<b>-14.3</b>	<b>-13.4</b>	<b>-15.0</b>	<b>-11.5</b>	<b>-11.2</b>	<b>-10.6</b>	<b>-12.5</b>
Tax	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
<b>Net profit/loss for the period</b>	<b>-8.1</b>	<b>-5.5</b>	<b>-9.3</b>	<b>-11.2</b>	<b>-10.1</b>	<b>-9.8</b>	<b>-8.2</b>	<b>-4.1</b>	<b>-9.8</b>	<b>-12.6</b>	<b>-11.2</b>	<b>-16.2</b>	<b>-15.7</b>	<b>-14.3</b>	<b>-13.4</b>	<b>-15.0</b>	<b>-11.5</b>	<b>-11.2</b>	<b>-10.6</b>	<b>-12.5</b>

## ACTIVE BIOTECH PARENT COMPANY – INCOME STATEMENT, CONDENSED

SEK M	Oct-Dec		Jan-Dec	
	2023	2022	2023	2022
<b>Net Sales</b>	-	-	-	-
Administration expenses	-3.2	-5.0	-14.0	-15.0
Research and development costs	-9.6	-9.9	-32.7	-42.9
<b>Operating profit/loss</b>	<b>-12.9</b>	<b>-14.9</b>	<b>-46.7</b>	<b>-57.9</b>
<i>Profit/loss from financial items:</i>				
Result from participations in group companies	0.8	-	0.8	20.0
Interest income and similar income-statement items	0.3	0.0	0.9	0.0
Interest expense and similar income-statement items	-	0.3	-0.0	-0.3
<b>Profit/loss after financial items</b>	<b>-11.7</b>	<b>-14.5</b>	<b>-45.0</b>	<b>-38.2</b>
Tax	-	-	-	-
<b>Net profit/loss for the period</b>	<b>-11.7</b>	<b>-14.5</b>	<b>-45.0</b>	<b>-38.2</b>
<b>Statement of comprehensive income parent company</b>				
Net profit/loss for the period	-11.7	-14.5	-45.0	-38.2
Other comprehensive income	-	-	-	-
<b>Total comprehensive profit/loss for the period</b>	<b>-11.7</b>	<b>-14.5</b>	<b>-45.0</b>	<b>-38.2</b>

## ACTIVE BIOTECH PARENT COMPANY – BALANCE SHEET, CONDENSED

SEK M	Dec 31	
	2023	2022
Intangible fixed assets	0.2	0.2
Financial fixed assets	0.9	40.9
<b>Total fixed assets</b>	<b>1.1</b>	<b>41.1</b>
Current receivables	2.9	2.7
Short-term investments	-	39.5
Cash and bank balances	36.2	2.1
<b>Total current assets</b>	<b>39.1</b>	<b>44.4</b>
<b>Total assets</b>	<b>40.2</b>	<b>85.5</b>
Shareholders equity	30.4	33.4
Current liabilities	9.8	52.1
<b>Total equity and liabilities</b>	<b>40.2</b>	<b>85.5</b>

## ACTIVE BIOTECH PARENT COMPANY – CHANGES IN SHAREHOLDERS EQUITY

SEK M	Dec 31	
	2023	2022
Opening balance	33.4	25.4
Loss for the period	-45.0	-38.2
Other comprehensive income for the period	-	-
<i>Comprehensive profit/loss for the period</i>	<i>-45.0</i>	<i>-38.2</i>
New share issue	41.8	45.5
Share-based payments that are settled with equity instruments, IFRS2	0.2	0.7
<b>Balance at close of period</b>	<b>30.4</b>	<b>33.4</b>

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: FAIR VALUE OF FINANCIAL INSTRUMENTS**

SEK M	Dec 31, 2023 Level 2	Dec 31, 2022 Level 2
Short-term investments	0.0	39.5

## 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 Report Q1, 2024: May 8, 2024
- Annual General Meeting: May 22, 2024
- Interim Report Q2, 2024: Aug 22, 2024
- Interim Report Q3, 2024: Nov 7, 2024
- Year-end Report 2024: Feb 13, 2025

The reports will be available from these dates at [www.activebiotech.com](http://www.activebiotech.com)

This interim report is unaudited.

The interim report for the January – December period 2023 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. The interim report has been reviewed by the company's auditors.

Lund February 8, 2024

Helén Tuve  
*President and CEO*

## 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: The wholly owned 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 in clinical development for treatment of non-infectious uveitis and a clinical phase I study with a topical ophthalmic formulation has been concluded. Naptumomab, a targeted anti-cancer immunotherapy, partnered to NeoTX Therapeutics, is in a phase Ib/II clinical program in patients with advanced solid tumors. Please visit [www.activebiotech.com](http://www.activebiotech.com) for more information.