Active Biotech

Q1 Q2 Q3 Q4

INTERIM REPORT Q2 2024 | ACTIVE BIOTECH AB

Our development projects continued to advance

SECOND QUARTER IN BRIEF

- Start of enrollment to the clinical phase I biodistribution study with laquinimod eye drops (April 3)
- Active Biotech acquired exclusive rights to patents of tasquinimod in combination therapy in multiple myeloma (May 22)
- Clinical activity and safety of naptumomab and docetaxel in non-small cell lung cancer were presented at ASCO 2024 (May 28)

EVENTS AFTER THE END OF THE PERIOD

- Active Biotech entered agreement for a clinical study of tasquinimod in myelofibrosis (July 1)
- Active Biotech provided an update on the clinical phase Ib/IIa study with tasquinimod in relapsed refractory multiple myeloma (July 15)

FINANCIAL SUMMARY

SEK M	Apr-Jun 2024	Apr-Jun 2023	Jan-Jun 2024	Jan-Jun 2023	Full-year 2023
Net sales	–	–	–	–	–
Operating profit/loss	–10.7	–11.3	–21.4	–23.1	–46.5
Profit/loss after tax	–10.6	–11.2	–21.1	–22.7	–45.8
Earnings per share (SEK)	–0.03	–0.04	–0.06	–0.09	–0.17
Cash and cash equivalents (at close of period)			13.9	15.7	36.2

The report is also available at www.activebiotech.com

Active Biotech AB (Corp. reg. no. 556223-9227) / Scheelevägen 22, SE-223 63 Lund / +46 (0)46 19 20 00 / www.activebiotech.com
Helén Tuvesson, CEO: +46 (0)46 19 21 56 / Hans Kolam, CFO: +46 (0)46 19 20 44

Helén Tuvesson
CEO

Our main focus in the tasquinimod project is on the clinical programs in myelofibrosis in Europe and the US

COMMENTS FROM THE CEO

Our clinical development projects in cancer and inflammatory eye diseases continue to progress well. In the laquinimod project, recruitment of patients for the ocular biodistribution study continues at the Beyers Eye Institute at Stanford University. In the tasquinimod project, preparations are complete for the myelofibrosis study in the US, whereas in Europe, we are in the start-up phase and expect to start in the third quarter of this year. We recently reported promising interim data from the ongoing trial of tasquinimod in multiple myeloma, where three out of nine patients who are not expected to respond to ixazomib, lenalidomide, and dexamethasone (IRd) alone responded well to treatment with tasquinimod in combination with IRd. Tasquinimod in combination with IRd was well tolerated and did not show unexpected or dose-limiting toxicity. These are promising data that we hope to verify in additional patients. We continue to work actively to strengthen patent protection around our compounds and we recently acquired exclusive rights to a patent for tasquinimod in combination therapy in multiple myeloma.

The safety of the newly developed eye drop formulation of laquinimod was recently confirmed in a phase I safety and tolerability study in healthy subjects. To verify that laquinimod reaches the posterior parts of the eye after administration of the eye drops, a clinical ocular biodistribution study with laquinimod in patients who will undergo vitrectomy is now being conducted. The recruitment of patients for the study continues and we look forward to the study results later in the year. Commercial activities are otherwise ongoing in the project, where we believe that the biodistribution study will be an important part for future partner discussions.

Our main focus in the tasquinimod project is on the clinical programs in myelofibrosis in Europe and the US. The clinical trial currently being prepared in Europe has external funding from the Oncode Institute and will be conducted in collaboration with the HOVON research network at clinics in the Netherlands and Germany. A clinical trial agreement is already in place, and once we have received approvals from regulatory authorities and ethical committees, the study is estimated to start in Q3 2024. The clinical study in myelofibrosis in the US is conducted in collaboration with MD Anderson. We expect the first patient will be dosed shortly as the study has regulatory and ethical approval and the study agreement is in place.

We recently reported data from the expansion cohort of tasquinimod in combination with IRd in the multiple myeloma trial ongoing at the Abrahamson Cancer Center, University of Pennsylvania. We see clinically meaningful treatment responses in three of nine patients with highly refractory multiple myeloma who were not expected to respond to IRd therapy itself, based on their prior treatment history. Recruitment to the study continues to further confirm the clinical benefit of tasquinimod in multiple myeloma. Further, as an all-oral regimen, the combination of tasquinimod with IRd presents an advantage over parenterally administered anti-myeloma therapies. We are encouraged by the good safety and preliminary efficacy of tasquinimod in this heavily pretreated patient population and look forward to reviewing and reporting results from the study towards the end of 2024.

Our partner NeoTX reported interim data from the clinical trial with naptumomab in combination with docetaxel in advanced lung cancer at the American Society of Cancer's annual meeting, ASCO 2024. The study included 38 patients with non-small cell lung cancer previously treated with a checkpoint inhibitor. Although the results of the study suggest limited disease control with naptumomab the results indicated no increase of the overall response rate (primary endpoint) compared to docetaxel alone. The safety of naptumomab in this combination was acceptable. In the combination study with naptumomab and durvalumab, the start of the planned expansion cohort study in esophageal cancer is dependent on new funding and the timing of the start is therefore uncertain.

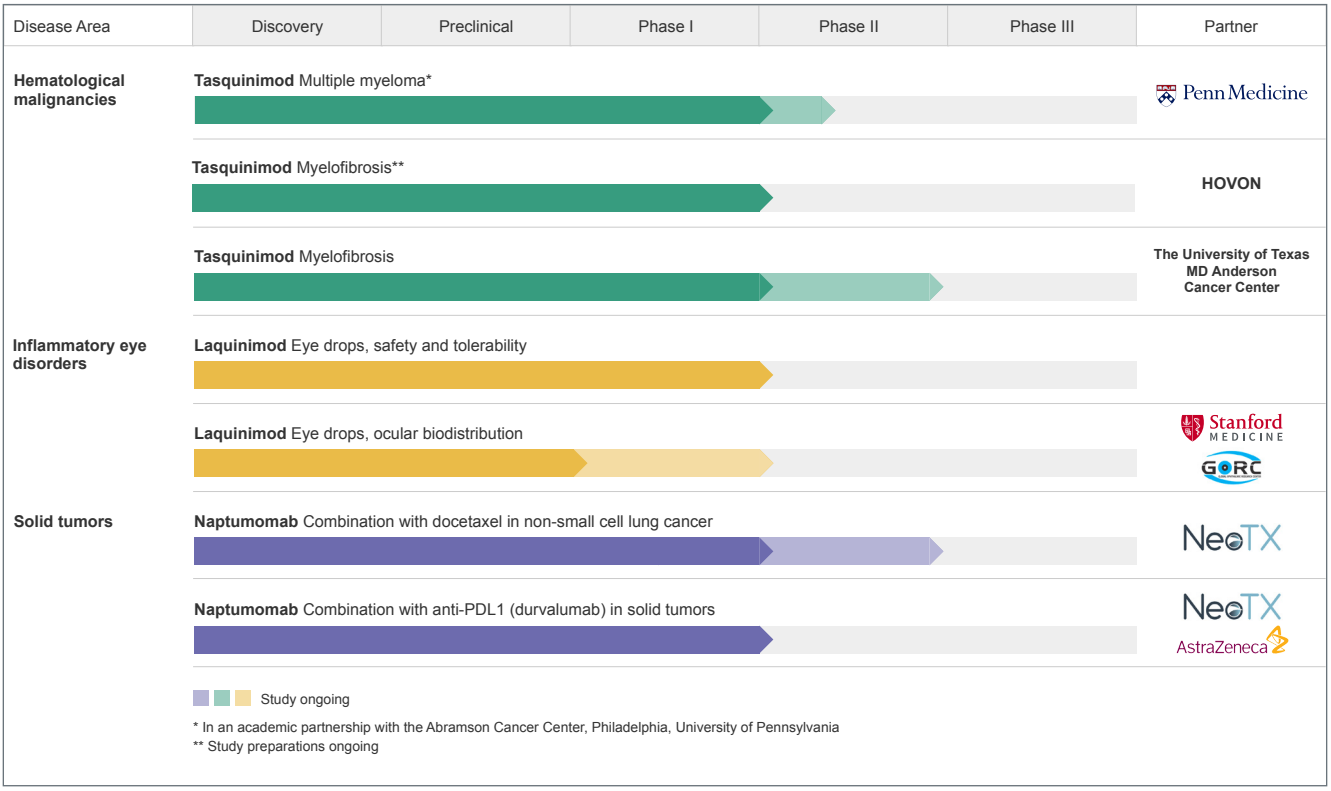
In the second quarter of the year, we realized strong progress in our wholly owned projects. We continue to focus our efforts on tasquinimod where we now have clinical programs ongoing in myelofibrosis and multiple myeloma. Both programs are pursued in collaborations with world-leading academic groups who support the exploration of tasquinimod in patients in need of effective and safe treatments. Consequently, we have achieved low development costs through contributions by external partners.

We are actively evaluating various sources of funding to ensure the company's viability. During the past three months several paths have been identified but no decision has yet been taken.

Helén Tuvesson, CEO

PROJECTS

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



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

The 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, May 2023, and July 2024 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 eight of the 10 patients were triple refractory to IMiDs, proteosome inhibitors, and anti-CD-38 monoclonal antibodies.

While none of the patients formally achieved a partial response, three 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 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, PI:s 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.

In July 2024, data from eleven patients treated with the combination of tasquinimod + IRd were reported. The combination was well tolerated with no unexpected safety issues. The antimyeloma activity of tasquinimod was evidenced by two more patients with clinical benefit (minimal responses) in addition to the previously reported partial response, out of nine patients previously refractory to PI+IMiD combination. Enrollment into the study continues to further confirm these results.

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 (NCT04405167).

Myelofibrosis

Myelofibrosis is a rare (orphan) blood cancer belonging to a group of disorders called myeloproliferative neoplasms 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 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) are 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 Cancer Center, TX. The study in Europe will be conducted by the HOVON (Stichting HematoOncologie 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, CA. 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 US Food and Drug Administration (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.

SECOND QUARTER IN BRIEF

- Active Biotech acquired exclusive rights to patents of tasquinimod in combination therapy in multiple myeloma (May 22)

EVENTS AFTER THE END OF THE PERIOD

- Active Biotech entered agreement for a clinical study of tasquinimod in myelofibrosis (July 1)
- Active Biotech provided an update on the clinical phase Ib/IIa study with tasquinimod in relapsed refractory multiple myeloma (July 15)

Laquinimod

Laquinimod is a first-in-class immunomodulator with a novel mode of action in development 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 is 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 (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 is being conducted in collaboration with researchers at the Byers Eye Institute, Stanford University (Palo Alto, CA) with the Principal Investigator Quan Dong Nguyen, MD, MSc, FAAO, FARVO, FASRS, Professor of Ophthalmology, Medicine, and Pediatrics, Stanford University School of Medicine. The study is recruiting and results from the study are expected during this year.

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.

SECOND QUARTER IN BRIEF

- Start of enrollment to the clinical phase I biodistribution study with laquinimod eye drops (April 3)

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).

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 immunooncology 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 following obinutuzumab pretreatment in patients with advanced or metastatic non-small cell lung cancer (NSCLC) previously treated with checkpoint inhibitors has finished recruitment and results were presented at ASCO on June 3, 2024. The primary endpoint was overall response rate (ORR) and duration of response (DOR) based on institutional iRECIST review. Secondary objectives included safety, progression free survival (PFS) and overall survival (OS). The first patient was enrolled in October 2021.

The trial enrolled 38 patients with NSCLC previously treated with platinum and checkpoint-inhibitor (CPI) therapy. Safety of naptumomab was acceptable with mostly grade 1-2 infusion related reactions, were generally easily manageable and rapidly reversable.

32 patients were evaluable for response. Five patients had partial response (PR), two of them unconfirmed, and overall response rate (primary endpoint) was 16%. Two patients had prolonged responses: one lasted for 22 months and the second had a complete response lasting for 24 months despite CNS progression. Mean duration of response was 7.3 months (1.3 – 20.8). Mean PFS was 4.6 months, 18 patients (56%) had stable disease, disease-control rate was 72%, with mean duration of 5.3 months. Median OS was 8 months with 11 patients (34%) still alive at database lock. Pretreatment with obinutuzumab successfully eliminated anti-drug antibodies (ADAs), which enables prolonged naptumomab exposure. In conclusion, the combination of naptumomab and docetaxel show preliminary evidence of activity with acceptable safety in heavily pre-treated NSCLC patients.

For more information about the trial, visit clinicaltrials.gov (NCT04880863) and 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, FA, 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 pre-treatment with obinutuzumab, a B-cell therapy, reduces the formation of ADAs 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 (NCT03983954) and at neotx.com.

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.

SECOND QUARTER IN BRIEF

- Clinical activity and safety of naptumomab and docetaxel in non-small cell lung cancer were presented at ASCO 2024 (May 28)

FINANCIAL INFORMATION

Comments on the Group's results for the period January – June 2024
No sales were recorded during the period. The operational costs amounted to SEK 21.4 M (23.1), a 7% decrease. Research and development expenses amounted to SEK 14.2 M (15.4), a 8% decrease in costs, reflecting lower laquinimod development costs and increased activities and costs in the two tasquinimod clinical trials in myelofibrosis.

The company's research efforts during the first six months have been focused on the clinical development of tasquinimod in multiple myeloma, the planning for the start of both the two phase II proof-of-concept studies in myelofibrosis and the phase I biodistribution 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, results are expected in the second half of 2024.
- the planning for start of two proof of concept studies with tasquinimod in myelofibrosis scheduled to start in the second half of 2024.
- the development of laquinimod as a new product class for treatment of inflammatory eye diseases. A phase I bio-distribution study was initiated in Q1 2024 and results are expected later in the year.

Administrative expenses amounted to SEK 7.2 M (7.7). The operating loss for the period amounted to SEK 21.4 M (loss: 23.1), the net financial income for the period amounted to SEK 0.3 M (inc: 0.4) and the loss after tax to SEK 21.1 M (loss: 22.7).

Comments on the Group's results for the period April – June 2024
No sales were recorded during the period. The operational costs totaled SEK 10.7 M (11.3) whereof research and development expenses amounted to SEK 7.1 M (7.3), the decreased costs represents a balance of increased activity and costs in the tasquinimod development in myelofibrosis and substantially lower costs in the laquinimod project.

Administrative expenses amounted to SEK 3.6 M (4.0). The operating loss for the period amounted to SEK 10.7 M (loss: 11.3), the net financial income for the period amounted to SEK 0.1 M (inc: 0.1) and the loss after tax to SEK 10.6 M (loss: 11.2).

Cash flow, liquidity and financial position, Group, for the period January – June 2024
Cash and cash equivalents at the end of the period amounted to SEK 13.9 M, compared with SEK 36.2 M at the end of 2023. Cash flow for the period amounted to a negative SEK 22.3 M (neg: 26.1). The cash flow from operating activities amounted to a negative SEK 21.5 M (neg: 25.3) and cash flow from financing activities amounted to a negative SEK 0.8 M (neg: 0.8).

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 – June 2024
No sales were recorded during the period. Operating expenses amounted to SEK 21.5 M (23.2).

The Parent Company's operating loss for the period was SEK 21.5 M (loss: 23.2). Net financial income amounted to a SEK 0.4 M (inc:0.5) and the loss after financial items was SEK 21.1 M (loss: 22.7). Cash and bank balances totaled SEK 13.9 M at the end of the period, compared with SEK 36.2 M on January 1, 2024.

Comments on the Parent Company's results and financial position for the period April – June 2024
No sales were recorded during the period. Operating expenses amounted to SEK 10.8 M (11.3).
The Parent Company's operating loss for the period was SEK 10.8 M (loss: 11.3). Net financial income amounted to a SEK 0.2 M (inc: 0.2) and the loss after financial items was SEK 10.6 M (loss: 11.2).

Shareholders' equity
Consolidated shareholders' equity at the end of the period amounted to SEK 9.6 M, compared with SEK 30,7 M at year-end 2023.

The number of shares outstanding at the end of the period totaled 361,813,142. At the end of the period, the equity/assets ratio for the Group was 43.4 percent, compared with 69.6 percent at year-end 2023. The corresponding figures for the Parent Company, Active Biotech AB, were 48.8 percent and 75.5 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 June 30, 2024, amounted to SEK 1,889 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 (8), 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. 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 results are expected in the second half of 2024. Preparations are ongoing for start of two proof of concept studies in Myelofibrosis in collaboration with leading academic groups 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. A phase I bio-distribution study was started in Q1 2024 and will be concluded during 2024.
- naptumomab, which is developed in collaboration with our partner NeoTX. Results from the clinical phase IIa trial in patients with lung cancer were presented at ASCO in June 2024. In addition, 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. NeoTX's start of this study 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 in myelofibrosis.

The laquinimod phase I biodistribution study will be concluded during 2024 and partnering activities are planned thereafter.

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 June 30, 2024 will fund continued operations into the fourth quarter of 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 six 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 2023 Annual Report, see pages 51-53 and 56 and in Note 18 on pages 89-90. The Annual Report is available on the company's website: www.activebiotech.com.

SECOND QUARTER IN BRIEF

- Start of enrollment to the clinical phase I biodistribution study with laquinimod eye drops (April 3)
- Active Biotech acquired exclusive rights to patents of tasquinimod in combination therapy in multiple myeloma (May 22)
- Clinical activity and safety of naptumomab and docetaxel in non-small cell lung cancer were presented at ASCO 2024 (May 28)

EVENTS AFTER THE END OF THE PERIOD

- Active Biotech entered agreement for a clinical study of tasquinimod in myelofibrosis (July 1)
- Active Biotech provided update on the clinical phase Ib/IIa study with tasquinimod in relapsed refractory multiple myeloma (July 15)

CONSOLIDATED PROFIT AND LOSS

SEK M	Apr-Jun 2024	Apr-Jun 2023	Jan-Jun 2024	Jan-Jun 2023	Full Year 2023
Net sales	**–**	**–**	**–**	**–**	**–**
Administrative expenses	–3.6	–4.0	–7.2	–7.7	–13.9
Research and development costs	–7.1	–7.3	–14.2	–15.4	–32.5
Operating profit/loss	**–10.7**	**–11.3**	**–21.4**	**–23.1**	**–46.5**
Net financial items	0.1	0.1	0.3	0.4	0.7
Profit/loss before tax	**–10.6**	**–11.2**	**–21.1**	**–22.7**	**–45.8**
Tax	–	–	–	–	–
Net profit/loss for the period	**–10.6**	**–11.2**	**–21.1**	**–22.7**	**–45.8**
Comprehensive profit/loss attributable to:					
Parent Company shareholders	–10.6	–11.2	–21.1	–22.7	–45.8
Non-controlling interest	–	–	–	–	–
Net profit/loss for the period	**–10.6**	**–11.2**	**–21.1**	**–22.7**	**–45.8**
Comprehensive profit/loss per share before dilution (SEK)	–0.03	–0.04	–0.06	–0.09	–0.17
Comprehensive profit/loss per share after dilution (SEK)	–0.03	–0.04	–0.06	–0.09	–0.17

STATEMENT OF PROFIT AND LOSS AND CONSOLIDATED COMPREHENSIVE INCOME

SEK M	Apr-Jun 2024	Apr-Jun 2023	Jan-Jun 2024	Jan-Jun 2023	Full Year 2023
Net profit/loss for the period	–10.6	–11.2	–21.1	–22.7	–45.8
Other comprehensive income	–	–	–	–	–
Total comprehensive profit/loss for the period	**–10.6**	**–11.2**	**–21.1**	**–22.7**	**–45.8**
Total other comprehensive profit/loss for the period attributable to:					
Parent Company shareholders	–10.6	–11.2	–21.1	–22.7	–45.8
Non-controlling interest	–	–	–	–	–
Total comprehensive profit/loss for the period	**–10.6**	**–11.2**	**–21.1**	**–22.7**	**–45.8**
Depreciation/amortization included in the amount of	0.4	0.4	0.8	0.8	1.7
Investments in tangible fixed assets	–	–	–	–	–
Weighted number of outstanding common shares before dilution (000s)	361,788	265,059	361,764	265,059	271,525
Weighted number of outstanding common shares after dilution (000s)	361,788	265,059	361,764	265,059	271,525
Number of shares at close of the period (000s)	361,813	265,145	361,813	265,145	361,739

CONSOLIDATED STATEMENT OF FINANCIAL POSITION

SEK M	Jun 30 2024	Jun 30 2023	Dec 31 2023
Intangible fixed assets	0.2	0.2	0.2
Tangible fixed assets	3.9	5.4	4.7
Long-term receivables	0.4	0.4	0.4
Total fixed assets	**4.6**	**6.0**	**5.3**
Current receivables	3.6	2.9	2.5
Cash and cash equivalents	13.9	15.7	36.2
Total current assets	**17.5**	**18.6**	**38.7**
Total assets	**22.1**	**24.6**	**44.0**
Shareholders equity	9.6	11.9	30.7
Long-term liabilities	2.3	3.7	3.0
Current liabilities	10.2	9.1	10.4
Total shareholders equity and liabilities	**22.1**	**24.6**	**44.0**

CONSOLIDATED STATEMENT OF CHANGES IN SHAREHOLDERS EQUITY

SEK M	Jun 30 2024	Jun 30 2023	Dec 31 2023
Opening balance	30.7	34.5	34.5
Loss for the period	–21.1	–22.7	–45.8
Other comprehensive income for the period	–	–	–
Comprehensive profit/loss for the period	*–21.1*	*–22.7*	*–45.8*
Share-based payments that are settled with equity instruments, IFRS2	0.0	0.1	0.2
New share issue	0.0	0.0	41.8
Balance at close of period	**9.6**	**11.9**	**30.7**

CONDENSED CONSOLIDATED CASH-FLOW STATEMENT

SEK M	Jan-Jun 2024	Jan-Jun 2023	Full Year 2023
Loss after financial items	**–21.1**	**–22.7**	**–45.8**
Adjustment for non-cash items, etc.	0.8	0.9	1.8
Cash flow from operating activities before changes in working capital	**–20.3**	**–21.8**	**–44.0**
Changes in working capital	–1.2	–3.5	–1.8
Cash flow from operating activities	**–21.5**	**–25.3**	**–45.7**
New share issue	0.0	0.0	41.8
Loans raised/amortization of loan liabilities	–0.8	–0.8	–1.6
Cash flow from financing activities	**–0.8**	**–0.8**	**40.2**
Cash flow for the period	**–22.3**	**–26.1**	**–5.6**
Opening cash and cash equivalents	**36.2**	**41.8**	**41.8**
Closing cash and cash equivalents	**13.9**	**15.7**	**36.2**

KEY FIGURES

	Jun 30		Dec 31
	2024	2023	2023
Shareholders equity, SEK M	9.6	11.9	30.7
Equity per share, SEK	0.03	0.04	0.08
Equity/assets ratio in the Parent Company	48.8 %	17.9 %	75.5 %
Equity/assets ratio in the Group	43.4 %	48.2 %	69.6 %
Average number of annual employees	8	8	8

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

CONSOLIDATED PROFIT AND LOSS

	2020				2021				2022				2023				2024	
SEK M	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2
Net Sales	**0.5**	–	–	**6.2**	–	–	–	–	–	–	–	–	–	–	–	–	–	–
Administration expenses	-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	-3.6	-3.6
Research and development costs	-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	-7.1	-7.1
Operating profit/loss	**-9.7**	**-10.1**	**-8.3**	**-4.1**	**-9.7**	**-12.6**	**-11.3**	**-16.1**	**-15.3**	**-14.0**	**-13.4**	**-15.2**	**-11.8**	**-11.3**	**-10.6**	**-12.8**	**-10.7**	**-10.7**
Net financial items	-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	0.2	0.1
Profit/loss before tax	**-10.1**	**-9.8**	**-8.2**	**-4.1**	**-9.8**	**-12.6**	**-11.2**	**-16.2**	**-15.7**	**-14.3**	**-13.4**	**-15.0**	**-11.5**	**-11.2**	**-10.6**	**-12.5**	**-10.5**	**-10.6**
Tax	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–
Net profit/ loss for the period	**-10.1**	**-9.8**	**-8.2**	**-4.1**	**-9.8**	**-12.6**	**-11.2**	**-16.2**	**-15.7**	**-14.3**	**-13.4**	**-15.0**	**-11.5**	**-11.2**	**-10.6**	**-12.5**	**-10.5**	**-10.6**

ACTIVE BIOTECH PARENT COMPANY – INCOME STATEMENT, CONDENSED

SEK M	Apr-Jun 2024	Apr-Jun 2023	Jan-Jun 2024	Jan-Jun 2023	Full Year 2023
Net Sales	**–**	**–**	**–**	**–**	**–**
Administration expenses	–3.6	–4.0	–7.2	–7.8	–14.0
Research and development costs	–7.2	–7.3	–14.3	–15.4	–32.7
Operating profit/loss	**–10.8**	**–11.3**	**–21.5**	**–23.2**	**–46.7**
Profit/loss from financial items:					
Result from participations in group companies	–	–	–	–	0.8
Interest income and similar income-statement items	0.2	0.2	0.4	0.5	0.9
Interest expense and similar income-statement items	–0.0	–0.0	–0.0	–0.0	-0.0
Profit/loss after financial items	**–10.6**	**–11.2**	**–21.1**	**–22.7**	**–45.0**
Tax	–	–	–	–	–
Net profit/loss for the period	**–10.6**	**–11.2**	**–21.1**	**–22.7**	**–45.0**
Statement of comprehensive income parent company					
Net profit/loss for the period	–10.6	–11.2	–21.1	–22.7	–45.0
Other comprehensive income	–	–	–	–	–
Total comprehensive profit/loss for the period	**–10.6**	**–11.2**	**–21.1**	**–22.7**	**–45.0**

ACTIVE BIOTECH PARENT COMPANY – BALANCE SHEET, CONDENSED

SEK M	Jun 30 2024	Jun 30 2023	Dec 31 2023
Intangible fixed assets	0.2	0.2	0.2
Financial fixed assets	0.9	40.9	0.9
Total fixed assets	**1.1**	**41.1**	**1.1**
Current receivables	4.0	3.4	2.9
Short-term investments	–	10.0	–
Cash and bank balances	13.9	5.5	36.2
Total current assets	**17.9**	**18.8**	**39.1**
Total assets	**19.0**	**59.9**	**40.2**
Shareholders equity	9.3	10.8	30.4
Current liabilities	9.7	49.2	9.8
Total equity and liabilities	**19.0**	**59.9**	**40.2**

ACTIVE BIOTECH PARENT COMPANY – CHANGES IN SHAREHOLDERS EQUITY

SEK M	Jun 30 2024	Jun 30 2023	Dec 31 2023
Opening balance	30.4	33.4	33.4
Loss for the period	–21.1	–22.7	–45.0
Other comprehensive income for the period	–	–	–
Comprehensive profit/loss for the period	–21.1	–22.7	–45.0
New share issue	0.0	0.0	41.8
Share-based payments that are settled with equity instruments, IFRS2	0.0	0.1	0.2
Balance at close of period	**9.3**	**10.8**	**30.4**

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.

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 Q3, 2024: Nov 7, 2024
- Year-end Report 2024: Feb 13, 2025

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

This interim report is unaudited.

The interim report for the January – June period 2024 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, August 22, 2024

Michael Shalmi
Chairman

Uli Hacksell
Board Member

Aleksandar Danilovski
Board Member

Peter Thelin
Board Member

Axel Glasmacher
Board Member

Helén Tuvesson
President and CEO

Active Biotech AB (publ) (NASDAQ Stockholm: ACTI) is a biotechnology company that develops first-in-class immunomodulatory treatments for oncology and immunology indications with a high unmet medical need and significant commercial potential. Active Biotech currently holds three projects in its portfolio, of which tasquinimod and laquinimod are wholly owned small molecule immunomodulators with a mode of action that includes modulation of myeloid immune cell function. The projects are in clinical development for hematological malignancies and inflammatory eye disorders, respectively. The company's core focus is on the development of tasquinimod in myelofibrosis, a rare blood cancer, where clinical proof-of-concept studies are being prepared. Also ongoing is a clinical Phase Ib/IIa study in multiple myeloma. Laquinimod is in clinical development for the treatment of non-infectious uveitis. A clinical phase I program with a topical ophthalmic formulation is ongoing to support phase II development together with a partner. The third pipeline project is naptumomab, a targeted anti-cancer immunotherapy, partnered to NeoTX Therapeutics, which is in a phase Ib/II clinical program in patients with advanced solid tumors. Please visit www.activebiotech.com for more information.