

Q1 Q2 Q3 Q4

INTERIM REPORT Q1 2024 | ACTIVE BIOTECH AB

Our development projects continued to advance

FIRST QUARTER IN BRIEF

- Preparations ongoing for start of the clinical proof of concept studies with tasquinimod in myelofibrosis
- The expansion cohort of the study in multiple myeloma is ongoing according to plan

EVENTS AFTER THE END OF THE PERIOD

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

FINANCIAL SUMMARY

SEK M	Jan-Mar		Full-year
	2024	2023	2023
Net sales	-	-	-
Operating profit/loss	-10.7	-11.8	-46.5
Profit/loss after tax	-10.5	-11.5	-45.8
Earnings per share (SEK)	-0.03	-0.04	-0.17
Cash and cash equivalents (at close of period)	25.4	30.2	36.2

The report is also available at www.activebiotech.com

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Helén Tuveßon
CEO



In the beginning of this year, we have focused on the preparations to start the two planned clinical proof-of-concept studies with tasquinimod in myelofibrosis

COMMENTS FROM THE CEO

In the first quarter of 2024, our development projects in cancer and inflammatory eye diseases continued to advance. Our focus is on tasquinimod in myelofibrosis, a rare blood cancer with limited treatment options available. In preclinical models tasquinimod has demonstrated its potential as a disease modifying treatment with effect on spleen size, hematopoiesis, and bone marrow fibrosis. In the beginning of this year, we have commenced preparations to start two planned clinical proof-of-concept studies with tasquinimod in myelofibrosis together with HOVON in Europe and with MD Anderson in the US. In the laquinimod project, the ocular biodistribution study at Stanford University, US of laquinimod eye drops is now enrolling patients.

Following a strategic review in 2023 of our programs and their financing, we decided to focus our main activities to the two clinical programs for tasquinimod in myelofibrosis in Europe and the US. The clinical study currently being prepared in Europe has external funding from the Oncode Institute and will be conducted in partnership with the HOVON research network at clinics in the Netherlands and Germany. A clinical trial agreement was signed in July 2023, and when we have received approvals from regulatory authorities and ethic committees, the study could 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 to start in H1 2024.

Both studies are backed by preclinical evidence and data indicating tasquinimod's ability to affect critical pathways involved in progression of myelofibrosis. Furthermore, in the preclinical experiments, tasquinimod effectively ameliorated the hallmarks of myelofibrosis and it reduced the spleen size, fibrosis and normalized the hematopoiesis indicating effect of tasquinimod on key features of the disease. The clinical studies have been designed to enable documentation of such effects, and we look forward to report further from the trial-initiation during 2024.

The expansion cohort of the multiple myeloma study that is ongoing at the Abrahamson Cancer Center, University of Pennsylvania, with tasquinimod in combination with ixazomib, lenalidomide and dexamethasone (IRd) continue progressing. We are encouraged by the good safety and preliminary responses to tasquinimod treatment in this heavily pretreated group of patients and look forward to review and report the final data of the study towards end of 2024. From a safety and efficacy perspective, the data for tasquinimod established in patients with multiple myeloma has provided a bridge towards the program within myelofibrosis, and thereby contributes to documentation of tasquinimod's therapeutic potential in hematological cancers.

The safety of the newly developed eye drop formulation of laquinimod was confirmed in a phase I safety and tolerability study in healthy subjects in 2023. To verify that laquinimod reaches the back of the eye after administration of the eye drops, the clinical ocular biodistribution of laquinimod will be studied in patients that are to undergo vitrectomy. The study, which will be performed at Beyers Eye Institute at Stanford in the US, is now enrolling patients, and we look forward to the results of the study later in the year.

Conducting research in collaboration with academic centers is important for us. It allows us to work in a close relationship with talented researchers in well-known groups and translate preclinical research into clinical studies. Read more about the advantages of conducting Investigator-Initiated Trials and the current state of the biotech sector in the interview with our board member Prof. Dr. Axel Glasmacher, see below.

The ongoing clinical studies with naptumomab in selected solid tumors, together with our partner NeoTX, proceed according to plan. We expect to provide the results from the phase IIa study with naptumomab in lung cancer in the first half of this year. In the combination study with naptumomab and durvalumab, we expect an expansion cohort to start in 2024. 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. Due to the current financial situation, the planned study with naptumomab and pembrolizumab in urothelial cancer will not be initiated.

In summary, in the opening quarter of the year, our focus has been on preparing for start of the clinical programs with tasquinimod in myelofibrosis in Europe and in the US. In the laquinimod project, the clinical ocular biodistribution study is now ongoing, and I look forward to updating you as our clinical projects progress.



Helén Tuveesson, CEO



Axel Glasmacher
Board member



I cannot envisage the past or future development of drug treatment without the many contributions of small biopharma companies

Interview with Prof. Dr. Axel Glasmacher, Independent Board Member at Active Biotech

In collaboration with academic centers in the US and Europe, Active Biotech is about to start two clinical proof-of-concept studies with tasquinimod in Myelofibrosis, a rare blood cancer with high unmet medical need. We discussed with Prof. Glasmacher regarding his views on the biotech sector at present, his experience from working with academic groups and what he thinks about the potential of tasquinimod in myelofibrosis.

– Please let us know about your professional development.

– I am a physician with a focus on hematological malignancies. From 1988 to 2006 I worked at the University Clinic in Bonn with a clinical and scientific focus on these patients, from 2000 as an attending physician with professorial teaching qualification (Privat-Dozent). In 2009 I was appointed adjunct professor of medicine at the faculty of the University of Bonn.

In 2006 I joined Celgene as Medical Director in Germany and led the medical side of the lenalidomide (Revlimid®), azacitidine (Vidaza®) and thalidomide launch, including the risk management systems. From 2010 to 2014 I worked as Head of Medical Affairs in Europe, Middle East and Africa. In this period we worked intensively and successfully on the EMA Article 20 procedure for lenalidomide that was caused by a concern caused by second primary malignancies. From 2015-2017 my role was Therapeutic Area Head Myeloid Diseases in Global Clinical Research and Development working from Summit, NJ, USA. In this period we brought enasidenib (Idifa®) to FDA approval and established the clinical development plans for luspatercept (Reblozyl®) and durvalumab in hematological malignancies. In 2016 I was promoted to Senior Vice President and led the Global Clinical Research and Development team in hematology-oncology.

In 2018 I retired from Celgene and we returned to Europe. Since then I am working as a consultant for pharmaceutical companies and academic organisations as well as on the board of various biotech companies. I joined the board of the Cancer Drug Development Forum, CDDF, a non-profit organisation dedicated to advancing oncology drug development with all stakeholders, in 2018 (www.cddf.org). I am also the treasurer of the CDDF.

I have been working with Active Biotech as a consultant since 2018 and joined its board of directors in 2020.

– How do you see the prospects of small biotech companies in the current climate?

– The financial crisis in the biotech sector began in 2022 with the abrupt withdrawal of capital from the sector after a huge inflow in 2020-2021. Since then the majority of small biotech companies have been under huge pressure to refinance and the number of companies that restructured or closed has increased significantly. IPOs were rare and of lower volume. However, in 2024 signs of an improvement have been observed on several parameters.

It is necessary to understand that these small biotech companies are the true source of innovative medicines. Last year, a study demonstrated that of the 138 drugs from the top 20 revenue companies approved by the FDA 70% originated from acquisitions or partnerships with biotech companies. Despite their enormous financial resources, the large pharmaceutical companies have not been able to scale up their research to match the success of small biotech companies.

Additionally, in an era of important financial constraints on healthcare systems small biotech companies have the opportunity to carry out development of new drugs at much lower cost which could potentially result in the introduction of innovative drugs at lower prices.

I cannot envisage the past or future development of drug treatment without the many contributions of small biopharma companies.

– How do you see the importance of tasquinimod for the treatment of hematological malignancies?

– Tasquinimod is an allosteric inhibitor of HDAC4 and interacts with the alarmins S100A8 and S100A9. Tasquinimod thus targets myeloid cells such as myeloid-derived suppressor cells (MDSC) and tumour-associated macrophages (TAM), which have proinflammatory and immunosuppressive effects. S100A8 and S100A9 are damage-associated molecules secreted by activated myeloid cells. S100A9 activates MDSCs, TLR4 and RAGE, which promote proinflammatory responses. Tasquinimod binds S100A8/S100A9 and blocks their effects. The laboratory of Prof Rebekka Schneider-Kramann was able to show that tasquinimod can effectively block fibrotic transformation of the bone marrow. This is the central pathogenic mechanism in myelofibrosis. At the same time there is good pre-clinical evidence that this mechanism could also result in disease-modifying activity in Myelodysplastic Neoplasias (MDS). Similarly, tasquinimod has demonstrated pre-clinical and clinical activity in Multiple Myeloma.

– What are the crucial pieces of data that you would like to see for proof-of-concept of tasquinimod in myelofibrosis?

– Active Biotech is collaborating with two very experienced groups to test tasquinimod in myelofibrosis: the Dutch multicentric group HOVON and the M.D. Anderson Cancer Center. These studies will be able to demonstrate proof-of-concept for tasquinimod in patients with myelofibrosis who have failed standard-of-care treatment (JAK inhibitors). The established endpoint in this disease is the reduction of spleen-size and health-related quality-of-life. Additionally, very important in regard to the findings of in-vitro studies, bone marrow fibrosis will be monitored. Together with an in-depth correlative science program it will be possible to demonstrate proof-of-concept for tasquinimod in myelofibrosis.

– What are your experiences working with Investigator Initiated Trials (IITs) in collaboration with academic groups?

– My experience goes back to the time in the clinic when I was the principal investigator in IITs that our group ran to explore new treatments in hematological malignancies. Later, during my work in Celgene Medical Affairs our team spearheaded a very large independent, investigator-lead research program with more than 200 trials for lenalidomide, pomalidomide and azacitidine in a broad range of indications. Measured by the number and quality of publications and citation indexes this program was very successful.

Celgene also ran pivotal phase III trials (e.g. in multiple myeloma, lymphoma and CNS malignancies) in close collaboration with multicenter study groups like IMF, GELARC/LYSARC and EORTC.

In general, my experience is highly positive. The close relationship with top researchers and clinical study groups that running such trials establish leads to a better alignment of trials with clinical practice and scientific insight. The disadvantage can be a somewhat slower clinical trial execution than in purely commercial structures.

– What are the biggest challenges and opportunities in the current regulatory environment?

– The FDA has brought forward a series of draft guidances documents that affect early clinical development, including Project Optimus for dose optimization and Project Frontrunner for accelerated approval. In my view these initiatives address important areas of clinical development and will lead to its improvement. The request for randomized dose optimization studies in phase II may increase

the financial burden for small biotech companies in a critical phase of early development. However, tasquinimod has already a huge clinical data set in solid tumors and some data in hematological malignancies, so the need for dose optimization studies will need to be discussed once the necessary clinical and scientific data is available.

The mechanism of action of tasquinimod is likely to be more efficient in earlier disease stages. Therefore, the opportunity to achieve an early accelerated approval based on an intermediary endpoint out of a randomized study may be quite advantageous for the development of tasquinimod.

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 					Penn Medicine
	Tasquinimod Myelofibrosis* 					MD Anderson HOVON
Inflammatory eye disorders	Laquinimod Eye drops, safety and tolerability 					
	Laquinimod Eye drops, ocular biodistribution 					Stanford MEDICINE GORC
Solid tumors	Naptumomab Combination with docetaxel in non-small cell lung cancer 					NeoTX
	Naptumomab Combination with anti-PDL1 (durvalumab) in solid tumors 					NeoTX AstraZeneca

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, 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 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, 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 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 favourable 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, PIs 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 (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 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.

FIRST QUARTER IN BRIEF

- Preparations ongoing for start of two clinical proof of concept studies with tasquinimod in myelofibrosis
- The expansion cohort of the study in multiple myeloma is ongoing according to plan

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 totalled 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, 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 AFTER THE END OF THE PERIOD

- 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 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 (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, 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 (NCT03983954) and at neotx.com. A new phase I study is also planned with naptumomab in combination with the checkpoint inhibitor pembrolizumab in patients with urothelial cancer. Due to the financial situation the study will currently not be initiated.

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.

FINANCIAL INFORMATION

Comments on the Group's results for the period January – March 2024

No sales were recorded during the period. The operational costs totalled SEK 10.7 M (11.8) whereof research and development expenses amounted to SEK 7.1 M (8.1), a 12% decrease in costs reflecting the concluded phase I laquinimod clinical trial and decreased costs for clinical drug.

The company's research efforts during the first quarter have been focused on the clinical development of tasquinimod in multiple myeloma, the planning for start of the two phase II proof-of-concept studies in myelofibrosis and the start of 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 be initiated in 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 3.6 M (3.8). The operating loss for the period amounted to SEK 10.7 M (loss: 11.8), the net financial income for the period amounted to SEK 0.2 M (inc: 0.3) and the loss after tax to SEK 10.5 M (loss: 11.5).

Cash flow, liquidity and financial position, Group, for the period January – March 2024

Cash and cash equivalents at the end of the period amounted to SEK 25.4 M, compared with SEK 36.2 M at the end of 2023. Cash flow for the period amounted to a negative SEK 10.9 M (neg: 11.6). The cash flow from operating activities amounted to a negative SEK 10.5 M (neg: 11.2) and cash flow from financing activities amounted to a negative SEK 0.4 M (neg: 0.4).

Investments

Investments in tangible fixed assets amounted to SEK 0.0 M (0.0).

Comments on the Parent Company's results and financial position for the period January – March 2024

No sales were recorded during the period. Operating expenses amounted to SEK 10.8 M (11.9).

The Parent Company's operating loss for the period was SEK 10.8 M (loss: 11.9). Net financial income amounted to a SEK 0.2 M (inc:0.3) and the loss after financial items was SEK 10.5 M (loss: 11.5). Cash and bank balances totalled SEK 25.3 M at the end of the period, compared with SEK 36.2 M on January 1, 2024.

Shareholders' equity

Consolidated shareholders' equity at the end of the period amounted to SEK 20.1 M, compared with SEK 30,7 M at year-end 2023.

The number of shares outstanding at the end of the period totalled 361,739,047. At the end of the period, the equity/assets ratio for the Group was 60.0 percent, compared with 69.6 percent at year-end 2023. The corresponding figures for the Parent Company, Active Biotech AB, were 65.8 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 March 31, 2024, amounted to SEK 1883 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 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.
- 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. 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 March 31, 2024 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 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.

FIRST QUARTER IN BRIEF

- Preparations ongoing for start of the clinical proof of concept studies with tasquinimod in myelofibrosis
- The expansion cohort of the study in multiple myeloma is ongoing according to plan

EVENTS AFTER THE END OF THE PERIOD

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

CONSOLIDATED PROFIT AND LOSS

SEK M	Jan-Mar		Full Year 2023
	2024	2023	
Net sales	-	-	-
Administrative expenses	-3.6	-3.8	-13.9
Research and development costs	-7.1	-8.1	-32.5
Operating profit/loss	-10.7	-11.8	-46.5
Net financial items	0.2	0.3	0.7
Profit/loss before tax	-10.5	-11.5	-45.8
Tax	-	-	-
Net profit/loss for the period	-10.5	-11.5	-45.8
Comprehensive profit/loss attributable to:			
Parent Company shareholders	-10.5	-11.5	-45.8
Non-controlling interest	-	-	-
Net profit/loss for the period	-10.5	-11.5	-45.8
Comprehensive profit/loss per share before dilution (SEK)	-0.03	-0.04	-0.17
Comprehensive profit/loss per share after dilution (SEK)	-0.03	-0.04	-0.17

STATEMENT OF PROFIT AND LOSS AND CONSOLIDATED COMPREHENSIVE INCOME

SEK M	Jan-Mar		Full Year 2023
	2024	2023	
Net profit/loss for the period	-10.5	-11.5	-45.8
Other comprehensive income	-	-	-
Total comprehensive profit/loss for the period	-10.5	-11.5	-45.8
Total other comprehensive profit/loss for the period attributable to:			
Parent Company shareholders	-10.5	-11.5	-45.8
Non-controlling interest	-	-	-
Total comprehensive profit/loss for the period	-10.5	-11.5	-45.8
Depreciation/amortization included in the amount of	0.4	0.4	1.7
Investments in tangible fixed assets	-	-	-
Weighted number of outstanding common shares before dilution (000s)	361,739	264,973	271,525
Weighted number of outstanding common shares after dilution (000s)	361,739	264,973	271,525
Number of shares at close of the period (000s)	361,739	265,145	361,739

CONSOLIDATED STATEMENT OF FINANCIAL POSITION

SEK M	Mar 31		Dec 31
	2024	2023	2023
Intangible fixed assets	0.2	0.2	0.2
Tangible fixed assets	4.3	5.8	4.7
Long-term receivables	0.4	0.4	0.4
Total fixed assets	4.9	6.5	5.3
Current receivables	3.3	2.8	2.5
Cash and cash equivalents	25.4	30.2	36.2
Total current assets	28.6	33.0	38.7
Total assets	33.6	39.5	44.0
Shareholders equity	20.1	23.0	30.7
Long-term liabilities	2.6	4.1	3.0
Current liabilities	10.8	12.4	10.4
Total shareholders equity and liabilities	33.6	39.5	44.0

CONSOLIDATED STATEMENT OF CHANGES IN SHAREHOLDERS EQUITY

SEK M	Mar 31		Dec 31
	2024	2023	2023
Opening balance	30.7	34.5	34.5
Loss for the period	-10.5	-11.5	-45.8
Other comprehensive income for the period	-	-	-
<i>Comprehensive profit/loss for the period</i>	-10.5	-11.5	-45.8
Share-based payments that are settled with equity instruments, IFRS2	0.0	0.0	0.2
New share issue	-	0.0	41.8
Balance at close of period	20.1	23.0	30.7

CONDENSED CONSOLIDATED CASH-FLOW STATEMENT

SEK M	Jan-Mar		Full Year
	2024	2023	2023
Loss after financial items	-10.5	-11.5	-45.8
Adjustment for non-cash items, etc.	0.4	0.4	1.8
Cash flow from operating activities before changes in working capital	-10.1	-11.1	-44.0
Changes in working capital	-0.3	-0.1	-1.8
Cash flow from operating activities	-10.5	-11.2	-45.7
New share issue	-	0.0	41.8
Loans raised/amortization of loan liabilities	-0.4	-0.4	-1.6
Cash flow from financing activities	-0.4	-0.4	40.2
Cash flow for the period	-10.9	-11.6	-5.6
Opening cash and cash equivalents	36.2	41.8	41.8
Closing cash and cash equivalents	25.4	30.2	36.2

KEY FIGURES

	Mar 31		Dec 31
	2024	2023	2023
Shareholders equity, SEK M	20.1	23.0	30.7
Equity per share, SEK	0.06	0.09	0.08
Equity/assets ratio in the Parent Company	65.8 %	29.4 %	75.5 %
Equity/assets ratio in the Group	60.0 %	58.3 %	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 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	2020				2021				2022				2023				2024	
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	
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	
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	
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	
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	
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	
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	

ACTIVE BIOTECH PARENT COMPANY – INCOME STATEMENT, CONDENSED

SEK M	Jan-Mar		Full Year 2023
	2024	2023	
Net Sales	–	–	–
Administration expenses	–3.6	–3.8	–14.0
Research and development costs	–7.1	–8.1	–32.7
Operating profit/loss	–10.8	–11.9	–46.7
<i>Profit/loss from financial items:</i>			
Result from participations in group companies	–	–	0.8
Interest income and similar income-statement items	0.2	0.3	0.9
Interest expense and similar income-statement items	–	–	–0.0
Profit/loss after financial items	–10.5	–11.5	–45.0
Tax	–	–	–
Net profit/loss for the period	–10.5	–11.5	–45.0
Statement of comprehensive income parent company			
Net profit/loss for the period	–10.5	–11.5	–45.0
Other comprehensive income	–	–	–
Total comprehensive profit/loss for the period	–10.5	–11.5	–45.0

ACTIVE BIOTECH PARENT COMPANY – BALANCE SHEET, CONDENSED

SEK M	Mar 31		Dec 31 2023
	2024	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	3.7	3.2	2.9
Short-term investments	–	27.8	–
Cash and bank balances	25.3	2.2	36.2
Total current assets	29.0	33.3	39.1
Total assets	30.1	74.4	40.2
Shareholders equity	19.8	21.9	30.4
Current liabilities	10.3	52.5	9.8
Total equity and liabilities	30.1	74.4	40.2

ACTIVE BIOTECH PARENT COMPANY - CHANGES IN SHAREHOLDERS EQUITY

SEK M	Mar 31		Dec 31 2023
	2024	2023	
Opening balance	30.4	33.4	33.4
Loss for the period	–10.5	–11.5	–45.0
Other comprehensive income for the period	–	–	–
Comprehensive profit/loss for the period	–10.5	–11.5	–45.0
New share issue	–	0.0	41.8
Share-based payments that are settled with equity instruments, IFRS2	0.0	0.0	0.2
Balance at close of period	19.8	21.9	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

- 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

This interim report is unaudited.

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

Lund May 8, 2024

Helén Tuve
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.