

Q1 Q2 Q3 Q4

INTERIM REPORT Q3 2024 | ACTIVE BIOTECH AB

“Focus on the start of phase II studies in myelofibrosis”

THIRD QUARTER IN BRIEF

- Active Biotech entered agreement with MD Anderson 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)
- Active Biotech reported intriguing intraocular concentrations achieved in a clinical biodistribution study of laquinimod eye drops (September 10)
- Active Biotech announced a rights issue (September 23)

EVENTS AFTER THE END OF THE PERIOD

- Active Biotech adjusts the terms in the announced rights issue (October 2)

FINANCIAL SUMMARY

SEK M	Jul-Sep		Jan-Sep		Full Year 2023
	2024	2023	2024	2023	
Net sales	–	–	–	–	–
Operating profit/loss	–8.1	–10.6	–29.5	–33.7	–46.5
Profit/loss after tax	–8.0	–10.6	–29.1	–33.3	–45.8
Earnings per share (SEK)	–0.02	–0.04	–0.08	–0.13	–0.17
Cash and cash equivalents (at close of period)			6.2	5.6	36.2

The report is also available at www.activebiotech.com

The information was submitted for publication, through the agency of the contact persons set out below, at 2024-10-21 22.30 CEST.



Helén Tuveesson
CEO



All subjects had significant concentrations of laquinimod in vitreous as well as in the anterior chamber fluid when sampled during surgery

COMMENTS FROM THE CEO

During the third quarter of the year, we mainly focused on initiating the planned phase Ib/II studies with tasquinimod in myelofibrosis. The US study at MD Anderson is now recruiting patients, and the European study is progressing towards start in the last quarter of the year. Alongside tasquinimod, we reported the first results from the ongoing biodistribution study with laquinimod eye drops. The results demonstrate that laquinimod is distributed to the posterior parts of the eye, which is important for the continued development of laquinimod for eye diseases. In late September, we announced a rights issue to provide the company with the financial stability required to pursue the planned activities related to our prioritized programs for the coming 12 months.

In the past year, we have worked continuously to refine our project focus. Our focus going forward is directed to the clinical programs with tasquinimod in myelofibrosis. For laquinimod, we are increasing our activities to find a partner for the planned phase II development.

Regarding the clinical programs with tasquinimod in myelofibrosis, we finalized the clinical trial agreement with MD Anderson, TX, US during the summer. The study, which is a two-arm study with tasquinimod monotherapy in one arm and tasquinimod in combination with JAK2 inhibitor in the other arm, is now enrolling patients. We expect the first patient will be dosed shortly. The clinical trial in Europe is conducted with the HOVON research network at clinics in the Netherlands and Germany, and this monotherapy study of tasquinimod is estimated to start in Q4, following the approvals from regulatory authorities and ethical committees. More details of the studies can be found on clinicaltrials.gov, study numbers NCT04405167 and NCT06605586.

Recruitment to the multiple myeloma trial with tasquinimod in combination with IRd at the Abrahamson Cancer Center, University of Pennsylvania, is ongoing to further confirm the clinical benefit of tasquinimod in multiple myeloma. We remain encouraged by the good safety and preliminary efficacy of tasquinimod in these heavily pretreated patients and look forward to reporting the results from the study within the next six months.

In September, we announced the first data from the ongoing biodistribution study with laquinimod. The study, which is being conducted by principal investigator Professor Dr Nguyen at the Byers Eye Institute, Stanford University, Palo Alto, aims to evaluate if laquinimod reaches the anterior and the posterior chambers of the eye when administered as eye drops, to support further development in patients with uveitis.

All subjects enrolled had significant concentrations of laquinimod in vitreous as well as in the anterior chamber fluid when sampled during surgery. This supports distribution of laquinimod from the cornea and sclera into the anterior chamber and onwards to the posterior parts of the eye. The results also show that administration of laquinimod eye drops leads to concentrations of

laquinimod in the vitreous that are therapeutically relevant, based on previous studies in patients with multiple sclerosis. Evidence from one patient in the study suggests that laquinimod exhibited a potent anti-inflammatory effect in the anterior chamber after 14 days of treatment according to the protocol, without any concurrent corticosteroid therapy.

The study is ongoing, and we are looking forward to the full results in late 2024/early 2025.

In the naptumomab project our partner NeoTX is preparing for start of the planned expansion cohort study in esophageal cancer with the combination of naptumomab and durvalumab. Timing of study start is currently uncertain.

The board of directors of Active Biotech AB has resolved on a rights issue of approximately SEK 36.2 million. The proceeds from the rights issue are intended to provide the company with funds required to pursue the planned activities related to the company's prioritized tasquinimod program for the coming twelve months. In case of oversubscription there is, through the exercise of an over-allotment option, on the same terms as those of the rights issue, a possibility to increase the subscription with up to a further 20%. This will at full exercise raise approximately SEK 7 million in additional proceeds.

With the necessary funding in place, we can fully concentrate our activities on the clinical programs in myelofibrosis, as well as finding a partner for the continued phase II development of laquinimod in uveitis. I am looking forward to an exciting and rewarding period ahead for our company, with several important milestones that will help us to shape the future of Active Biotech.

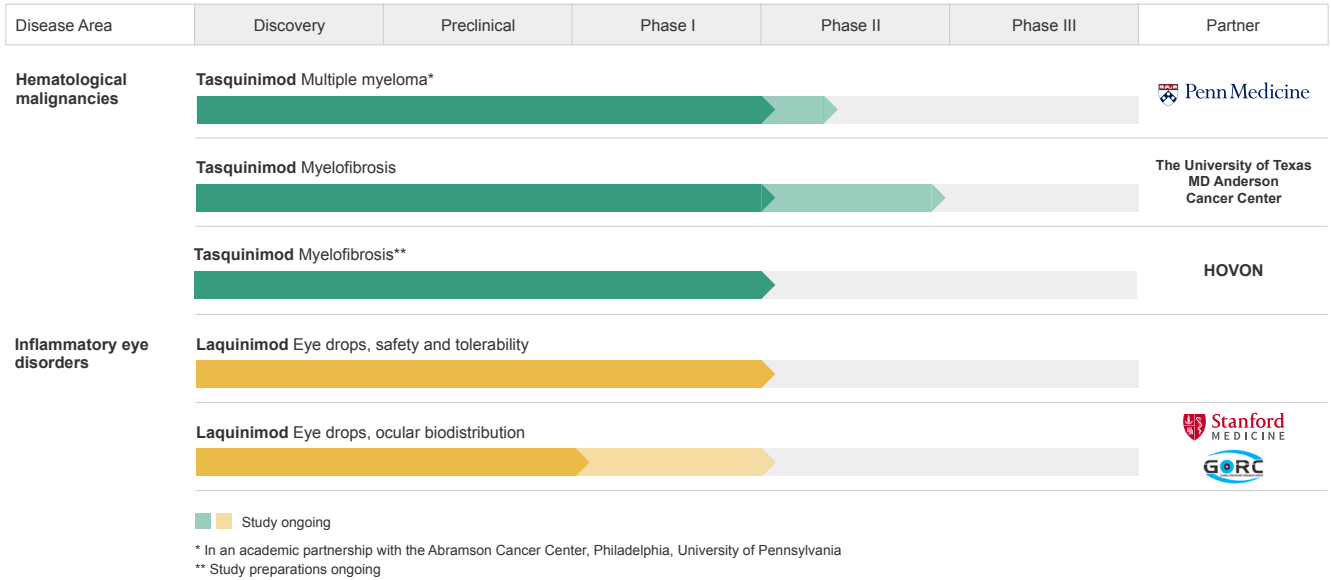


Helén Tuvešson, CEO

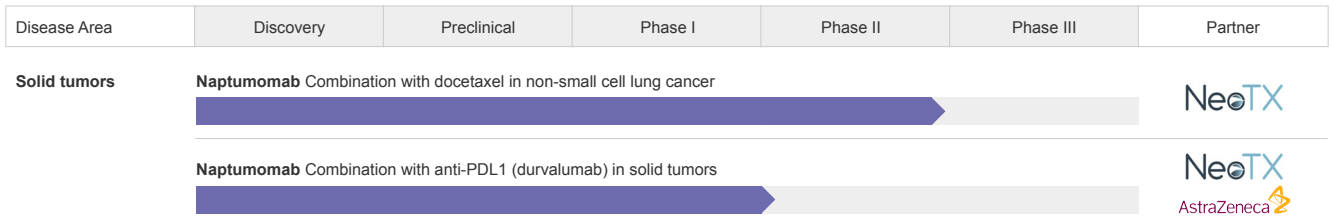
PROJECTS

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

WHOLLY OWNED PROJECTS



LICENSED PROJECTS



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 myelofibrosis and multiple myeloma.

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.

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 JAK2 inhibitors to reduce spleen size. Today the following drugs are approved for these patients as symptom-directed therapy: Hydroxy-urea, ruxolitinib, pacritinib, momelotinib and fedratinib (the latter four are JAK2 inhibitors, JAKi). At present there are no approved treatment options 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 eight 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 research groups at Erasmus MC, the Netherlands and at MD Anderson Cancer Center, US, 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. Preclinical results from a collaboration with a research group at MD Anderson 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 drugs in models of advanced myelofibrosis. The positive results create a rationale for a clinical study in patients with myelofibrosis.

Tasquinimod was granted orphan designation in myelofibrosis by the US Food and Drug Administration (FDA) in May 2022.

Ongoing clinical development

In July 2024, Active Biotech announced that it has entered into a clinical trial agreement with MD Anderson Cancer Center, US, to start a clinical phase II trial in patients with myelofibrosis. MD Anderson is the world leading cancer center performing cutting edge clinical and translational science. The study is actively enrolling patients since August 2024. The study is composed of two separate cohorts which recruit patients parallelly. Cohort 1 evaluates tasquinimod as a single agent in patients with JAKi refractory disease and in patients who are ineligible for JAKi treatment. Cohort 2 evaluates tasquinimod in combination with the JAKi ruxolitinib in patients who have a suboptimal response to ruxolitinib alone. The study will enroll up to 33 patients: 12 in cohort 1 and 21 in cohort 2. The primary endpoint for both cohorts is efficacy: Objective Response Rate (ORR) according to the International Working Group (IWG-MRT) criteria for treatment response in myelofibrosis. ORR is defined as the proportion of patients with Complete Remission, Partial Response or Clinical Improvement after six cycles of treatment. Secondary endpoints include safety and tolerability, time to response, response duration, changes in spleen volume and symptom score as well as bone marrow fibrosis grade. For more information about the study, see clinicaltrials.gov (NCT06327100).

A clinical trial agreement has been signed between Active Biotech, Oncode institute and HOVON, which is one of the leading European clinical study groups in hematologic malignancies and will be the legal sponsor of the study. The clinical study will be financed by Oncode Institute and is planned to start during 2024. The study will evaluate tasquinimod as monotherapy in patients with myelofibrosis that have previously been treated with a JAK2 inhibitor (JAKi) or who are not suitable for treatment with JAKi. Apart from safety and tolerability, the study will investigate the efficacy of tasquinimod on the disease by measuring changes in clinically meaningful variables including spleen volume, symptom control and bone marrow fibrosis grade. For more information about the study, see clinicaltrials.gov (NCT06605586).

Since both studies are open-label studies, preliminary results may be available during the study. Preplanned interim analyses will be conducted as part of the protocols and will be reported at scientific meetings as applicable.

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 are 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. Of the total market sales, the US accounts for around 60 percent, the EU for approximately 23 percent and Japan and China for 17 percent (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.

Tasquinimod was granted orphan designation in multiple myeloma by the US Food and Drug Administration (FDA) in 2017.

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.

The monotherapy part A1 was completed in October 2021. Ten patients had been treated with increasing doses of tasquinimod and the safety read-out showed that tasquinimod was generally well tolerated. The optimal dose and schedule of tasquinimod, when used as a single agent in patients with multiple myeloma has been established at 1 mg per day after a one-week run in of 0.5 mg daily. This is similar to the treatment schedule used in previous studies of tasquinimod. The patients enrolled in this study phase were heavily pre-treated, with a median of eight prior lines of therapy; eight of the ten patients were triple-class refractory to immunomodulatory drugs (IMiDs, like lenalidomide, pomalidomide), proteasome inhibitors (PIs) and anti-CD38 monoclonal antibodies (mAbs). While none of the patients formally achieved a partial response, three patients with 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 (B1), in which treatment with tasquinimod will be tested in patients with multiple myeloma together with the orally administered anti-myeloma agents ixazomib, lenalidomide, and dexamethasone (IRd). In May 2023, Active Biotech announced that tasquinimod as monotherapy, or in combination with IRd, has a favorable safety profile in heavily pretreated patients with a median of eight previous treatments. All 15 patients who were part of this interim assessment were previously refractory against IMiDs, proteasome inhibitors 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, it was announced that the dose optimization in the IRd-combination was successfully completed and that the study hence, according to plan, is being expanded to ensure the safety and effect of tasquinimod (B2). In July 2024, Active Biotech announced that 11 patients had been dosed with the combination of tasquinimod and IRd. Out of these, 9 patients were refractory to the latest PI+IMiD combination and hence were not expected to respond to IRd alone. Out of these nine patients, three showed clinical benefit from tasquinimod + IRd: one with a partial response (PR) reported earlier and two with minimal responses. The study continues to recruit patients into part B2.

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).

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.

THIRD QUARTER IN BRIEF

- Active Biotech entered agreement with MD Anderson 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 innovative eye drop formulation of laquinimod has been developed, taking the specific physico-chemical characteristics of laquinimod into account, to facilitate that clinically relevant intraocular concentrations can be obtained. A preclinical safety program for topical treatment has been completed. A phase I study of laquinimod eye drops in healthy subjects started in December 2021 (NCT05187403). The study enrolled a total of 54 healthy subjects that were treated in part 1 with a single ascending dose of laquinimod eye drops and in part two with repeated doses of laquinimod eye drops.

The primary objective of the study was safety and tolerability to laquinimod eye drops and the secondary readouts included ocular toxicity, pharmacokinetics and exposure. The eye drop formulation of laquinimod was well tolerated both in single doses and multiple doses, without serious side effects that could be linked to laquinimod. The Company expects to achieve therapeutic concentrations in the posterior part of the eye with the dose levels that were used. Data from the completed phase I study together with preclinical data from the biodistribution study in rabbits, showing that laquinimod reaches the back part of the eye, was presented at the International Ocular Inflammation Society (IOIS), in 2023.

A biodistribution study in patients who are to undergo a vitreous surgery is currently enrolling patients. The study investigates the concentration of laquinimod in the back and front of the eye after increasing doses of the eye drop formulation. The study is conducted at the Byers Eye Institute at the University of Stanford, USA, and the Principal Investigator Quan Dong Nguyen, MD, Professor of Ophthalmology, Medicine and Pediatrics, Stanford University School of Medicine.

The biodistribution study aims to evaluate whether laquinimod reaches the posterior chamber of the eye to support further development in patients with uveitis (NA-NIU). Patients undergoing planned vitreous surgery will receive daily doses of laquinimod eye drops in the eye undergoing surgery, up to 15 patients divided into three separate dose groups and a fourth dose comparison group will receive laquinimod for 2 weeks prior to surgery. After surgery, samples from anterior chamber fluid and vitreous humor will be analyzed together with plasma samples for concentration of laquinimod in these tissues.

The first results from the study were reported in September 2024. All subjects had significant concentrations of laquinimod in vitreous as well as in anterior chamber when sampled during surgery.

This supports distribution of laquinimod from the cornea and sclera into the anterior chamber and onwards to the posterior parts of the eye. The bioanalytical results also show that administration of laquinimod eye drops leads to quantities of laquinimod in vitreous humour at therapeutically relevant concentrations, as determined from prior studies in multiple sclerosis patients.

In parallel with the biodistribution study, activities will continue to establish a partnership for the clinical phase II development of laquinimod in patients with uveitis.

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.

THIRD QUARTER IN BRIEF

- Active Biotech reported intriguing intraocular concentrations achieved in a clinical biodistribution study of laquinimod eye drops (September 10)

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 immune-oncology market has demonstrated strong growth. Therapies aimed at targeting immune suppression are dominated by biological drugs classified as checkpoint inhibitors. Several new checkpoint inhibitors have been approved for various types of solid tumors.

Naptumomab in Solid Tumors

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

Checkpoint inhibitors are a group of cancer drugs which function by unleashing the immune system to attack the tumor. Despite the successes in recent years with these immunotherapies in the treatment of solid tumors, it remains a challenge for the immune system to recognize tumor cells and there is a need to optimize the therapeutic effect of checkpoint inhibitors.

Ongoing Clinical Development

An open label clinical phase IIa study in US testing naptumomab in combination with docetaxel 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 reversible.

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, FL, 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. However, the start of the extension study is dependent on new funding and the timing of the start is therefore uncertain. More information about the study is available at clinicaltrials.gov (NCT03983954).

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 – September 2024

No sales were recorded during the period. The operational costs amounted to SEK 29.5 M (33.7), a 12% decrease. Research and development expenses amounted to SEK 19.6 M (22.9), a 14% 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 nine 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 biodistribution study with laquinimod eye drop. 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 within the coming 6 months
- Two proof of concept studies with tasquinimod in myelofibrosis are scheduled to start during 2024, the US study is recruiting patients and the European study is scheduled to start in the fourth quarter
- 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 9.9 M (10.7). The operating loss for the period amounted to SEK 29.5 M (loss: 33.7), the net financial income for the period amounted to SEK 0.4 M (inc: 0.4) and the loss after tax to SEK 29.1 M (loss: 33.3).

Comments on the Group's results for the period July – September 2024

No sales were recorded during the period. The operational costs totaled SEK 8.1 M (10.6) whereof research and development expenses amounted to SEK 5.4 M (7.6), the decreased costs represent 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 2.7 M (3.0). The operating loss for the period amounted to SEK 8.1 M (loss: 10.6), the net financial income for the period amounted to SEK 0.0 M (inc: 0.0) and the loss after tax to SEK 8.0 M (loss: 10.6).

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

Cash and cash equivalents at the end of the period amounted to SEK 6.2 M, compared with SEK 36.2 M at the end of 2023. Cash flow for the period amounted to a negative SEK 30.0 M (neg: 36.2). The cash flow from operating activities amounted to a negative SEK 28.7 M (neg: 34.9) and cash flow from financing activities amounted to a negative SEK 1.2 M (neg: 1.3).

Investments

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

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

No sales were recorded during the period. Operating expenses amounted to SEK 29.6 M (33.8). The Parent Company's operating loss for the period was SEK 29.6 M (loss: 33.8). Net financial income amounted to SEK 0.5 M (inc: 0.6) and the loss after financial items was SEK 29.1 M (loss: 33.2). Cash and bank balances totaled SEK 6.2 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 July – September 2024

No sales were recorded during the period. Operating expenses amounted to SEK 8.1 M (10.6). The Parent Company's operating loss for the period was SEK 8.1 M (loss: 10.6). Net financial income amounted to SEK 0.1 M (inc: 0.1) and the loss after financial items was SEK 8.0 M (loss: 10.5).

Shareholders' equity

Consolidated shareholders' equity at the end of the period amounted to SEK 1.4 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 9.7 percent, compared with 69.6 percent at year-end 2023. The corresponding figures for the Parent Company, Active Biotech AB, were 9.3 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 September 30, 2024, amounted to SEK 1,856 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 6 whereof 3 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 within the coming 6 months. Start of two proof of concept studies in Myelofibrosis 2024 in collaboration with leading academic groups in Europe and US. The US study is recruiting patients and the European study is scheduled to start in Q4 and 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. A phase Ib/II study is ongoing with naptumomab in combination with the checkpoint inhibitor durvalumab, in patients with selected solid tumors. All development of naptumomab is financed by NeoTX and the start of new studies are subject to new financing.

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 is scheduled to be concluded during 2024 and partnering activities are initiated.

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 September 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.

On September 23, 2024 the Company informed that the board of directors had, subject to approval from an extraordinary general meeting, resolved on a rights issue of appr. SEK 35 million, before transaction costs. Proposed terms included the issuance of 844,230,664 new shares at a subscription price of SEK 0.0415 per share. The right to subscribe for new shares vest with the Company's shareholders with pre-emptive rights, whereby 3 existing shares entitle to subscription for 7 new shares. Subscription can also be made without pre-emptive rights.

As the planned share issue is limited to cover cost of twelve months operations, the Company may, through exercise of an over-allotment option, on the same terms as those of the rights issue, increase the subscription with up to a further 20% in case of oversubscription. Upon full exercise of the over-allotment option, the Company will raise approximately SEK 7 million in additional proceeds through the issuance of 168,846,132 shares. Such share issue will be made by the board of directors based on a new issue authorization proposed to the extraordinary general meeting on October 23, 2024. Active Biotech's largest shareholders, MGA Holding AB, Sjuenda Holding and the Fourth Swedish National Pension Fund, have together undertaken to subscribe for shares in the rights issue at a nominal value of approximately SEK 14.1 million. In addition, the Board of Directors and company management have provided subscription undertakings amounting to approximately SEK 1.2 million, in total subscription commitments amounting to 42.2 percent of the offer.

On October 2, 2024 the Company informed that in order to accommodate the technical requirements in the Euroclear system, which handles certain account keeping measures associated with the rights issue, the previously announced terms were adjusted. The adjusted terms entitle existing shareholders to subscribe for 2 new shares for 1 existing share at SEK 0.05 per share. The adjustment of the terms of the rights issue entails that the proceeds from the rights issue, upon full subscription, amount to approximately SEK 36.2 million, compared to previously approximately SEK 35 million through the issuance of 723,626,284 new shares if the rights issue is fully subscribed. Upon full exercise of the over-allotment option the Company will raise additional approximately SEK 7.2 million, compared to previously approximately SEK 7 million.

As the company 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 a material uncertainty regarding the company's ability to operate as a going concern.

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.

THIRD QUARTER IN BRIEF

- Active Biotech entered agreement with MD Anderson 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)
- Active Biotech reported intriguing intraocular concentrations achieved in a clinical biodistribution study of laquinimod eye drops (September 10)
- Active Biotech announced a rights issue (September 23)

EVENTS AFTER THE END OF THE PERIOD

- Active Biotech adjusts the terms in the announced rights issue (October 2)

CONSOLIDATED PROFIT AND LOSS

SEK M	Jul-Sep		Jan-Sep		Full Year 2023
	2024	2023	2024	2023	
Net sales	-	-	-	-	-
Administrative expenses	-2.7	-3.0	-9.9	-10.7	-13.9
Research and development costs	-5.4	-7.6	-19.6	-22.9	-32.5
Operating profit/loss	-8.1	-10.6	-29.5	-33.7	-46.5
Net financial items	0.0	0.0	0.4	0.4	0.7
Profit/loss before tax	-8.0	-10.6	-29.1	-33.3	-45.8
Tax	-	-	-	-	-
Net profit/loss for the period	-8.0	-10.6	-29.1	-33.3	-45.8
Comprehensive profit/loss attributable to:					
Parent Company shareholders	-8.0	-10.6	-29.1	-33.3	-45.8
Non-controlling interest	-	-	-	-	-
Net profit/loss for the period	-8.0	-10.6	-29.1	-33.3	-45.8
Comprehensive profit/loss per share before dilution (SEK)	-0.02	-0.04	-0.08	-0.13	-0.17
Comprehensive profit/loss per share after dilution (SEK)	-0.02	-0.04	-0.08	-0.13	-0.17

STATEMENT OF PROFIT AND LOSS AND CONSOLIDATED COMPREHENSIVE INCOME

SEK M	Jul-Sep		Jan-Sep		Full Year 2023
	2024	2023	2024	2023	
Net profit/loss for the period	-8.0	-10.6	-29.1	-33.3	-45.8
Other comprehensive income	-	-	-	-	-
Total comprehensive profit/loss for the period	-8.0	-10.6	-29.1	-33.3	-45.8
Total other comprehensive profit/loss for the period attributable to:					
Parent Company shareholders	-8.0	-10.6	-29.1	-33.3	-45.8
Non-controlling interest	-	-	-	-	-
Total comprehensive profit/loss for the period	-8.0	-10.6	-29.1	-33.3	-45.8
Depreciation/amortization included in the amount of	0.4	0.4	1.2	1.3	1.7
Investments in tangible fixed assets	-	-	-	-	-
Weighted number of outstanding common shares before dilution (000s)	361,813	265,145	361,780	265,087	271,525
Weighted number of outstanding common shares after dilution (000s)	361,813	265,145	361,780	265,087	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	Sep 30		Dec 31
	2024	2023	2023
Intangible fixed assets	0.2	0.2	0.2
Tangible fixed assets	3.5	5.0	4.7
Long-term receivables	0.4	0.4	0.4
Total fixed assets	4.2	5.6	5.3
Current receivables	4.4	3.1	2.5
Cash and cash equivalents	6.2	5.6	36.2
Total current assets	10.7	8.7	38.7
Total assets	14.9	14.3	44.0
Shareholders equity	1.4	1.3	30.7
Long-term liabilities	1.9	3.4	3.0
Current liabilities	11.5	9.6	10.4
Total shareholders equity and liabilities	14.9	14.3	44.0

CONSOLIDATED STATEMENT OF CHANGES IN SHAREHOLDERS EQUITY

SEK M	Sep 30		Dec 31
	2024	2023	2023
Opening balance	30.7	34.5	34.5
Loss for the period	-29.1	-33.3	-45.8
Other comprehensive income for the period	-	-	-
<i>Comprehensive profit/loss for the period</i>	<i>-29.1</i>	<i>-33.3</i>	<i>-45.8</i>
Share-based payments that are settled with equity instruments, IFRS2	0.0	0.1	0.2
New share issue	-0.1	-0.1	41.8
Balance at close of period	1.4	1.3	30.7

CONDENSED CONSOLIDATED CASH-FLOW STATEMENT

SEK M	Jan-Sep		Full Year
	2024	2023	2023
Loss after financial items	-29.1	-33.3	-45.8
Adjustment for non-cash items, etc.	1.2	1.4	1.8
Cash flow from operating activities before changes in working capital	-28.0	-31.9	-44.0
Changes in working capital	-0.8	-3.0	-1.8
Cash flow from operating activities	-28.7	-34.9	-45.7
New share issue	-0.1	-0.1	41.8
Loans raised/amortization of loan liabilities	-1.2	-1.2	-1.6
Cash flow from financing activities	-1.2	-1.3	40.2
Cash flow for the period	-30.0	-36.2	-5.6
Opening cash and cash equivalents	36.2	41.8	41.8
Closing cash and cash equivalents	6.2	5.6	36.2

KEY FIGURES

	Sep 30		Dec 31
	2024	2023	2023
Shareholders equity, SEK M	1.4	1.3	30.7
Equity per share, SEK	0.00	0.00	0.08
Equity/assets ratio in the Parent Company	9.3 %	0.4 %	75.5 %
Equity/assets ratio in the Group	9.7 %	9.0 %	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	Q2	Q3
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	-2.7
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	-5.4
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	-8.1
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	0.0
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	-8.0
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	-8.0

ACTIVE BIOTECH PARENT COMPANY – INCOME STATEMENT, CONDENSED

SEK M	Jul-Sep		Jan-Sep		Full Year 2023
	2024	2023	2024	2023	
Net Sales	-	-	-	-	-
Administration expenses	-2.6	-3.0	-9.9	-10.7	-14.0
Research and development costs	-5.5	-7.6	-19.8	-23.1	-32.7
Operating profit/loss	-8.1	-10.6	-29.6	-33.8	-46.7
<i>Profit/loss from financial items:</i>					
Result from participations in group companies	-	-	-	-	0.8
Interest income and similar income-statement items	0.1	0.1	0.6	0.6	0.9
Interest expense and similar income-statement items	-0.0	-	-0.1	-0.0	-0.0
Profit/loss after financial items	-8.0	-10.5	-29.1	-33.2	-45.0
Tax	-	-	-	-	-
Net profit/loss for the period	-8.0	-10.5	-29.1	-33.2	-45.0
Statement of comprehensive income parent company					
Net profit/loss for the period	-8.0	-10.5	-29.1	-33.2	-45.0
Other comprehensive income	-	-	-	-	-
Total comprehensive profit/loss for the period	-8.0	-10.5	-29.1	-33.2	-45.0

ACTIVE BIOTECH PARENT COMPANY – BALANCE SHEET, CONDENSED

SEK M	Sep 30		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	4.8	3.5	2.9
Short-term investments	-	-	-
Cash and bank balances	6.2	5.4	36.2
Total current assets	11.0	8.9	39.1
Total assets	12.2	50.0	40.2
Shareholders equity	1.1	0.2	30.4
Current liabilities	11.0	49.8	9.8
Total equity and liabilities	12.2	50.0	40.2

ACTIVE BIOTECH PARENT COMPANY – CHANGES IN SHAREHOLDERS EQUITY

SEK M	Sep 30		Dec 31 2023
	2024	2023	
Opening balance	30.4	33.4	33.4
Loss for the period	-29.1	-33.2	-45.0
Other comprehensive income for the period	-	-	-
Comprehensive profit/loss for the period	-29.1	-33.2	-45.0
New share issue	-0.1	-0.1	41.8
Share-based payments that are settled with equity instruments, IFRS2	0.0	0.1	0.2
Balance at close of period	1.1	0.2	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

- Extra General Meeting: Oct 23, 2024
- Year-end Report 2024: Feb 13, 2025

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

The interim report has been reviewed by the company's auditors.

The interim report for the January – September 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, October 21, 2024
Active Biotech AB (publ)

Helén Tuvesson
President and CEO

AUDITOR'S REPORT

(This is a translation of the Swedish language original)

Active Biotech AB (publ) reg. no. 556223-9227

Introduction

We have reviewed the condensed interim financial information (interim report) of Active Biotech AB (publ) as of 30 September 2024 and the nine-month period then ended. The board of directors and the CEO are responsible for the preparation and presentation of the interim financial information in accordance with IAS 34 and the Swedish Annual Accounts Act. Our responsibility is to express a conclusion on this interim report based on our review.

Scope of Review

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

Conclusion

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

Material Uncertainty Related to Going Concern

We would like to draw attention to the section "Financing and financial position" on page 16 in the interim report where it is described that there is ongoing work related to the continued financing of the operations. The ongoing work means that the company does not, at the time of issuing our review report, have secured funding. This condition indicates that there is a material uncertainty that may cast significant doubt on the company's ability to continue as a going concern. Our conclusion is not modified in respect of this matter.

Malmö, 21 October 2024
Öhrlings PricewaterhouseCoopers AB

Cecilia Andrén Dorselius
Authorized Public Accountant

About Active Biotech

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 has been initiated. 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.