

Q1 Q2 Q3 Q4

INTERIM REPORT Q3 2023 | ACTIVE BIOTECH AB

“Focus on myelofibrosis”

THIRD QUARTER IN BRIEF

- Collaboration agreement for clinical study with tasquinimod in myelofibrosis signed (July 31)
- Tasquinimod successfully completed dose optimization in patients with multiple myeloma and advances into the pre-planned expansion cohort (September 11)
- Clinical safety and preclinical ocular biodistribution for laquinimod eye drops presented at the IOIS meeting is made available on Active Biotech’s website (September 13)

EVENTS AFTER THE END OF THE PERIOD

- Preclinical data of tasquinimod in myelofibrosis awarded oral presentation at ASH 2023 (November 2)
- The board of directors resolved on November 9, based on the authorization from the general meeting, to carry out a rights issue of approximately SEK 51 million (before issue costs) to secure financing of the ongoing and planned development programs for tasquinimod and laquinimod

FINANCIAL SUMMARY

SEK M	Jul-Sep		Jan-Sep		Full Year 2022
	2023	2022	2023	2022	
Net sales	-	-	-	-	-
Operating profit/loss	-10.6	-13.4	-33.7	-42.6	-57.9
Profit/loss after tax	-10.6	-13.4	-33.3	-43.4	-58.4
Earnings per share (SEK)	-0.04	-0.06	-0.13	-0.19	-0.25
Cash and cash equivalents (at close of period)			5.6	55.0	41.8

The report is also available at www.activebiotech.com

This information is information that Active Biotech is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons set out below, at 2023-11-09 08:30 CEST.



Our plan is to commence two clinical studies within myelofibrosis in 2024

COMMENTS FROM THE CEO

During the summer we decided to focus our main activities on the ongoing programs with tasquinimod in myelofibrosis, following a strategic review of our potential clinical programs and their financing. The recently announced preclinical proof-of-concept data for tasquinimod in myelofibrosis, from our collaboration with Professor Kapil Bhalla at MD Anderson in USA, which have been granted an oral presentation at ASH 2023, supports our excitement for this direction. The data demonstrate that tasquinimod administered in models of myelofibrosis, given either as monotherapy or in combination with front-line therapy for advanced myelofibrosis has a clear therapeutic effect and thereby a clinical potential in this indication. Our plan is to commence two clinical studies within myelofibrosis in 2024 and preparations for the externally funded phase II study in Europe is advancing well.

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

Results from preclinical models of myelofibrosis indicate that tasquinimod has the potential to modify the disease in broad sense, i.e., by reducing fibrosis, and by normalizing spleen size and hematopoiesis, which are the key manifestations of the disease. The phase II study currently being prepared in Europe, has external funding from the Oncode Institute, and will be conducted in the HOVON research network at clinics in The Netherlands and Germany. Active Biotech and the study sponsor plan to pursue study start in Q1 2024, but due to the complexity of the trial, it cannot be excluded that it will not commence until the following quarter. An additional phase II clinical study in myelofibrosis is being planned to start in the US in collaboration with MD Anderson, although the time for the start of this trial is currently not firmly defined.

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

For laquinimod, the final results of the clinical phase I study of the novel eye drop formulation were presented and well received at the International Ocular Inflammation Society (IOIS) 2023 meeting in Berlin, Germany, in September. A clean safety profile was shown at repeat doses where we expect therapeutic concentrations of laquinimod. We also presented distribution data suggesting ocular distribution of laquinimod in the rabbit eye upon application of the eye drops. To support the further development of this formulation in patients with uveitis, a clinical ocular biodistribution study of the eye drop formulation will be conducted at the Byers Eye Institute at Stanford University, USA, which is planned to start in H1 2024. In parallel, commercial activities will be initiated to establish a partnership for the continued development of laquinimod in patients with uveitis.

With respect to naptumomab, the phase IIa study where it is combined with docetaxel in patients with lung cancer is nearing completion, and results are expected in H1 2024. Our partner NeoTX is also preparing for start of a cohort expansion from the combination study with durvalumab in patients with esophageal cancer as well as new phase I study with naptumomab combined with the checkpoint inhibitor pembrolizumab in patients with urothelial cancer.

After an evaluation of various sources of future financing, based on the authorization from the general meeting, the board of directors resolved in November to carry out a rights issue to secure financing of the ongoing prioritized development programs until the end of 2024. This will provide the company with the financial stability required to reach clinically important milestones and enable continued discussions with potential partners.

I am very pleased with the progress of our projects, including the privilege to present tasquinimod as an oral podium presentation at the prestigious ASH 2023 hematology meeting. We continue to be strengthened in our conviction and belief that our projects have the potential to treat diseases of great medical need. I look forward to updating you of our upcoming important clinical and company milestones.



Helén Tu vesson, CEO

PROJECTS

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

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

Tasquinimod

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

This is tasquinimod

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

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

Multiple myeloma

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

The market for treatment of multiple myeloma

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

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

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

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

Current treatments

Multiple myeloma patients undergo several lines of treatment. In both early and later treatment lines, the goal is to reduce tumor burden, improve symptoms and thereby achieve as long a period of effective disease control as possible. To support deeper and durable responses and overcome treatment resistance patients are as standard treated with combinations of drugs from available product classes. Currently, the market is dominated by drugs that can be divided into the following classes: immunomodulatory imides (IMiDs), proteasome inhibitors (PI), monoclonal antibodies, bispecific antibodies, Chimeric Antigen Receptor T- cells (CAR-T) and alkylating agents.

Tasquinimod in multiple myeloma

Tasquinimod is being developed as a new product class with a distinct and novel mechanism of action and thus has the potential to overcome the problem of drug resistance. The clinical safety profile of tasquinimod is well known from previous clinical phase I-III trials. Given the good tolerability and the possibility to combine with available product classes, tasquinimod has the potential to expand over time from an initial position as the 3rd line treatment to earlier lines of treatment, similar to the patient population in the ongoing clinical study. There is a significant market opportunity for a novel drug in a new product class in multiple myeloma.

Ongoing clinical development

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

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

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

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

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

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

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

In May 2023, Active Biotech announced that tasquinimod as monotherapy, or in combination with IRd, has a favorable safety profile in heavily pretreated patients with a median of eight previous treatments. All 15 patients who were part of this interim assessment were previously refractory against immunomodulatory imides (IMiDs), proteasome inhibitors (PI) and CD38 mAbs. One patient who had been resistant to previous Pi+IMiD combination had a durable partial response ongoing for over a year. The results were presented at the annual meeting of American Society of Clinical Oncology (ASCO) 2023. In September, Active Biotech announced that the dose optimization of tasquinimod + IRd was completed, and the expansion part of the study will start 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, and causes of death include 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, fedratinib and pacritinib (the latter three are JAK inhibitors). 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 phase II studies with tasquinimod in myelofibrosis patients are planned to start in Europe and at MD Anderson in the USA. The study in Europe is funded by Oncode Institute. Active Biotech also has a preclinical collaboration with a research group at MD Anderson, Texas, USA. In May 2022 FDA granted orphan drug designation for tasquinimod in myelofibrosis.

Previous clinical experience of tasquinimod

Tasquinimod has been in development for the treatment of prostate cancer and has completed a phase I-III clinical development program. While the results from the phase III trial in prostate cancer showed that tasquinimod prolonged progression-free survival (PFS) compared to placebo, tasquinimod did not extend overall survival (OS) in this patient population and the development for prostate cancer was discontinued. Tasquinimod was studied in both healthy subjects and cancer patients. Clinical effects and a favorable safety profile have been demonstrated in more than 1,500 patients, equivalent to more than 650 patient-years of exposure to tasquinimod. Extensive datasets including a regulatory package of preclinical and clinical safety and full commercial scale CMC documentation has been generated.

EVENTS DURING THE THIRD QUARTER

- Collaboration agreement for clinical study with tasquinimod in myelofibrosis signed (July 31)
- Tasquinimod successfully completed dose optimization in patients with multiple myeloma and advances into the pre-planned expansion cohort (September 11)

EVENTS AFTER THE END OF THE PERIOD

- Preclinical data of tasquinimod in myelofibrosis awarded oral presentation at ASH 2023 (November 2)

Laquinimod

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

This is laquinimod

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

Non-Infectious Uveitis

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

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

The market

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

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

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

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

Current treatments

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

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

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

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

Laquinimod in non-infectious uveitis

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

Clinical development

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

The primary objective of the study was safety and tolerability of laquinimod eye drops and the secondary readouts included ocular toxicity, pharmacokinetics, and plasma exposure. More information about the study design is available at clinicaltrials.gov (NCT05187403). The eye drop formulation of laquinimod was well tolerated showing a beneficial safety and tolerability profile at dose levels where we expect to achieve therapeutic concentrations. No serious adverse events were reported. Data from the recently completed phase I study together with preclinical data showing the distribution of laquinimod to the back of the eye after administration of the eye drop formulation to rabbits were presented at a poster session at the International Ocular Inflammation Society (IOIS) 2023 meeting in Berlin, Germany, 6-9 September 2023. To ensure that laquinimod reaches the posterior chamber of the eye to support further development in patients with non-anterior uveitis, a clinical ocular biodistribution study of the eye drop formulation will be conducted. The study will be conducted in collaboration with researchers at the Byers Eye Institute, Stanford University (Palo Alto, CA, USA) with the Principal Investigator Quan Dong Nguyen, MD, MSc, FAAO, FARVO, FASRS, Professor of Ophthalmology, Medicine, and Pediatrics, Stanford University School of Medicine.

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

Previous clinical experience with laquinimod

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

EVENTS DURING THE THIRD QUARTER

- Clinical safety and preclinical ocular biodistribution for laquinimod eye drops presented at the IOIS meeting is made available on Active Biotech's website (September 13)

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 will assess naptumomab in combination with docetaxel in patients who had been previously treated with checkpoint inhibitors and have advanced or metastatic non-small cell lung cancer (NSCLC). 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 and aims to establish the maximum tolerated dose in the phase Ib study before advancing to a phase II cohort expansion study.

The trial was initiated in 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 recommended phase II dose. 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.

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 – September 2023

No sales were recorded during the period. The operational costs totaled SEK 33.7 M (42.6) whereof research and development expenses amounted to SEK 22.9 M (32.6), a 30% decrease in costs reflecting the finalization of the laquinimod phase I study and decreased costs for clinical drug.

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

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

- the ongoing phase Ib/IIa clinical study with tasquinimod for treatment of multiple myeloma initiated in August 2020 in collaboration with Penn University, USA. The study is progressing according to plan
- the planning for start of phase II studies with tasquinimod in myelofibrosis scheduled to be initiated in 2024
- the development of laquinimod as a new product class for treatment of inflammatory eye diseases. The topical ophthalmic formulation of laquinimod was tested in a phase I clinical study, that was concluded during the first half of 2023, the positive study results supports the further development of laquinimod for inflammatory eye diseases

Administrative expenses amounted to SEK 10.7 M (10.1). The operating loss for the period amounted to SEK 33.7 M (loss: 42.6), the net financial income for the period amounted to SEK 0.4 M (loss: 0.7) and the loss after tax to SEK 33.3 M (loss: 43.4).

Comments on the Group's results for the period July – September 2023

No sales were recorded during the period. The operational costs totaled SEK 10.6 M (13.4) whereof research and development expenses amounted to SEK 7.6 M (10.3), the decrease in costs is mainly explained by the finalization of the laquinimod phase I study.

Administrative expenses amounted to SEK 3.0 M (3.0). The operating loss for the period amounted to SEK 10.6 M (loss: 13.4), the net financial income for the period amounted to SEK 0.0 M (income: 0.0) and the loss after tax to SEK 10.6 M (loss: 13.4).

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

Cash and cash equivalents at the end of the period amounted to SEK 5.6 M, compared with SEK 41.8 M at the end of 2022. Cash flow for the period amounted to a negative SEK 36.2 M (pos: 1.9). The cash flow from operating activities amounted to a negative SEK 34.9 M (neg: 41.7). Cash flow from investing activities amounted to SEK 0.0 M (neg: 0.2) and financing activities amounted to a negative SEK 1.3 M (pos: 43.8).

Investments

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

Comments on the Parent Company's results and financial position for the period January – September 2023

No sales were recorded during the period. Operating expenses amounted to SEK 33.8 M (43.1). The Parent Company's operating loss for the period was SEK 33.8 M (loss: 43.1). Net financial income amounted to a SEK 0.6 M (19.3) and the loss after financial items was SEK 33.2 M (loss: 23.7). Cash and cash equivalents including short-term investments totaled SEK 5.4 M at the end of the period, compared with SEK 41.6 M on January 1, 2023.

Comments on the Parent Company's results and financial position for the period July – September 2023

No sales were recorded during the period. Operating expenses amounted to SEK 10.6 M (13.4). The Parent Company's operating loss for the period was SEK 10.6 M (loss: 13.4). Net financial income amounted to a SEK 0.1 M (0.0) and the loss after financial items was SEK 10.5 M (loss: 13.4).

Shareholders' equity

Consolidated shareholders' equity at the end of the period amounted to SEK 1.3 M, compared with SEK 34,5 M at year-end 2022.

The number of shares outstanding at the end of the period totaled 265,144,687. At the end of the period, the equity/assets ratio for the Group was 9.0 percent, compared with 67.7 percent at year-end 2022. The corresponding figures for the Parent Company, Active Biotech AB, were 0.4 percent and 39.0 percent, respectively.

At the end of the third quarter 2023, the parent company Active Biotech AB's shareholders' equity was less than one-half of the registered share capital. However, based on the investment commitments received from two of the Company major shareholders (as previously communicated) the Board did not consider that a special purpose balance sheet had to be prepared.

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 871,837 shares (Savings shares) in the market during the period 2020 to June 2023 in the respective incentive programs. Total costs, including social contributions, as of June 30, 2023, amounted to SEK 1831 K.

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

Organization

The average number of employees during the reporting period was 8 (9), of which the number of employees in the research and development organization accounted for 5 (6). The number of employees at the end of the period amounted to 8 whereof 5 in the research and development organization.

Outlook, including significant risks and uncertainties

Active Biotech's ability to develop pharmaceutical projects to the point at which partnership agreements can be secured, and the partner assumes responsibility for the future development and commercialization of the project, is decisive for the company's long-term financial strength and stability. Active Biotech has currently three projects in its portfolio:

- tasquinimod, targeted towards hematological malignancies is in clinical phase Ib/IIa treatment of multiple myeloma and preparations are ongoing for start of phase II studies in Myelofibrosis in Europe and US. The study in Europe will mainly be funded by Onco Institute
- laquinimod, targeted towards inflammatory eye disorders. A clinical phase I trial with a topical ophthalmic formulation was concluded in January, 2023. The planning of a phase I bio-distribution study is ongoing, study start is scheduled the first half of 2024
- naptumomab, a tumor directed immunotherapy, partnered to NeoTX, is in phase Ib/II clinical development in patients with advanced solid tumors and in phase IIa development in combination with docetaxel in NSCLC. All development of naptumomab is financed by NeoTX

The ongoing preclinical and clinical programs are advancing positively. The company regularly receive inbound approaches from scientists who wish to explore the potential of tasquinimod or laquinimod in different disease areas. Active Biotech will maintain focus for tasquinimod within hematological malignancies and laquinimod within inflammatory eye disorders.

Active Biotech focuses its activities to secure long-term value growth and conduct commercial activities aimed at entering new partnerships for the fully 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 will fund continued operations into Q4 2023, and Active Biotech will therefore require access to further growth capital to maintain progress of its unpartnered project portfolio. To secure the financing of Active Biotech's operations, it was communicated in the interim report for the period January – June 2023 that two major shareholders provided a financing commitment of approximately 20 MSEK to the company. The financing commitment has provided the time necessary to conclude on the ongoing financing opportunities. Various sources of financing has been explored, including partnering the company's development programs, directed share issuances to new investors as well as rights issue to current 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 significant uncertainty factor regarding the company's ability to continue operation on a longer term.

As a research company, Active Biotech is characterized by high operational and financial risk, since the projects in which the company is involved have development, regulatory and commercialization risks. In addition, the ability of the company to attract and retain key people with both insights to the field of research, and relevant product development experiences is a significant risk.

In brief, the operation is associated with risks related to such factors as pharmaceutical development, competition, advances in technology, patents, regulatory requirements, capital requirements, currencies and interest rates.

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

THIRD QUARTER IN BRIEF

- Collaboration agreement for clinical study with tasquinimod in myelofibrosis signed (July 31)
- Tasquinimod successfully completed dose optimization in patients with multiple myeloma and advances into the pre-planned expansion cohort (September 11)
- Clinical safety and preclinical ocular biodistribution for laquinimod eye drops presented at the IOIS meeting is made available on Active Biotech's website (September 13)

EVENTS AFTER THE END OF THE PERIOD

- Preclinical data of tasquinimod in myelofibrosis awarded oral presentation at ASH 2023 (November 2)
- The board of directors resolved on November 9, based on the authorization from the general meeting 2023, to carry out a rights issue of approximately SEK 51 million (before issue costs) to secure financing of ongoing and planned development programs for tasquinimod and laquinimod

CONSOLIDATED PROFIT AND LOSS

SEK M	Jul-Sep		Jan-Sep		Full Year
	2023	2022	2023	2022	2022
Net sales	-	-	-	-	-
Administrative expenses	-3.0	-3.0	-10.7	-10.1	-15.1
Research and development costs	-7.6	-10.3	-22.9	-32.6	-42.8
Operating profit/loss	-10.6	-13.4	-33.7	-42.6	-57.9
Net financial items	0.0	-0.0	0.4	-0.7	-0.5
Profit/loss before tax	-10.6	-13.4	-33.3	-43.4	-58.4
Tax	-	-	-	-	-
Net profit/loss for the period	-10.6	-13.4	-33.3	-43.4	-58.4
Comprehensive profit/loss attributable to:					
Parent Company shareholders	-10.6	-13.4	-33.3	-43.4	-58.4
Non-controlling interest	-	-	-	-	-
Net profit/loss for the period	-10.6	-13.4	-33.3	-43.4	-58.4
Comprehensive profit/loss per share before dilution (SEK)	-0.04	-0.06	-0.13	-0.19	-0.25
Comprehensive profit/loss per share after dilution (SEK)	-0.04	-0.06	-0.13	-0.19	-0.25

STATEMENT OF PROFIT AND LOSS AND CONSOLIDATED COMPREHENSIVE INCOME

SEK M	Jul-Sep		Jan-Sep		Full Year
	2023	2022	2023	2022	2022
Net profit/loss for the period	-10.6	-13.4	-33.3	-43.4	-58.4
Other comprehensive income	-	-	-	-	-
Total comprehensive profit/loss for the period	-10.6	-13.4	-33.3	-43.4	-58.4
Total other comprehensive profit/loss for the period attributable to:					
Parent Company shareholders	-10.6	-13.4	-33.3	-43.4	-58.4
Non-controlling interest	-	-	-	-	-
Total comprehensive profit/loss for the period	-10.6	-13.4	-33.3	-43.4	-58.4
Depreciation/amortization included in the amount of	0.4	0.4	1.3	1.3	1.5
Investments in tangible fixed assets	-	-	-	-	-
Weighted number of outstanding common shares before dilution (000s)	265,145	227,921	265,087	222,750	233,652
Weighted number of outstanding common shares after dilution (000s)	265,145	227,921	265,087	222,750	233,652
Number of shares at close of the period (000s)	265,145	264,887	265,145	264,887	264,887

CONSOLIDATED STATEMENT OF FINANCIAL POSITION

SEK M	Sep 30		Dec 31
	2023	2022	2022
Intangible fixed assets	0.2	0.2	0.2
Tangible fixed assets	5.0	6.2	6.3
Long-term receivables	0.4	0.4	0.4
Total fixed assets	5.6	6.9	6.9
Current receivables	3.1	3.8	2.3
Cash and cash equivalents	5.6	55.0	41.8
Total current assets	8.7	58.8	44.1
Total assets	14.3	65.6	51.0
Shareholders equity	1.3	49.2	34.5
Long-term liabilities	3.4	4.5	4.4
Current liabilities	9.6	12.0	12.1
Total shareholders equity and liabilities	14.3	65.6	51.0

CONSOLIDATED STATEMENT OF CHANGES IN SHAREHOLDERS EQUITY

SEK M	Sep 30		Dec 31
	2023	2022	2022
Opening balance	34.5	46.7	46.7
Loss for the period	-33.3	-43.4	-58.4
Other comprehensive income for the period	-	-	-
<i>Comprehensive profit/loss for the period</i>	-33.3	-43.4	-58.4
Share-based payments that are settled with equity instruments, IFRS2	0.1	0.4	0.7
New share issue	-0.1	45.5	45.5
Balance at close of period	1.3	49.2	34.5

CONDENSED CONSOLIDATED CASH-FLOW STATEMENT

SEK M	Jan-Sep		Full Year
	2023	2022	2022
Loss after financial items	-33.3	-43.4	-58.4
Adjustment for non-cash items, etc.	1.4	1.7	2.2
Cash flow from operating activities before changes in working capital	-31.9	-41.7	-56.2
Changes in working capital	-3.0	-0.0	1.3
Cash flow from operating activities	-34.9	-41.7	-54.8
Investments in intangible assets	-	-0.2	-0.2
Cash flow from investments	-	-0.2	-0.2
New share issue	-0.1	45.5	45.5
Loans raised/amortization of loan liabilities	-1.2	-1.7	-1.8
Cash flow from financing activities	-1.3	43.8	43.8
Cash flow for the period	-36.2	1.9	-11.3
Opening cash and cash equivalents	41.8	53.1	53.1
Closing cash and cash equivalents	5.6	55.0	41.8

KEY FIGURES

	Sep 30		Dec 31
	2023	2022	2022
Shareholders equity, SEK M	1.3	49.2	34.5
Equity per share, SEK	0.00	0.19	0.13
Equity/assets ratio in the Parent Company	0.4 %	47.7 %	39.0 %
Equity/assets ratio in the Group	9.0 %	75.0 %	67.7 %
Average number of annual employees	8	9	9

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

CONSOLIDATED PROFIT AND LOSS

SEK M	2019				2020				2021				2022				2023		
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3
Net Sales	5.5	1.1	0.9	0.9	0.5	-	-	6.2	-	-	-	-	-	-	-	-	-	-	-
Administration expenses	-2.8	-3.6	-2.7	-3.2	-3.4	-3.8	-2.9	-3.4	-3.3	-3.5	-3.5	-5.0	-3.6	-3.4	-3.0	-5.0	-3.8	-4.0	-3.0
Research and development costs	-9.1	-5.2	-5.3	-8.8	-6.8	-6.3	-5.5	-7.0	-6.4	-9.2	-7.8	-11.2	-11.7	-10.5	-10.3	-10.3	-8.1	-7.3	-7.6
Other operating expenses/income	-	2.2	-2.2	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Operating profit/loss	-6.4	-5.4	-9.3	-11.2	-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
Net financial items	-1.7	-0.0	-0.0	-0.1	-0.4	0.3	0.1	0.0	-0.0	-0.0	0.0	-0.0	-0.4	-0.3	-0.0	0.3	0.3	0.1	0.0
Profit/loss before tax	-8.1	-5.5	-9.3	-11.2	-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
Tax	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Net profit/loss for the period	-8.1	-5.5	-9.3	-11.2	-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

ACTIVE BIOTECH PARENT COMPANY – INCOME STATEMENT, CONDENSED

SEK M	Jul-Sep		Jan-Sep		Full Year
	2023	2022	2023	2022	2022
Net Sales	-	-	-	-	-
Administration expenses	-3.0	-3.0	-10.7	-10.1	-15.0
Research and development costs	-7.6	-10.3	-23.1	-33.0	-42.9
Operating profit/loss	-10.6	-13.4	-33.8	-43.1	-57.9
<i>Profit/loss from financial items:</i>					
Result from participations in group companies	-	-	-	20.0	20.0
Interest income and similar income-statement items	0.1	0.0	0.6	0.0	0.0
Interest expense and similar income-statement items	-	0.0	0.0	-0.7	-0.3
Profit/loss after financial items	-10.5	-13.4	-33.2	-23.7	-38.2
Tax	-	-	-	-	-
Net profit/loss for the period	-10.5	-13.4	-33.2	-23.7	-38.2
Statement of comprehensive income parent company					
Net profit/loss for the period	-10.5	-13.4	-33.2	-23.7	-38.2
Other comprehensive income	-	-	-	-	-
Total comprehensive profit/loss for the period	-10.5	-13.4	-33.2	-23.7	-38.2

ACTIVE BIOTECH PARENT COMPANY – BALANCE SHEET, CONDENSED

SEK M	Sep 30		Dec 31
	2023	2022	2022
Intangible fixed assets	0.2	0.2	0.2
Financial fixed assets	40.9	40.9	40.9
Total fixed assets	41.1	41.1	41.1
Current receivables	3.5	3.8	2.7
Short-term investments	-	8.1	39.5
Cash and bank balances	5.4	46.7	2.1
Total current assets	8.9	58.6	44.4
Total assets	50.0	99.7	85.5
Shareholders equity	0.2	47.5	33.4
Current liabilities	49.8	52.1	52.1
Total equity and liabilities	50.0	99.7	85.5

Any errors in additions are attributable to rounding of figures.

NOTE 1: ACCOUNTING POLICIES

The interim report of the Group has been prepared in accordance with IAS 34 Interim Financial Reporting and applicable parts of the Annual Accounts Act. The interim report of the Parent Company has been prepared in accordance with Chapter 9 of the Annual Accounts Act. For the Group and the Parent Company, the same accounting policies and accounting estimates and assumptions were applied in this interim report as were used in the preparation of the most recent annual report.

NOTE 2: FAIR VALUE OF FINANCIAL INSTRUMENTS

SEK M	Sep 30, 2023 Level 2	Dec 31, 2022 Level 2
Short-term investments	0.0	39.5

LEGAL DISCLAIMER

This financial report includes statements that are forward-looking and actual results may differ materially from those anticipated. In addition to the factors discussed, other factors that can affect results are developments in research programs, including clinical trials, the impact of competing research programs, the effect of economic conditions, the effectiveness of the company's intellectual patent protection, obstacles due to technological development, exchange-rate and interest-rate fluctuations, and political risks.

FINANCIAL CALENDAR

- Year End Report 2023: February 8, 2024

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

The interim report for the January – September period 2023 provides a true and fair view of the Parent Company's and the Group's operations, position and results, and describes significant risks and uncertainties that the Parent Company and Group companies face. The interim report has been reviewed by the company's auditors.

Lund, November 9, 2023

Helén Tuve
President and CEO

AUDITOR'S REPORT

(Translation from Swedish original, In case of discrepancies, the Swedish version shall prevail.)

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 2023 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 14 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 November 9, 2023
Öhrlings PricewaterhouseCoopers AB

Cecilia Andrén Dorselius
Authorized Public Accountant

About Active Biotech

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