INTERIM REPORT Q1 2023 | ACTIVE BIOTECH AB

Inspiring start to the new year for all our projects

FIRST QUARTER IN BRIEF

- Active Biotech confirmed positive clinical safety profile of laquinimod eye drops (January 30)
- Active Biotech published new preclinical data highlighting the mechanisms behind the anti-tumor activity of tasquinimod in hematological malignances
- New preclinical data on naptumomab published

EVENTS AFTER THE END OF THE PERIOD

- Safety and preliminary activity of naptumomab in combination with durvalumab presented at AACR 2023 (April 19)
- New clinical data on tasquinimod in multiple myeloma to be presented at ASCO 2023 (April 27)

FINANCIAL SUMMARY

	Jan-Mar		Full-year
SEK M	2023	2022	2022
Net sales	–	–	–
Operating profit/loss	–11.8	–15.3	–57.9
Profit/loss after tax	–11.5	–15.7	–58.4
Earnings per share (SEK)	–0.04	–0.07	–0.25
Cash and cash equivalents (at close of period)	30.2	37.8	41.8

The report is also available at www.activebiotech.com

Active Biotech is obligated to make public the information contained in this report pursuant to the EU Market Abuse Regulation. This information was provided to the media, through the agency of the contact person set out below, for publication on May 4, 2023, at 08.30 a.m. CET.

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Helén Tuvesson
CEO

We started the new year with positive announcements

COMMENTS FROM THE CEO

We have put a productive year behind us, and I look forward to an exciting 2023 with upcoming results and the start of studies in our projects in cancer and inflammatory eye disorders. It felt rewarding that we could start the new year with positive announcements regarding all our prioritized projects, which bodes well for future development.

In January, we presented the first results from the phase I study of the laquinimod eye drop formulation in healthy subjects. The eye drops were well tolerated, both as single and repeated doses for up to 21 days, and no adverse events were reported. Full analysis of study data is now underway, and we will report more detailed results in H2 2023. In parallel, intense preparations are ongoing to initiate the first clinical study with laquinimod in patients with uveitis. The study is planned to start in late 2023, subject to new financing.

The safety and preliminary efficacy data from the phase Ib study of naptumomab were presented at the American Association for Cancer Research (AACR) annual meeting in Orlando, Florida. The study enrolled 59 patients with previously treated advanced or metastatic disease and a high likelihood of tumor 5T4 expression. The results from the dose-escalation and MTD expansion part of the study show that naptumomab in combination with durvalumab is generally well tolerated with limited toxicity at the recommended phase II dose (RP2D) of 10mcg/kg.

Furthermore, preliminary results indicate that pre-treatment with obinutuzumab reduces the formation of anti-drug-antibodies to naptumomab and preserves naptumomab plasma levels. Durable responses were seen, including complete responses in patients, where response to monotherapy with checkpoint inhibitor was not expected. In the next step, cohort expansions are planned, also including patients with esophageal cancer.

The phase IIa trial with naptumomab in combination with docetaxel in patients with lung cancer is ongoing, and results are expected by end of 2023 at the earliest.

The Phase Ib/IIa study in multiple myeloma is ongoing and in April we reported that new data from the study will be presented at the prestigious American Society of Clinical Oncology (ASCO) Annual Meeting, June 2-6, 2023 in Chicago.

Preparations are ongoing for the start of a proof-of-concept study with tasquinimod in myelofibrosis in the second half of 2023.

Our external collaborations have lately generated several publications that further increase our understanding of important mechanism underpinning the anti-tumor effect of tasquinimod and naptumomab. In January, there were two new publications focused on tasquinimod. In the first publication (Fan R. et al. J Immunother Cancer 2023 Jan;11), it was shown that tasquinimod treatment led to decreased tumor cell growth and bone resorption in a mice model of multiple myeloma. Results further suggested that the effect was due to dual targeting of the immunosuppressive tumor microenvironment and the tumor cells.

The second publication (Lin C. et al. in Cancer Research Communications 2023 13;3(3):420-430), presented the anti-tumor effect of tasquinimod alone and in combination with standard multiple myeloma treatments in mouse models. The effects mediated by the interaction with S100A9 resulted

in a blockade of expansion of megakaryocytes, an important cell type involved in multiple myeloma and other hematological malignances.

In a publication by our partner NeoTX in the naptumomab project (Azulay M. et al. in J of Translational Medicine 2023 21:222), it was demonstrated that repeated doses of naptumomab, led to a potent anti-tumor effect and a long-term antitumor immune response in the mice. These data strongly support the clinical programs ongoing with naptumomab in solid tumors.

During the last years, we have built a clinical position for our fully owned projects tasquinimod and laquinimod in hematological malignances and inflammatory eye disorder, respectively. Both projects have shown solid clinical proof-of-concept and favorable safety in previous development, and we can leverage the full documentation packages for a time and cost-efficient development in the targeted indications. We have broadened the IP rights around our assets, clarified the mechanisms of action and established collaborations with prestigious academic and commercial partners in Europe and US for the continued development.

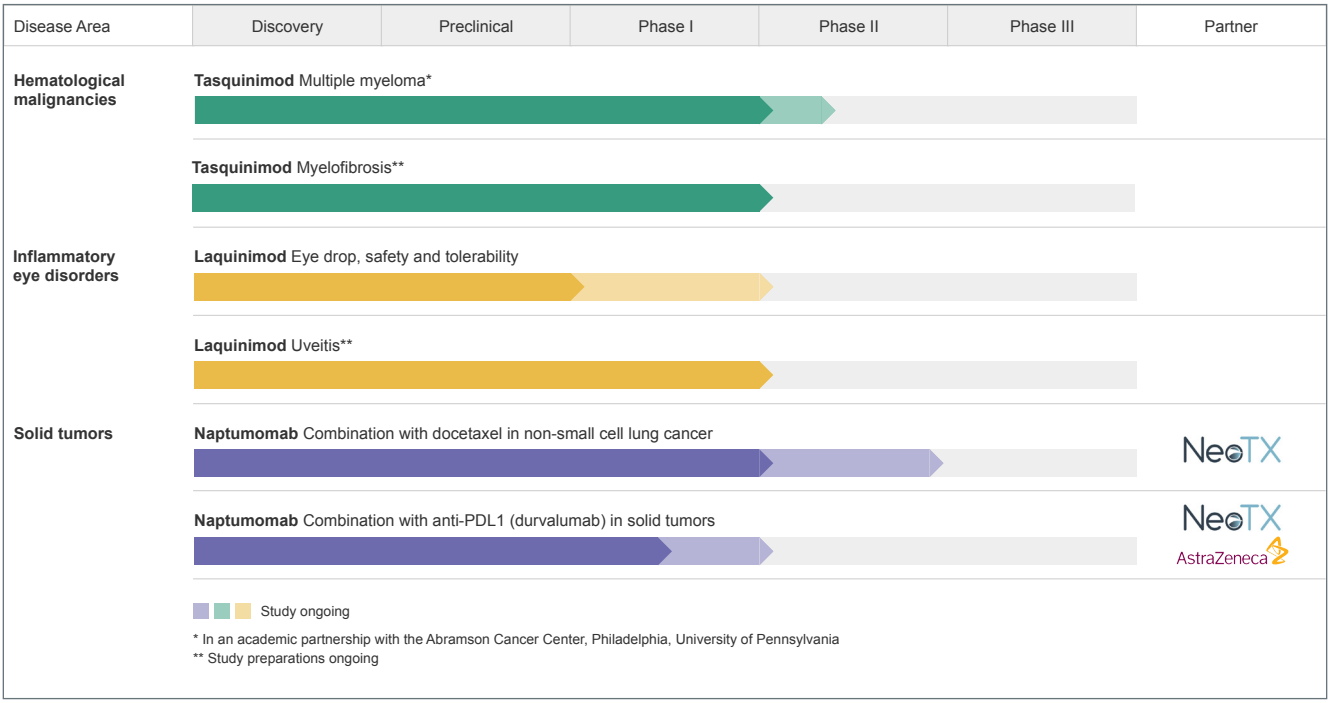
With the positive safety profile of the laquinimod eye drop formulation confirmed and the presentation of interim data from the tasquinimod clinical trial in multiple myeloma at ASCO in June, we are preparing to advance our projects to the next step of demonstrating clinical proof of concept in the new indications. During the period 2023-2025, the currently planned clinical development programs include the start of phase II studies with tasquinimod in hematological malignances as well as a phase II study in uveitis with laquinimod. Advancing the full portfolio will be challenging despite that part of the studies are investigator driven and to a major extent externally funded. Therefore, the Board together with management has initiated a strategic review of the planned clinical programs and their financing.

We have an exciting year ahead of us, and I look forward to updating you as the projects progress in 2023.

Helén Tuvesson, CEO

PROJECTS

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



Tasquinimod

Tasquinimod is an orally active small molecule immunomodulator with a novel mode of action, blocking tumor supporting pathways in the bone marrow microenvironment. Tasquinimod is being developed for the treatment of blood cancers, 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 four different classes: immunomodulatory imides (IMiDs), proteasome inhibitors (PI), monoclonal antibodies 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 and February 2022, 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 IMDs, proteosome inhibitors, and anti-CD-38 monoclonal antibodies. While none of the patients formally achieved a partial response, 2 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 in patients with multiple myeloma together with the orally administered anti-myeloma agents ixazomib, lenalidomide, and dexamethasone (IRd). Recruitment into the dose-escalation part of the combination cohort is ongoing. Once an optimal dose and schedule of tasquinimod for the IRd combination is established, an expansion cohort will be recruited to further document the biological activity of tasquinimod in myeloma patients. Key secondary endpoints will include anti-myeloma activity using the response criteria of the International Myeloma Working Group.

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 there are three drugs approved for these patients as symptom-directed therapy: Hydroxy-urea, ruxolitinib and fedratinib (the latter two are JAK2-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 market is less developed but projected at over USD 0.8 billion by 2027 (Global Data Report October 2016 – Myelofibrosis – Global Forecast 2015-2025).

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. A proof-of-concept phase II study with tasquinimod in myelofibrosis patients previously treated with JAK inhibitor (JAKi) or ineligible to JAKi is planned to start in 2023. The study is funded by Oncode Institute. Active Biotech also has a collaboration with a research group at MD Anderson, Texas, US with a current focus on preclinical experiments. 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 FIRST QUARTER

- New preclinical data highlighting the mechanisms behind the anti-tumor activity of tasquinimod in hematological malignances, published

EVENTS AFTER THE END OF THE PERIOD

- New clinical data on tasquinimod in multiple myeloma to be presented at ASCO 2023 (April 27)

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 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 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 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 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 lasquinimod 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 profile atdose levels where we expect to achieve therapeutic concentrations. Full study results will be reported in H2 2023.

In parallel, planning is ongoing for a phase II clinical study of oral and eye drop formulations of laquinimod in patients with non-infectious 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.

EVENTS DURING THE FIRST QUARTER

- Active Biotech confirms positive clinical safety profile of laquinimod eye drops (January 30)

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

Naptumomab in solid tumors

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

Checkpoint inhibitors are a group of cancer drugs, which function by unleashing the immune system to attack the tumor. Despite the successes over 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). On October 20, 2021, it was announced that the first patient was enrolled. The primary endpoint is objective response rate. 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. 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 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.

EVENTS DURING THE FIRST QUARTER

- New preclinical data on naptumomab published

EVENTS AFTER THE END OF THE PERIOD

- Safety and preliminary activity of naptumomab in combination with durvalumab presented at AACR 2023 (April 19)

FINANCIAL INFORMATION

Comments on the Group's results for the period January – March 2023
No sales were recorded during the period. The operational costs totaled SEK 11.8 M (15.3) whereof research and development expenses amounted to SEK 8.1 M (11.7), a 31% decrease in costs reflecting the finalization of the laquinimod phase I study.

The company's research efforts during the reporting period have been focused on the clinical development of tasquinimod in multiple myeloma and the eye drop formulation of 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 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 of a phase II study with tasquinimod in myelofibrosis scheduled to be initiated in the second half of 2023, mainly financed by Oncode Institute.
- 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 in January 2023. The study results are being analyzed and planning for a phase II proof-of-concept study is underway.

Administrative expenses amounted to SEK 3.8 M (3.6). The operating loss for the period amounted to SEK 11.8 M (loss: 15.3), the net financial income for the period amounted to SEK 0.3 M (loss: 0.4) and the loss after tax to SEK 11.5 M (loss: 15.7).

Cash flow, liquidity and financial position, Group, for the period January – March 2023
Cash and cash equivalents at the end of the period amounted to SEK 30.2 M, compared with SEK 41.8 M at the end of 2022. Cash flow for the period amounted to a negative SEK 11.6 M (neg: 15.3). The cash flow from operating activities amounted to a negative SEK 11.2 M (neg: 14.7). Cash flow from investing activities amounted to SEK 0.0 M (neg: 0.2) and financing activities amounted to a negative SEK 0.4 M (neg: 0.3).

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 – March 2023
No sales were recorded during the period. Operating expenses amounted to SEK 11.9 M (15.3).
The Parent Company's operating loss for the period was SEK 11.9 M (loss: 15.3). Net financial income amounted to a SEK 0.3 M (neg: 0.4) and the loss after financial items was SEK 11.5 M (loss: 15.7).

Cash and cash equivalents including short-term investments totaled SEK 30.0 M at the end of the period, compared with SEK 41.6 M on January 1, 2023.

Shareholders' equity
Consolidated shareholders' equity at the end of the period amounted to SEK 23.0 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 58.3 percent, compared with 67.7 percent at year-end 2022. The corresponding figures for the Parent Company, Active Biotech AB, were 29.4 percent and 39.0 percent, respectively.

Long Term Incentive Programs

The Annual General Meeting on May 19, 2020, resolved to adopt two Long Term Incentive Programs (LTIPs), Plan 2020/2024 to include the employees within the Active Biotech Group and the Board Plan 2020/2023 to include all Board members of Active Biotech.

Employees and Board members acquired in total 871 837 shares (Savings shares) in the market during the period 2020 to March 2023 in the respective incentive programs. Total costs, including social contributions, as of March 31, 2023, amounted to SEK 1723 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 is also in development for a clinical phase II study in Myelofibrosis, the study is scheduled to start second half of 2023 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 January, 2023. The planning of a phase II proof-of-concept study has been initiated, study start is scheduled late 2023 bu pending new financing.
- 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 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 at March 31 funds continued operations through 2023 and Active Biotech will therefore require access to further growth capital to maintain progress of its unpartnered project portfolio. Various sources of financing are being 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 assurance at the time of submission of this report means that there is a significant uncertainty factor regarding the company´s ability to continue operation.

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 an added uncertainty related to the situation in Ukraine and through the financial instability with rising inflation and general macroeconomic 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.

EVENTS DURING THE FIRST QUARTER

- Active Biotech confirmed positive clinical safety profile of laquinimod eye drops (January 30)
- Active Biotech published new preclinical data highlighting the mechanisms behind the anti-tumor activity of tasquinimod in hematological malignances
- New preclinical data on naptumomab published

EVENTS AFTER THE END OF THE PERIOD

- Safety and preliminary activity of naptumomab in combination with durvalumab presented at AACR 2023 (April 19)
- New clinical data on tasquinimod in multiple myeloma to be presented at ASCO 2023 (April 27)

CONSOLIDATED PROFIT AND LOSS

SEK M	Jan-Mar 2023	Jan-Mar 2022	Full Year 2022
Net sales	**–**	**–**	**–**
Administrative expenses	–3,8	–3,6	–15,1
Research and development costs	–8,1	–11,7	–42,8
Operating profit/loss	**–11,8**	**–15,3**	**–57,9**
Net financial items	0,3	–0,4	–0,5
Profit/loss before tax	**–11,5**	**–15,7**	**–58,4**
Tax	–	–	–
Net profit/loss for the period	**–11,5**	**–15,7**	**–58,4**
Comprehensive profit/loss attributable to:			
Parent Company shareholders	–11,5	–15,7	–58,4
Non-controlling interest	–	–	–
Net profit/loss for the period	**–11,5**	**–15,7**	**–58,4**
Comprehensive profit/loss per share before dilution (SEK)	–0,04	–0,07	–0,25
Comprehensive profit/loss per share after dilution (SEK)	–0,04	–0,07	–0,25

STATEMENT OF PROFIT AND LOSS AND CONSOLIDATED COMPREHENSIVE INCOME

SEK M	Jan-Mar 2023	Jan-Mar 2022	Full Year 2022
Net profit/loss for the period	–11.5	–15.7	–58.4
Other comprehensive income	–	–	–
Total comprehensive profit/loss for the period	**–11.5**	**–15.7**	**–58.4**
Total other comprehensive profit/loss for the period attributable to:			
Parent Company shareholders	–11.5	–15.7	–58.4
Non-controlling interest	–	–	–
Total comprehensive profit/loss for the period	**–11.5**	**–15.7**	**–58.4**
Depreciation/amortization included in the amount of	0.4	0.3	1.5
Investments in tangible fixed assets	–	–	–
Weighted number of outstanding common shares before dilution (000s)	264,973	217,999	233,652
Weighted number of outstanding common shares after dilution (000s)	264,973	217,999	233,652
Number of shares at close of the period (000s)	265,145	218,055	264,887

CONSOLIDATED STATEMENT OF FINANCIAL POSITION

SEK M	Mar 31 2023	Mar 31 2022	Dec 31 2022
Intangible fixed assets	0.2	0.2	0.2
Tangible fixed assets	5.8	0.6	6.3
Long-term receivables	0.4	0.0	0.4
Total fixed assets	**6.5**	**0.9**	**6.9**
Current receivables	2.8	3.6	2.3
Cash and cash equivalents	30.2	37.8	41.8
Total current assets	**33.0**	**41.5**	**44.1**
Total assets	**39.5**	**42.3**	**51.0**
Shareholders equity	23.0	31.0	34.5
Long-term liabilities	4.1	0.2	4.4
Current liabilities	12.4	11.1	12.1
Total shareholders equity and liabilities	**39.5**	**42.3**	**51.0**

CONSOLIDATED STATEMENT OF CHANGES IN SHAREHOLDERS EQUITY

SEK M	Mar 31 2023	Mar 31 2022	Dec 31 2022
Opening balance	34.5	46.7	46.7
Loss for the period	–11.5	–15.7	–58.4
Other comprehensive income for the period	–	–	–
Comprehensive profit/loss for the period	*–11.5*	*–15.7*	*–58.4*
Share-based payments that are settled with equity instruments, IFRS2	0.0	0.0	0.7
New share issue	0.0	0.0	45.5
Balance at close of period	**23.0**	**31.0**	**34.5**

CONDENSED CONSOLIDATED CASH-FLOW STATEMENT

SEK M	Jan-Mar 2023	Jan-Mar 2022	Full Year 2022
Loss after financial items	**–11.5**	**–15.7**	**–58.4**
Adjustment for non-cash items, etc.	0.4	0.3	2.2
Cash flow from operating activities before changes in working capital	**–11.1**	**–15.4**	**–56.2**
Changes in working capital	–0.1	0.6	1.3
Cash flow from operating activities	**–11.2**	**–14.7**	**–54.8**
Investments in intangible assets	–	–0.2	–0.2
Cash flow from investments	**–**	**–0.2**	**–0.2**
New share issue	0.0	0.0	45.5
Loans raised/amortization of loan liabilities	–0.4	–0.3	–1.8
Cash flow from financing activities	**–0.4**	**–0.3**	**43.8**
Cash flow for the period	**–11.6**	**–15.3**	**–11.3**
Opening cash and cash equivalents	**41.8**	**53.1**	**53.1**
Closing cash and cash equivalents	**30.2**	**37.8**	**41.8**

KEY FIGURES

	Mar 31		Dec 31
	2023	2022	2022
Shareholders equity, SEK M	23.0	31.0	34.5
Equity per share, SEK	0.09	0.14	0.13
Equity/assets ratio in the Parent Company	29.4 %	11.9 %	39.0 %
Equity/assets ratio in the Group	58.3 %	73.2 %	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 meets its financial commitments. The equity/assets ratio is calculated by dividing recognized shareholders´equity by recognizes total assets. Equity per share is calculated by dividing recognized shareholders´equity by the number of shares.

CONSOLIDATED PROFIT AND LOSS

	2019				2020				2021				2022				2023
SEK M	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1
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
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
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**
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
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**
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**

ACTIVE BIOTECH PARENT COMPANY – INCOME STATEMENT, CONDENSED

SEK M	Jan-Mar 2023	Jan-Mar 2022	Full Year 2022
Net Sales	**–**	**–**	**–**
Administration expenses	–3.8	–3.6	–15.0
Research and development costs	–8.1	–11.7	–42.9
Operating profit/loss	**–11.9**	**–15.3**	**–57.9**
Profit/loss from financial items:			
Result from participations in group companies	–	–	20.0
Interest income and similar income-statement items	0.3	–	0.0
Interest expense and similar income-statement items	–	–0.4	–0.3
Profit/loss after financial items	**–11.5**	**–15.7**	**–38.2**
Tax	–	–	–
Net profit/loss for the period	**–11.5**	**–15.7**	**–38.2**
Statement of comprehensive income parent company			
Net profit/loss for the period	–11.5	–15.7	–38.2
Other comprehensive income	–	–	–
Total comprehensive profit/loss for the period	**–11.5**	**–15.7**	**–38.2**

ACTIVE BIOTECH PARENT COMPANY – BALANCE SHEET, CONDENSED

SEK M	Mar 31 2023	Mar 31 2022	Dec 31 2022
Intangible fixed assets	0.2	0.2	0.2
Financial fixed assets	40.9	40.5	40.9
Total fixed assets	**41.1**	**40.7**	**41.1**
Current receivables	3.2	3.6	2.7
Short-term investments	27.8	32.4	39.5
Cash and bank balances	2.2	5.2	2.1
Total current assets	**33.3**	**41.3**	**44.4**
Total assets	**74.4**	**82.0**	**85.5**
Shareholders equity	21.9	9.7	33.4
Current liabilities	52.5	72.3	52.1
Total equity and liabilities	**74.4**	**82.0**	**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	Mar 31, 2023 Level 2	Dec 31, 2022 Level 2
Short-term investments	27.8	39.5

LEGAL DISCLAIMER

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

FINANCIAL CALENDAR

- Interim reports 2023: August 24 (Q2), November 9 (Q3)
- Annual General Meeting: May 24, 2023
- Year End Report 2023: February 8, 2024

This interim report is unaudited.

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

The interim report for the January – March 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.

Lund May 4, 2023

Helén Tuvesson
President and CEO

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 a clinical phase I study with a topical ophthalmic formulation, to be followed by phase II-study for treatment of non-infectious uveitis. 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.