Active Biotech

INTERIM REPORT Q2 2022 | ACTIVE BIOTECH AB

Clinical trials are ongoing in all projects

SECOND QUARTER IN BRIEF

- **Laquinimod** eye drop phase I single ascending-dose part in healthy subjects was completed without reported safety concerns, multiple-dose part started
- Active Biotech strengthened the patent protection for **laquinimod** in eye disorders (April 26)
- FDA granted Orphan Drug Designation for **tasquinimod** in myelofibrosis (May 18)
- Successful completion of the first stage of the phase IIa clinical study of **naptumomab** in combination with docetaxel, with the study now enrolling into the second stage (June 1)

EVENTS AFTER THE END OF THE PERIOD

- The first part of the multiple-dose of **laquinimod** eye drops in the phase I study has been completed without any serious side effects that can be linked to laquinimod and the study has been expanded with another dose group
- The board of directors resolved on August 4, 2022, based on the authorisation from the general meeting, to carry out a rights issue of approximately SEK 55 million to secure financing of the ongoing and planned development programs

FINANCIAL SUMMARY

	Apr-Jun		Jan-Jun		Full-year
SEK M	2022	2021	2022	2021	2021
Net sales	–	–	–	–	–
Operating profit/loss	–14.0	–12.6	–29.3	–22.4	–49.8
Profit/loss after tax	–14.3	–12.6	–30.0	–22.4	–49.8
Earnings per share (SEK)	–0.07	–0.06	–0.14	–0.11	–0.24
Cash and cash equivalents (at close of period)			21.9	78.5	53.1

The report is also available at www.activebiotech.com

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Helén Tuvesson
CEO

In May, the FDA granted orphan drug designation for tasquinimod in myelofibrosis. This designation provides for a seven-year marketing exclusivity period

COMMENTS FROM THE CEO

I am pleased to announce that we further advanced all our prioritized projects in cancer and inflammatory eye diseases during the second quarter. The patent protection for laquinimod in eye disorders was strengthened, and we received orphan drug designation from the US Food and Drug Administration (FDA) for tasquinimod in myelofibrosis. In the naptumomab project, we reported that the phase IIa study in lung cancer is advancing to its second stage after a futility analysis was successfully passed.

The phase I clinical trial to test the safety and tolerability of the newly developed eye drop formulation of laquinimod is ongoing. As previously reported, the single ascending-dose part of the study and the first of two multiple dose parts have successfully been completed, and the eye drop formulation was well tolerated without any serious side effects that can be linked to laquinimod at dose levels where we expect to reach therapeutic concentrations.

The study has therefore been expanded with an additional dose cohort to ensure correct determination of the recommended dose for further studies. We expect to review the full results of the study at the beginning of next year. In parallel, we are planning for a phase II study in patients with uveitis. We work with a group of reputable clinical eye experts to design and prepare the study, which is expected to start in 2023.

We work continuously with our patent portfolios to create comprehensive patent protection in the disease areas that we target with our projects. The now granted European patent of laquinimod further strengthens the protection of laquinimod in devastating eye diseases with high medical need.

The combination study with tasquinimod in multiple myeloma is ongoing. In the first cohort of the study, the safety and tolerability of tasquinimod combined with a standard oral treatment of ixazomib, lenalidomide and dexamethasone will be assessed together with preliminary efficacy. Our preclinical trials suggest possible synergy when these drugs are given together, and we look forward to concluding on the results late this year or early 2023.

In May, the FDA granted orphan drug designation for tasquinimod in myelofibrosis. This is an important step forward since it opens regulatory pathways facilitating rapid advancement of the development of tasquinimod in this rare and severe disease. Furthermore, this designation provides for a seven-year marketing exclusivity period.

Earlier this year we entered into an exclusive license agreement with Oncode Institute in the Netherlands and Erasmus University Medical Center (Erasmus MC), Rotterdam, for the global rights to patents relating to the use of tasquinimod in the treatment of myelofibrosis. We are preparing for a clinical proof of concept study in patients with this rare and severe disease. The clinical study will be financed by Oncode Institute and conducted in Europe, with a plan to start early 2023.

For patients with myelofibrosis, there is currently only a limited range of treatments, and the medical need for more treatment options is high. Initial preclinical data indicate that tasquinimod may have an effect on the disease, and we look forward to verifying this in a clinical program.

In parallel, we are working together with Dr. Kapil N. Bhalla, MD, Professor at MD Anderson Cancer Center, in Houston, TX, to further strengthen the program around tasquinimod in myelofibrosis.

Recently we reported together with our partner NeoTX that the first stage of the IIa clinical trial of naptumomab in combination with docetaxel in patients with advanced or metastatic non-small cell lung cancer (NSCLC) was completed, and the study has now advanced into the second stage. The study uses an adaptive design,Simon 2-stage, which is commonly used in cancer trials. The first stage of the trial required a minimum of two responses out of ten patients to move to the second stage, and this threshold was successfully reached in June. This is an early but positive indication of beneficial effect of this combination in the disease. NeoTX expects to have the full result of the study late next year.

In the clinical phase Ib/II study with naptumomab in combination with durvalumab in advanced solid tumors the cohort at the maximum tolerated dose (MTD) is also ongoing. We will provide an update from the study as soon as results are available, hopefully during 2022

Active Biotech has during the past years implemented a new direction for the company with focus on specialist indications within hematological malignances and inflammatory eye diseases for both our wholly owned projects tasquinimod and laquinimod. In addition, naptumomab, is being developed for the treatment of advanced solid tumors in collaboration with NeoTX. I believe we have laid a solid foundation for continued development in our projects, and the positive development has continued during the first half of 2022.

Clinical trials are ongoing in all projects, and I foresee multiple clinical milestones during the coming 12 months.

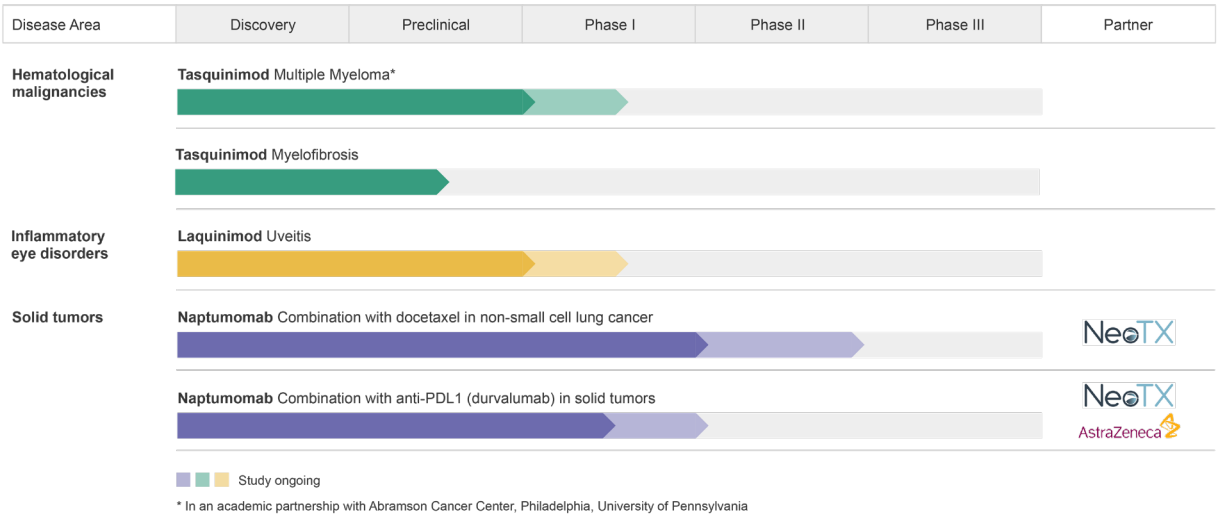
The board of directors resolved on August 4,2022, based on the authorisation from the general meeting, to carry out a rights issue to secure financing of the ongoing and planned development programs until the end of 2023. This will provide the company with the financial stability required to reach clinically important milestones and enable discussions with potential partners.

I look forward to giving you updates of our upcoming important clinical and company milestones, and I feel certain we will have a busy and rewarding period ahead of us.

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 a orally active small molecule immunomodulator with a novel mode of action, blocking tumor supporting pathways in the bone microenvironment. Tasquinimod is developed for the treatment of blood cancers including 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 7,000 new patients, respectively, are expected to be diagnosed each year.

The global sales of drugs for the treatment of multiple myeloma is projected at USD 27.8 billion in 2027 (Global Data Report March 2019).

The market for drugs used in the treatment of multiple myeloma experience 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 half of the market and the EU for approximately 40 percent of the total market sales.

Current treatments

Multiple myeloma patients undergo several lines of treatment. In both early and relapse treatment, the goal is to stabilize the patient's disease 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 will be developed as a new product class with a novel mechanism of action that differs from the others and thus has the potential to overcome the problem of drug resistance. The clinical safety profile of tasquinimod is well known. Given the good tolerability and the possibility to combine with the available product classes, tasquinimod has the potential to expand over time from an initial position as the 3rd line treatment as well as 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 calls refractory to Imids, proteosome inhibitors, and anti-CD-38 monoclonal antibodies. While none of the patients formally achieved a partial response, two patients with documented progressive myeloma at study entry achieved significant periods of stable disease on single-agent tasquinimod therapy.

In February 2022, the trial subsequently advanced to the previously planned combination part, 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). 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 0.1-1.0 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 present with 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. The market is projected at over USD 0.8 billion by 2028 (MarketWatch 2021).

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. A proof-of-concept study with tasquinimod in myelofibrosis patients is planned to start early 2023.

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 volunteers 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 SECOND QUARTER

- FDA granted Orphan Drug Designation for **tasquinimod** in myelofibrosis (May 18)

Laquinimod

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

Uveitis

Uveitis 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. 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, cataracts, glaucoma, damage to the optic nerve, and detachment of the retina.

The market

The treatment options for patients with non-infectious uveitis have not advanced substantially for a long period of time. 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.

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 not without risks.

Approximately 1.6 million people in the nine major markets were diagnosed with uveitis 2019, whereof approx. 600,000 patients received treatment. Of these about 240,000 will fail corticosteroids and are candidates for the 2nd line of treatment.

The global sales of drugs for uveitis totaled approx. USD 300 million in 2019 and sales are expected to reach approximately USD 0.8 billion by 2029 (Global Data Report 2021). 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.

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 in 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 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 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. The study will include up to 56 subjects treated in part 1 with an increasing dose of laquinimod eye drops and in part 2 with repeated doses of laquinimod eye drops.

The primary objective of the study is safety and tolerability to laquinimod eye drops and the secondary readouts include ocular toxicity, pharmacokinetics and exposure. More information about the study design is available at clinicaltrials.gov (NCT05187403). The single-ascending dose part of the study and the first multiple dose cohort are completed. The eye drop formulation of laquinimod was well tolerated, without serious side effects that can be linked to laquinimod at dose levels where we expect to achieve therapeutic concentrations. The multiple- dose part of the study is ongoing.

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

Previous clinical experience with laquinimod
During its years of advanced product development, clinical efficacy and safety data on laquinimod, oral formulation, 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 SECOND QUARTER

- **Laquinimod** eye drop phase I single ascending-dose part in healthy subjects was completed without reported safety concerns, multiple-dose part started
- Active Biotech strengthened the patent protection for **laquinimod** in eye disorders (April 26)

EVENTS AFTER THE END OF THE PERIOD

- The first part of the multiple-dose of **laquinimod** eye drops in the phase I study has been carried out without any serious side effects that can be linked to laquinimod and the study has therefore been expanded with another dose group

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 22 billion in 2019 (Global Newswire February 2020). The strong sales development for checkpoint inhibitors is expected to continue and sales are forecast at USD 40 billion in 2025 (Global Newswire February 2020).

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 both ongoing studies patients are pre-treated with obinutuzumab to lower the levels of anti-drug antibodies (ADA) to naptumomab. 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 will enroll 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.

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 SECOND QUARTER

- Successful completion of the first stage of the phase IIa clinical trial of **naptumomab** in combination with docetaxel and the study is now enrolling into the second stage (June 1)

FINANCIAL INFORMATION

Comments on the Group's results for the period January – June 2022
No sales were recorded during the period.

The operational costs totaled SEK 29.3 M (22.4) whereof research and development expenses amounted to SEK 22.2 M (15.6), the increase in costs representing an increased activity level which is reflected in the 30-percent cost increase.

The company's research efforts during the reporting period have been focused on the clinical development of tasquinimod in multiple myeloma and of the eye drop formulation of laquinimod in eye diseases. Collaborations to expand the preclinical and clinical development of tasquinimod and laquinimod are ongoing.

During the reporting period the financial resources have been focused on the preclinical and clinical development of the fully owned projects tasquinimod and laquinimod:

- The ongoing phase Ib/IIa clinical study with tasquinimod for treatment of multiple myeloma was initiated in August 2020 in collaboration with Penn University, USA. The study is progressing according to plan
- During the reporting period a patent licence agreement including preclinical and clinical collaboration for the development of tasquinimod in myelofibrosis was signed with Oncode Institute in the Netherlands
- Laquinimod is developed as a new product class for treatment of inflammatory eye diseases. A newly developed topical ophthalmic formulation is tested in a phase I clinical study, which was initiated in December 2021

Administrative expenses amounted to SEK 7.0 M (6.8).

The operating loss for the period amounted to SEK 29.3 M (loss: 22.4), the net financial loss for the period amounted to SEK 0.7 M (0.0) and the loss after tax to SEK 30.0 M (loss: 22.4).

Comments on the Group's results for the period April – June 2022
No sales were recorded during the period.

The operational costs totaled SEK 14.0 M (12.6) whereof research and development expenses amounted to SEK 10.5 M (9.2), the increase in costs is explained by increased preclinical and clinical activities for tasquinimod and laquinimod.

Administrative expenses amounted to SEK 3.4 M (3.5).

The operating loss for the period amounted to SEK 14.0 M (loss: 12.6), the net financial loss for the period amounted to SEK 0.3 M (0.0) and the loss after tax to SEK 14.3 M (loss: 12.6).

Cash flow, liquidity and financial position, Group, for the period January – June 2022
Cash and cash equivalents at the end of the period amounted to SEK 21.9 M, compared with SEK 53.1 M at the end of 2021. Cash flow for the period amounted to a negative SEK 31.3 M (pos: 52.3). The cash flow from operating activities amounted to a negative SEK 29.7 M (neg: 21.2). Cash flow from investing activities amounted to SEK 0.2 M (0.0) and financing activities amounted to a negative SEK 1.3 M (pos: 73.5) following the rights issue concluded in 2021 that added SEK 74.1 M to liquidity after issue costs.

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

Comments on the Parent Company's results and financial position for the period January – June 2022

No sales were recorded during the period. Operating expenses amounted to SEK 29.7 M (22.3). The Parent Company's operating loss for the period was SEK 29.7 M (loss: 22.3). Net financial income amounted to a SEK 19.3 M (0.0) and relates to an internal group transaction from the subsidiary Active Forskaren 1 KB, and the loss after financial items was SEK 10.4 M (loss: 22.4).

Cash and cash equivalents including short-term investments totaled SEK 21.6 M at the end of the period, compared with SEK 52.9 M on January 1, 2022.

Comments on the Parent Company's results and financial position for the period April – June 2022

No sales were recorded during the period. Operating expenses amounted to SEK 14.4 M (12.6). The Parent Company's operating loss for the period was SEK 14.4 M (loss: 12.6). Net financial income amounted to a SEK 19.7 M (0.0) and the income after financial items was SEK 5.3 M (loss: 12.6).

Shareholders' equity

Consolidated shareholders' equity at the end of the period amounted to SEK 16.9 M, compared with SEK 46.7 M at year-end 2021.

The number of shares outstanding at the end of the period totaled 218,054,720. At the end of the period, the equity/assets ratio for the Group was 51.5 percent, compared with 82.2 percent at year-end 2021. The corresponding figures for the Parent Company, Active Biotech AB, were 22.9 percent and 26.4 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 applicable time period in the respective incentive programs. Total costs, including social contributions, as of June 30, 2022, amounted to SEK 1115 K, whereof SEK 187 K refer to the period January-June, 2022.

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 9 (8), of which the number of employees in the research and development organization accounted for 6 (5). The number of employees at the end of the period amounted to 9 whereof 6 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 will be funded by Oncode Institute
- laquinimod, targeted towards inflammatory eye disorders. A clinical phase I trial with a topical ophthalmic formulation was initiated in December 2021
- 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

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

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 in myeloid disorders and laquinimod in eye disorders.

Financing and financial position:
The Board and the management team continuously assess the Groups financial viability and access to cash. The available liquidity can fund continued operations through the first quarter 2023 and Active Biotech therefore require access to further growth capital to maintain progress of its unpartnered project portfolio.

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 and interest rates. A detailed account of these risks and uncertainties is presented in the Directors' Report in the Annual Report 2021.

At the beginning of 2022, the situation between Russia and Ukraine deteriorated sharply which has created great uncertainty. The market reactions on the development have been strongly negative, which is shown through significant price drops in the stock markets, including the Swedish. In addition, the United States and Europe have imposed economic sanctions on Russia.

Active Biotech has no operations in Russia or Ukraine and has so far not been affected in any material way. However, it cannot be completely ruled out that the macro-economic uncertainty created in the financial markets, might have an impact on Active Biotech's possibilities for future financing of the operations. If such an impact on the operation is expected to arise, Active Biotech will provide updates as necessary.

With regards to the prevailing situation for COVID-19, it is still uncertain how global measures against COVID-19, and prioritization of health care resources, may affect timelines of project and the ongoing and planned clinical activities might be delayed with possible implications on the financing risks. The Group's operations are primarily conducted in the Parent Company, which is why risks and uncertainties refer to both the Group and the Parent Company.

EVENTS AFTER THE END OF THE PERIOD

- The first part of the multiple-dose of l**aquinimod** eye drops in the phase I study has been completed without any serious side effects that can be linked to laquinimod and the study has therefore been expanded with a dose group (July)
- On August 4, 2022, the Board of Directors decided, based on the authorization from the general meeting, to carry out a rights issue with preemptive rights for shareholders

CONSOLIDATED PROFIT AND LOSS

SEK M	Apr-Jun 2022	Apr-Jun 2021	Jan-Jun 2022	Jan-Jun 2021	Full Year 2021
Net sales	**–**	**–**	**–**	**–**	**–**
Administrative expenses	–3.4	–3.5	–7.0	–6.8	–15.2
Research and development costs	–10.5	–9.2	–22.2	–15.6	–34.5
Operating profit/loss	**–14.0**	**–12.6**	**–29.3**	**–22.4**	**–49.8**
Net financial items	–0.3	–0.0	–0.7	–0.0	–0.0
Profit/loss before tax	**–14.3**	**–12.6**	**–30.0**	**–22.4**	**–49.8**
Tax	–	–	–	–	–
Net profit/loss for the period	**–14.3**	**–12.6**	**–30.0**	**–22.4**	**–49.8**
Comprehensive profit/loss attributable to:					
Parent Company shareholders	–14.3	–12.6	–30.0	–22.4	–49.8
Non-controlling interest	–	–	–	–	–
Net profit/loss for the period	**–14.3**	**–12.6**	**–30.0**	**–22.4**	**–49.8**
Comprehensive profit/loss per share before dilution (SEK)	–0.07	–0.06	–0.14	–0.11	–0.24
Comprehensive profit/loss per share after dilution (SEK)	–0.07	–0.06	–0.14	–0.11	–0.24

STATEMENT OF PROFIT AND LOSS AND CONSOLIDATED COMPREHENSIVE INCOME

SEK M	Apr-Jun 2022	Apr-Jun 2021	Jan-Jun 2022	Jan-Jun 2021	Full Year 2021
Net profit/loss for the period	–14.3	–12.6	–30.0	–22.4	–49.8
Other comprehensive income	–	–	–	–	–
Total comprehensive profit/loss for the period	**–14.3**	**–12.6**	**–30.0**	**–22.4**	**–49.8**
Total other comprehensive profit/loss for the period attributable to:					
Parent Company shareholders	–14.3	–12.6	–30.0	–22.4	–49.8
Non-controlling interest	–	–	–	–	–
Total comprehensive profit/loss for the period	**–14.3**	**–12.6**	**–30.0**	**–22.4**	**–49.8**
Depreciation/amortization included in the amount of	0.6	0.3	1.0	0.7	1.3
Investments in tangible fixed assets	–	–	–	–	–
Weighted number of outstanding common shares before dilution (000s)	218,055	217,972	218,027	205,830	211,901
Weighted number of outstanding common shares after dilution (000s)	218,055	217,972	218,027	205,830	211,901
Number of shares at close of the period (000s)	218,055	217,972	218,055	217,972	217,972

CONSOLIDATED STATEMENT OF FINANCIAL POSITION

SEK M	Jun 30 2022	Jun 30 2021	Dec 31 2021
Intangible fixed assets	0.2	–	–
Tangible fixed assets	6.6	1.2	0.9
Long-term receivables	0.4	0.0	0.0
Total fixed assets	**7.2**	**1.2**	**0.9**
Current receivables	3.7	3.3	2.7
Cash and cash equivalents	21.9	78.5	53.1
Total current assets	**25.6**	**81.8**	**55.9**
Total assets	**32.8**	**83.0**	**56.8**
Shareholders equity	16.9	73.9	46.7
Long-term liabilities	4.8	0.1	0.2
Current liabilities	11.1	8.9	9.9
Total shareholders equity and liabilities	**32.8**	**83.0**	**56.8**

CONSOLIDATED STATEMENT OF CHANGES IN SHAREHOLDERS EQUITY

SEK M	Jun 30 2022	Jun 30 2021	Dec 31 2021
Opening balance	46.7	22.1	22.1
Loss for the period	–30.0	–22.4	–49.8
Other comprehensive income for the period	–	–	–
Comprehensive profit/loss for the period	*–30.0*	*–22.4*	*–49.8*
Share-based payments that are settled with equity instruments, IFRS2	0.2	0.1	0.3
New share issue	–	74.1	74.1
Balance at close of period	**16.9**	**73.9**	**46.7**

CONDENSED CONSOLIDATED CASH-FLOW STATEMENT

SEK M	Jan-Jun 2022	Jan-Jun 2021	Full Year 2021
Loss after financial items	**–30.0**	**–22.4**	**–49.8**
Adjustment for non-cash items, etc.	1.2	0.8	1.6
Cash flow from operating activities before changes in working capital	**–28.8**	**–21.6**	**–48.3**
Changes in working capital	–0.9	0.5	2.1
Cash flow from operating activities	**–29.7**	**–21.2**	**–46.2**
Investments in intangible assets	–0.2	–	–
Cash flow from investments	**–0.2**	**–**	**–**
New share issue	–	74.1	74.1
Loans raised/amortization of loan liabilities	–1.3	–0.7	–1.0
Cash flow from financing activities	**–1.3**	**73.5**	**73.1**
Cash flow for the period	**–31.3**	**52.3**	**26.9**
Opening cash and cash equivalents	**53.1**	**26.2**	**26.2**
Closing cash and cash equivalents	**21.9**	**78.5**	**53.1**

KEY FIGURES

	Jun 30		Dec 31
	2022	2021	2021
Shareholders equity, SEK M	16.9	73.9	46.7
Equity per share, SEK	0.08	0.34	0.21
Equity/assets ratio in the Parent Company	22.9 %	43.2 %	26.4 %
Equity/assets ratio in the Group	51.5 %	89.1 %	82.2 %
Average number of annual employees	9	8	8

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

CONSOLIDATED PROFIT AND LOSS

	2018				2019				2020				2021				2022	
SEK M	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q1
Net Sales	**4.8**	**5.7**	**4.7**	**4.8**	**5.5**	**1.1**	**0.9**	**0.9**	**0.5**	**–**	**–**	**6.2**	**–**	**–**	**–**	**–**	**–**	**–**
Administration expenses	-2.9	-2.6	-2.5	-2.5	-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
Research and development costs	-10.5	-10.4	-9.1	-9.4	-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
Other operating expenses/ income	–	–	–	–	–	2.2	-2.2	–	–	–	–	–	–	–	–	–	–	–
Operating profit/loss	**-8.5**	**-7.3**	**-6.9**	**-7.1**	**-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**
Net financial items	-1.7	-1.7	-1.8	-1.8	-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
Profit/loss before tax	**-10.2**	**-9.1**	**-8.7**	**-8.9**	**-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**
Tax	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–
Net profit/ loss for the period	**-10.2**	**-9.1**	**-8.7**	**-8.9**	**-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**

ACTIVE BIOTECH PARENT COMPANY – INCOME STATEMENT, CONDENSED

SEK M	Apr-Jun 2022	Apr-Jun 2021	Jan-Jun 2022	Jan-Jun 2021	Full Year 2021
Net Sales	**–**	**–**	**–**	**–**	**–**
Administration expenses	–3.4	–3.5	–7.1	–6.8	–15.3
Research and development costs	–11.0	–9.1	–22.6	–15.6	–34.6
Operating profit/loss	**–14.4**	**–12.6**	**–29.7**	**–22.3**	**–49.9**
Profit/loss from financial items:					
Result from participations in group companies	20.0	–	20.0	–	–
Interest income and similar income-statement items	–0.0	0.0	–	0.0	0.0
Interest expense and similar income-statement items	–0.3	–0.0	–0.7	–0.0	–0.0
Profit/loss after financial items	**5.3**	**–12.6**	**–10.4**	**–22.4**	**–49.9**
Tax	–	–	–	–	–
Net profit/loss for the period	**5.3**	**–12.6**	**–10.4**	**–22.4**	**–49.9**
Statement of comprehensive income parent company					
Net profit/loss for the period	5.3	–12.6	–10.4	–22.4	–49.9
Other comprehensive income	–	–	–	–	–
Total comprehensive profit/loss for the period	**5.3**	**–12.6**	**–10.4**	**–22.4**	**–49.9**

ACTIVE BIOTECH PARENT COMPANY – BALANCE SHEET, CONDENSED

SEK M	Jun 30 2022	Jun 30 2021	Dec 31 2021
Intangible fixed assets	0.2	–	–
Financial fixed assets	40.9	40.5	40.5
Total fixed assets	**41.1**	**40.5**	**40.5**
Current receivables	3.7	3.3	2.7
Short-term investments	20.1	74.9	50.8
Cash and bank balances	1.5	3.4	2.1
Total current assets	**25.4**	**81.6**	**55.7**
Total assets	**66.5**	**122.1**	**96.2**
Shareholders equity	15.2	52.7	25.4
Current liabilities	51.3	69.4	70.8
Total equity and liabilities	**66.5**	**122.1**	**96.2**

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.

NOT 2: FAIR VALUE OF FINANCIAL INSTRUMENTS

SEK M	Jun 30, 2022 Level 2	Dec 31, 2021 Level 2
Short-term investments	20.1	50.8

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 2022: November 3 (Q3)
- Year End Report 2022: February 9, 2023

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

The interim report for the January – June period 2022 provides a true and fair view of the Parent Company´s and the Group's operations, position and results, and describes significant risks and uncertainties that the Parent Company and Group companies face.

Lund August 4, 2022
Active Biotech AB (publ)

Michael Shalmi
Chairman

Uli Hacksell
Board Member

Aleksandar Danilovski
Board Member

Elaine Sullivan
Board Member

Peter Thelin
Board Member

Axel Glasmacher
Board Member

Helén Tuvesson
President and CEO

This interim report is unaudited.

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 a clinical phase I study with a topical ophthalmic formulation, to be followed by phase II 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.