Active Biotech

INTERIM REPORT Q3 2022 | ACTIVE BIOTECH AB

"Continued very positive developments in our projects"

THIRD QUARTER IN BRIEF

- Based on the authorization from the general meeting, the board of directors resolved to carry out a rights issue of approximately SEK 55 million to secure financing of the ongoing and planned development programs (Aug 4)
- 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
- Active Biotech announces final outcome of the Company´s rights issue (Sep 7)

EVENTS AFTER THE END OF THE PERIOD

- Active Biotech further strengthens the patent protection for laquinimod in eye disorders with a granted patent in US (Oct 24)

FINANCIAL SUMMARY

	Jul-Sep		Jan-Sep		Full Year
SEK M	2022	2021	2022	2021	2021
Net sales	–	–	–	–	–
Operating profit/loss	–13.4	–11.3	–42.6	–33.6	–49.8
Profit/loss after tax	–13.4	–11.2	–43.4	–33.7	–49.8
Earnings per share (SEK)	–0.06	–0.05	–0.19	–0.16	–0.24
Cash and cash equivalents (at close of period)			55.0	68.4	53.1

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 persons set out above, for publication on November 3, 2022, at 08.30 a.m. CET.

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Helén Tuvesson
CEO

We are in a solid position to reach the upcoming milestones in 2023

COMMENTS FROM CEO

Our unique projects in cancer and eye disorders continued to develop positively, and in August the board decided to conduct a rights offering to existing shareholders of approx. SEK 55 million to secure financing of the ongoing and planned development activities. The rights issue was concluded in early September and resulting in a cash injection of SEK 45,5 million after issue expenses. This will provide the company with the financial stability required to reach clinically important milestones.

The clinical phase I trial to test the safety and tolerability of the proprietary developed eye drop formulation of *laquinimod* is ongoing. During the summer, we decided based on the good tolerability and safety of laquinimod eye drops, to expand the study with an additional higher dose cohort to ensure correct determination of the recommended dose for further studies. We expect to have results available in the beginning of next year, and currently prepare for a phase II study in patients with uveitis, to be initiated in 2023.

Laquinimod is protected by a patent portfolio of strategically important patents and patent applications. The portfolio has recently been expanded with granted patents in Europe and US for use of laquinimod in eye disorders associated with excessive vascularization. The new patents provide protection until 2040.

In the *tasquinimod* project, we follow the ongoing study in multiple myeloma with excitement while preparing for the start of a study in myelofibrosis. The safety of the ongoing combination study with tasquinimod in relapsed refractory multiple myeloma is planned to be concluded late this year or early 2023. Thereafter, we can start a cohort expansion to determine preliminary efficacy at the identified safe dose of tasquinimod in this standard oral treatment combination of ixazomib, lenalidomide and dexamethasone.

Given the mode of action of tasquinimod modulating the myeloid cell function, we believe there is a broad potential of tasquinimod in hematological malignances besides multiple myeloma. Initial preclinical data propose that tasquinimod could act as a disease modifier in myelofibrosis, and together with Erasmus University Medical Center (Erasmus MC) in Rotterdam we prepare for a clinical proof-of-concept study in patients with this rare and severe disease. The clinical study will be conducted at clinical sites in Europe and financed by Oncode Institute, with the plan to start 2023.

In parallel, we work together with Dr. Kapil N. Bhalla, MD, Professor at MD Anderson Cancer Center, in Houston, TX, in an extended preclinical program for tasquinimod in myelofibrosis.

The clinical trials with *naptumomab* with different settings in advanced solid tumors, carried out by our partner NeoTX, are ongoing. The phase IIa trial of naptumomab in combination with docetaxel in patients with non-small cell lung cancer (NSCLC) is continuing after the successful response analysis communicated during the spring. NeoTX expects to have the full study results late next year.

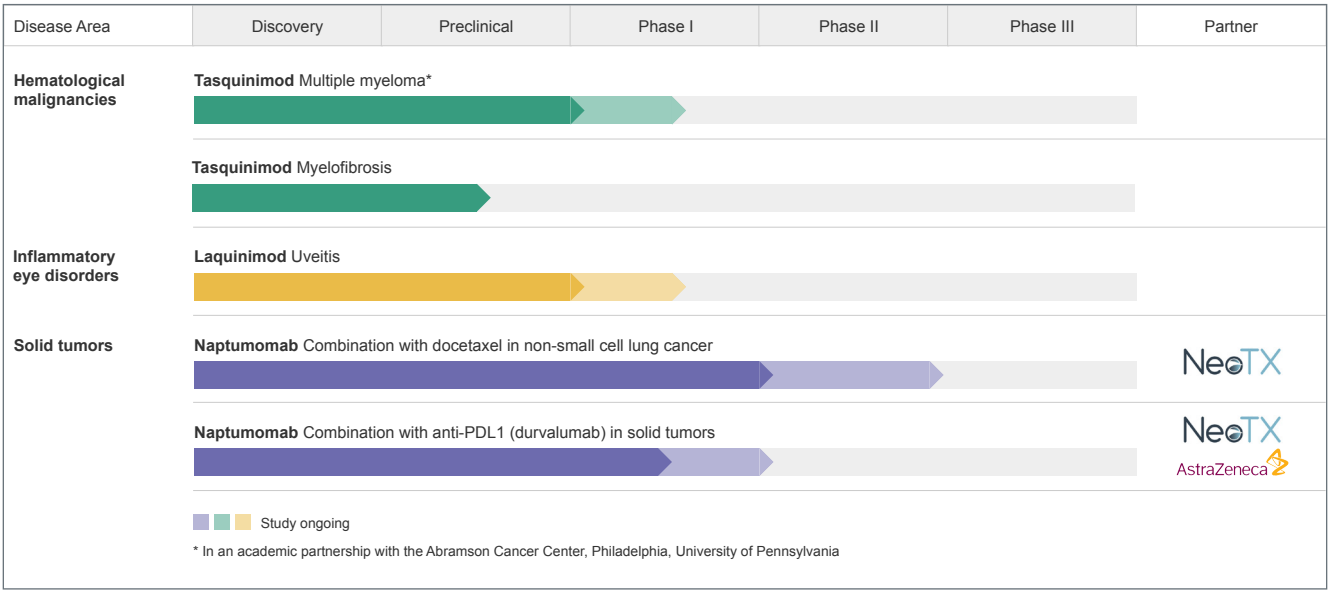
For the clinical phase Ib/II study with naptumomab in combination with durvalumab , we will provide an update from the study as soon as results are available, hopefully during this year.

I am pleased with the progress in our projects during the quarter and we now have a solid foundation for continued development of our programs in cancer and inflammatory eye disorders. With the completed rights issue, we have ensured the financing of the projects to achieve important planned clinical milestones. I am grateful for the support from both existing and new shareholders and will update the market as the projects advance.

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 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 7,000 new patients, respectively, are expected to be diagnosed each year (Global Data Report 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 27.8 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 half of the market and the EU for approximately 40 percent of the total market sales (Global Data Report 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 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 refractory to IMiDs, 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.

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 0.4-1.3 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. 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 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.

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.

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 (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 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 (Global Data Report 2021, Uveitis – Global Drug Forecast and Market Analysis to 2029).

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, Uveitis – Global Drug Forecast and Market Analysis to 2029). 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 THIRD QUARTER

- The first part of the multiple doses 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

EVENTS AFTER THE END OF THE PERIOD

- Active Biotech further strengthens the patent protection for laquinimod in eye disorders with a granted patent in US (Oct 24)

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.

FINANCIAL INFORMATION

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

The operational costs totaled SEK 42.6 M (33.6) whereof research and development expenses amounted to SEK 32.6 M (23.4), the increase in costs represents an increased activity in the projects which is reflected in the 39-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 development programs include:

- 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 license 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 10.1 M (10,3).

The operating loss for the period amounted to SEK 42.6 M (loss: 33.6), the net financial loss for the period amounted to SEK 0.7 M (0.0) and the loss after tax to SEK 43.4 M (loss: 33.7).

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

The operational costs totaled SEK 13.4 M (11.3) whereof research and development expenses amounted to SEK 10.3 M (7.8), the increase in costs is explained by increased preclinical and clinical activities for tasquinimod and laquinimod.

Administrative expenses amounted to SEK 3.0 M (3.5).

The operating loss for the period amounted to SEK 13.4 M (loss: 11.3), the net financial loss for the period amounted to SEK 0.0 M (0.0) and the loss after tax to SEK 13.4 M (loss: 11.2).

Cash flow, liquidity and financial position, Group, for the period January – September 2022
Cash and cash equivalents at the end of the period amounted to SEK 55.0 M, compared with SEK 53.1 M at the end of 2021. Cash flow for the period amounted to a positive SEK 1.9 M (pos: 42.2). The cash flow from operating activities amounted to a negative SEK 41.7 M (neg: 31.0). Cash flow from investing activities amounted to a negative SEK 0.2 M (0.0) and financing activities amounted to a positive SEK 43.8 M (pos: 73.1) following the rights issue concluded in the third quarter 2022 that added SEK 45.5 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 – September 2022

No sales were recorded during the period. Operating expenses amounted to SEK 43.1 M (33.6). The Parent Company's operating loss for the period was SEK 43.1 M (loss: 33.6). Net financial income amounted to a SEK 19.3 M (0.1) and relates to an internal group transaction from the subsidiary Active Forskaren 1 KB, and the loss after financial items was SEK 23.7 M (loss: 33.6).

Cash and cash equivalents including short-term investments totaled SEK 54.8 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 July – September 2022

No sales were recorded during the period. Operating expenses amounted to SEK 13.4 M (11.3).
The Parent Company's operating loss for the period was SEK 13.4 M (loss: 11.3). Net financial income amounted to a SEK 0.0 M (0.0) and the loss after financial items was SEK 13.4 M (loss: 11.2).

Shareholders' equity

Consolidated shareholders' equity at the end of the period amounted to SEK 49.2 M, compared with SEK 46.7 M at year-end 2021.

The number of shares outstanding at the end of the period totaled 264,886,797. At the end of the period, the equity/assets ratio for the Group was 75.0 percent, compared with 82.2 percent at year-end 2021. The corresponding figures for the Parent Company, Active Biotech AB, were 47.7 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 time period 2020 to 2022 in the respective incentive programs. Total costs, including social contributions, as of September 30, 2022, amounted to SEK 1339 K, whereof SEK 411 K refer to the period January-September, 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 hematological malignancies.

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 hematological malignancies 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. A rights issue was successfully concluded in September 2022 when SEK 45.5 M after issue costs was secured. The rights issue aimed at providing Active Biotech with the financial stability required to await the outcome of the ongoing clinical studies and to conduct negotiations with partners.

The available liquidity can fund continued operations through 2023 and Active Biotech will 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, currencies 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

- Active Biotech further strengthens the patent protection for laquinimod in eye disorders with a granted patent in US (Oct 24)

CONSOLIDATED PROFIT AND LOSS

SEK M	Jul-Sep 2022	Jul-Sep 2021	Jan-Sep 2022	Jan-Sep 2021	Full Year 2021
Net sales	**–**	**–**	**–**	**–**	**–**
Administrative expenses	–3.0	–3.5	–10.1	–10.3	–15.2
Research and development costs	–10.3	–7.8	–32.6	–23.4	–34.5
Operating profit/loss	**–13.4**	**–11.3**	**–42.6**	**–33.6**	**–49.8**
Net financial items	–0.0	0.0	–0.7	–0.0	–0.0
Profit/loss before tax	**–13.4**	**–11.2**	**–43.4**	**–33.7**	**–49.8**
Tax	–	–	–	–	–
Net profit/loss for the period	**–13.4**	**–11.2**	**–43.4**	**–33.7**	**–49.8**
Comprehensive profit/loss attributable to:					
Parent Company shareholders	–13.4	–11.2	–43.4	–33.7	–49.8
Non-controlling interest	–	–	–	–	–
Net profit/loss for the period	**–13.4**	**–11.2**	**–43.4**	**–33.7**	**–49.8**
Comprehensive profit/loss per share before dilution (SEK)	–0.06	–0.05	–0.19	–0.16	–0.23
Comprehensive profit/loss per share after dilution (SEK)	–0.06	–0.05	–0.19	–0.16	–0.23

STATEMENT OF PROFIT AND LOSS AND CONSOLIDATED COMPREHENSIVE INCOME

SEK M	Jul-Sep 2022	Jul-Sep 2021	Jan-Sep 2022	Jan-Sep 2021	Full Year 2021
Net profit/loss for the period	–13.4	–11.2	–43.4	–33.7	–49.8
Other comprehensive income	–	–	–	–	–
Total comprehensive profit/loss for the period	**–13.4**	**–11.2**	**–43.4**	**–33.7**	**–49.8**
Total other comprehensive profit/loss for the period attributable to:					
Parent Company shareholders	–13.4	–11.2	–43.4	–33.7	–49.8
Non-controlling interest	–	–	–	–	–
Total comprehensive profit/loss for the period	**–13.4**	**–11.2**	**–43.4**	**–33.7**	**–49.8**
Depreciation/amortization included in the amount of	0.4	0.3	1.3	1.0	1.3
Investments in tangible fixed assets	–	–	–	–	–
Weighted number of outstanding common shares before dilution (000s)	227,921	220,038	222,750	211,866	213,909
Weighted number of outstanding common shares after dilution (000s)	227,921	220,038	222,750	211,866	213,909
Number of shares at close of the period (000s)	264,887	217,972	264,887	217,972	217,972

CONSOLIDATED STATEMENT OF FINANCIAL POSITION

SEK M	Sep 30 2022	Sep 30 2021	Dec 31 2021
Intangible fixed assets	0.2	–	–
Tangible fixed assets	6.2	0.9	0.9
Long-term receivables	0.4	0.0	0.0
Total fixed assets	**6.9**	**0.9**	**0.9**
Current receivables	3.8	3.4	2.7
Cash and cash equivalents	55.0	68.4	53.1
Total current assets	**58.8**	**71.8**	**55.9**
Total assets	**65.6**	**72.7**	**56.8**
Shareholders equity	49.2	62.8	46.7
Long-term liabilities	4.5	0.1	0.2
Current liabilities	12.0	9.8	9.9
Total shareholders equity and liabilities	**65.6**	**72.7**	**56.8**

CONSOLIDATED STATEMENT OF CHANGES IN SHAREHOLDERS EQUITY

SEK M	Sep 30 2022	Sep 30 2021	Dec 31 2021
Opening balance	46.7	22.1	22.1
Loss for the period	–43.4	–33.7	–49.8
Other comprehensive income for the period	–	–	–
Comprehensive profit/loss for the period	*–43.4*	*–33.7*	*–49.8*
Share-based payments that are settled with equity instruments, IFRS2	0.4	0.2	0.3
New share issue	45.5	74.1	74.1
Balance at close of period	**49.2**	**62.8**	**46.7**

CONDENSED CONSOLIDATED CASH-FLOW STATEMENT

SEK M	Jan-Sep 2022	Jan-Sep 2021	Full Year 2021
Loss after financial items	**–43.4**	**–33.7**	**–49.8**
Adjustment for non-cash items, etc.	1.7	1.2	1.6
Cash flow from operating activities before changes in working capital	**–41.7**	**–32.5**	**–48.3**
Changes in working capital	–0.0	1.5	2.1
Cash flow from operating activities	**–41.7**	**–31.0**	**–46.2**
Investments in intangible assets	–0.2	–	–
Cash flow from investments	**–0.2**	**–**	**–**
New share issue	45.5	74.1	74.1
Loans raised/amortization of loan liabilities	–1.7	–1.0	–1.0
Cash flow from financing activities	**43.8**	**73.1**	**73.1**
Cash flow for the period	**1.9**	**42.2**	**26.9**
Opening cash and cash equivalents	**53.1**	**26.2**	**26.2**
Closing cash and cash equivalents	**55.0**	**68.4**	**53.1**

KEY FIGURES

	Sep 30		Dec 31
	2022	2021	2021
Shareholders equity, SEK M	49.2	62.8	46.7
Equity per share, SEK	0.19	0.29	0.21
Equity/assets ratio in the Parent Company	47.7 %	37.1 %	26.4 %
Equity/assets ratio in the Group	75.0 %	86.3 %	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	Q2	Q3
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	–3.0
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	–10.3
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**	**–13.4**
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	–0.0
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**	**–13.4**
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**	**–13.4**

ACTIVE BIOTECH PARENT COMPANY – INCOME STATEMENT, CONDENSED

SEK M	Jul-Sep 2022	Jul-Sep 2021	Jan-Sep 2022	Jan-Sep 2021	Full Year 2021
Net Sales	**–**	**–**	**–**	**–**	**–**
Administration expenses	–3.0	–3.5	–10.1	–10.3	–15.3
Research and development costs	–10.3	–7.8	–33.0	–23.4	–34.6
Operating profit/loss	**–13.4**	**–11.3**	**–43.1**	**–33.6**	**–49.9**
Profit/loss from financial items:					
Result from participations in group companies	–	–	20.0	–	–
Interest income and similar income-statement items	0.0	0.0	0.0	0.1	0.0
Interest expense and similar income-statement items	–0.0	0.0	–0.7	–0.0	–0.0
Profit/loss after financial items	**–13.4**	**–11.2**	**–23.7**	**–33.6**	**–49.9**
Tax	–	–	–	–	–
Net profit/loss for the period	**–13.4**	**–11.2**	**–23.7**	**–33.6**	**–49.9**
Statement of comprehensive income parent company					
Net profit/loss for the period	–13.4	–11.2	–23.7	–33.6	–49.9
Other comprehensive income	–	–	–	–	–
Total comprehensive profit/loss for the period	**–13.4**	**–11.2**	**–23.7**	**–33.6**	**–49.9**

ACTIVE BIOTECH PARENT COMPANY – BALANCE SHEET, CONDENSED

SEK M	Sep 30 2022	Sep 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	3.8	3.4	2.7
Short-term investments	8.1	66.9	50.8
Cash and bank balances	46.7	1.3	2.1
Total current assets	**58.6**	**71.6**	**55.7**
Total assets	**99.7**	**112.1**	**96.2**
Shareholders equity	47.5	41.6	25.4
Current liabilities	52.1	70.6	70.8
Total equity and liabilities	**99.7**	**112.1**	**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	Sep 30, 2022 Level 2	Dec 31, 2021 Level 2
Short-term investments	8.1	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

- 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 – September 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, November 3, 2022
Active Biotech AB (publ)

Helén Tuvesson
President and CEO

REVIEW REPORT

To the Board of Directors of Active Biotech AB (publ.)
Corp. id. 556223-9227

Introduction
We have reviewed the condensed interim financial information (interim report) of Active Biotech AB (publ.) as of 30 September 2022 and the nine-month period then ended. The Board of Directors and the Managing Director are responsible for the preparation and presentation of this interim report in accordance with IAS 34 and the Annual Accounts Act. Our responsibility is to express a conclusion on this interim report based on our review.

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

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

Malmö November 3, 2022
KPMG AB

Linda Bengtsson
Authorized Public Accountant

About Active Biotech

Active Biotech AB (publ) (NASDAQ Stockholm: ACTI) is a biotechnology company that deploys its extensive knowledge base and portfolio of compounds to develop first-in-class immunomodulatory treatments for specialist oncology and immunology indications with a high unmet medical need and significant commercial potential. Following a portfolio refocus, the business model of Active Biotech aims to advance projects to the clinical development phase and then further develop the programs internally or pursue in partnership. Active Biotech currently holds three projects in its portfolio:
The wholly owned small molecule immunomodulators, tasquinimod and laquinimod, both having a mode of actions that includes modulation of myeloid immune cell function, are targeted towards hematological malignancies and inflammatory eye disorders, respectively. Tasquinimod, is in clinical phase Ib/IIa for treatment of multiple myeloma. Laquinimod is in 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.