

# Q1 Q2 Q3 Q4

## INTERIM REPORT Q1 2022 | ACTIVE BIOTECH AB

The year has started well with an intensive first quarter

### FIRST QUARTER IN BRIEF

- Dr. Erik Vahtola appointed Chief Medical Officer (Jan 01)
- First patient dosed in the combination part of the phase Ib/IIa study of **tasquinimod** in multiple myeloma (Feb 07)
- Active Biotech entered into global patent license agreement with Oncode Institute for **tasquinimod** in myelofibrosis (Feb 9)

### EVENTS AFTER THE END OF THE PERIOD

- **Laquinimod** eye drop phase I single ascending-dose part in healthy subjects finished with no safety concerns, multiple-dose part started

### FINANCIAL SUMMARY

SEK M	Jan-Mar		Full-year 2021
	2022	2021	
Net sales	-	-	-
Operating profit/loss	-15.3	-9.7	-49.8
Profit/loss after tax	-15.7	-9.8	-49.8
Earnings per share (SEK)	-0.07	-0.05	-0.24
Cash and cash equivalents (at close of period)	37.8	92.0	53.1

The report is also available at [www.activebiotech.com](http://www.activebiotech.com)

Active Biotech is obligated to make public the information contained in this report pursuant to the EU Market Abuse Regulation. This information was provided to the media, through the agency of the contact person set out above, for publication on April 21, 2022, at 08.30 a.m. CET.



**Helén Tuveesson**  
CEO



*We have broadened the program around tasquinimod to include myelofibrosis, a rare blood cancer with limited treatment options.*

## COMMENTS FROM THE CEO

**We have put a productive year behind us where our prioritized projects in cancer and inflammatory eye diseases developed positively. At the beginning of 2022, we strengthened our clinical organization with Dr Erik Vahtola, Chief Medical Officer responsible for the growing clinical project portfolio. The year has started well with an intensive first quarter. We have broadened the program around tasquinimod to include myelofibrosis, a rare blood cancer with limited treatment options. The plan is to start a clinical study in patients with myelofibrosis in early 2023. Our other projects are progressing according to plan.**

In February 2022, we announced that we have entered into a patent license agreement with the OncoCode Institute in the Netherlands. We intend to collaborate on the development of tasquinimod in myelofibrosis. Our collaboration will include a preclinical program to extend the understanding of how tasquinimod works in the disease as well as attempts to support clinical development. At the same time, preparations are proceeding for a first clinical trial with tasquinimod in myelofibrosis. The plan for now is that the study will start early 2023. The study, which is funded by OncoCode Institute, will preferably be conducted in Europe. In parallel, we have initiated a preclinical collaboration with Dr. Kapil N. Bhalla, MD, Professor at MD Anderson Cancer Center, in Houston, TX, to further strengthen the program around tasquinimod in myelofibrosis.

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.

During the first quarter, the first patient was recruited to the combination part of the study with tasquinimod in multiple myeloma. In this part of the study, tasquinimod is combined with a standard oral treatment of ixazomib, lenalidomide and dexamethasone. Besides the main purpose of the study which is to ensure that the combination is safe and tolerable, the preliminary efficacy of the combination will also be measured. Our preclinical trials suggest possible synergy when these drugs are given together, and we look forward to following the study.

Since December 2021, we have conducted a phase I clinical trial in healthy subjects to test the safety and tolerability of our proprietary developed eye drop formulation of laquinimod. The first single ascending-dose part of the study is completed and laquinimod was well tolerated at all dose levels. The multiple-dose part of the study is currently ongoing. We look forward to reviewing the results of the study around the end of the first half of this year. Planning for a phase II study in patients with uveitis is ongoing and it is expected to start in 2023 depending on the results from phase I.

The clinical studies with naptumomab in selected solid tumors are proceeding according to plan. We expect to be able to provide an update from the phase Ib/II study with naptumomab in combination with durvalumab, during the first half of this year. For the phase II study in lung cancer, the first evaluation will take place in 2023.

Last year, we laid a solid foundation for continued development in our projects in cancer and inflammatory eye diseases. The positive development has continued during the first quarter of 2022, and I look forward to updating you as the projects progress.

Helén Tuveesson, CEO

# PROJECTS

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

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

## Tasquinimod

**Tasquinimod is a 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 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 is approximately 30,000 patients, in Europe and Japan an estimated 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, 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 early as well as 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.

An important milestone was reached in October 2021:

- Ten patients in part A have 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 trial has now 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](https://clinicaltrials.gov) (NCT04405167).

**Myelofibrosis**

Myelofibrosis is a rare (orphan) blood cancer belonging to a group of disorders called myeloproliferative neoplasms. 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.

Myelofibrosis is a rare form of blood cancer with an estimated annual incidence of 0.4-1.3 cases per 100 000 people in Europe. There are only limited treatment options available for myelofibrosis patients. The market is projected at over USD 1.0 billion by 2027 (MarketWatch 2021).

**Tasquinimod in myelofibrosis**

Active Biotech will explore myelofibrosis as a new high value orphan indication for tasquinimod within blood cancers in collaboration with a research group at Erasmus MC, Netherlands. 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 FIRST QUARTER**

- First patient dosed in the combination part of the Phase Ib/Ila study of tasquinimod in multiple myeloma (Feb 07)
- Active Biotech entered into global patent license agreement with Oncode Institute for tasquinimod in myelofibrosis (Feb 9)

## 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, meaning 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 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 colour 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 totalled apprx. 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 non-anterior 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 42 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](https://clinicaltrials.gov) (NCT05187403).

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 AFTER THE END OF THE PERIOD**

- Laquinimod eye-drop phase I single ascending-dose part in healthy subjects finished with no safety concerns, multiple-dose part started

## 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/cancer](http://www.who.int/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 (JP Morgan Equity research 2018).

### **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, 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 H2 2019 and is performed under an agreement with AstraZeneca. More information about the study is available at [clinicaltrials.gov](https://clinicaltrials.gov) (NCT03983954) and at [neotx.com](http://neotx.com).

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](https://clinicaltrials.gov) (NCT04880863) and [neotx.com](https://www.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 – March 2022

No sales were recorded during the period.

The total operational costs for the period amounted to SEK 15.3 M (9.7) whereof research and development expenses totaled SEK 11.7 M (6.4), representing an increased activity level which is reflected in the 83-percent cost increase.

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

The ongoing preclinical and clinical development of the fully owned development projects include:

- the ongoing phase Ib/IIa clinical study with tasquinimod for treatment of multiple myeloma that was initiated in August 2020 in collaboration with Penn University, USA is progressing according to plan. A collaboration agreement with Oncode Institute on the preclinical and clinical development of tasquinimod in myelofibrosis was concluded in the period
- laquinimod as a new product class for treatment of inflammatory eye diseases. A topical ophthalmic formulation has been developed and a phase I clinical study was initiated in December 2021, the study progresses according to plan

Administrative expenses amounted to SEK 3.6 M (3.3).

The operating loss for the period amounted to SEK 15.3 M (loss: 9.7), the net financial loss for the period amounted to SEK 0.4 M (0.0) and the loss after tax to SEK 15.7 M (loss: 9.8).

## Cash flow, liquidity and financial position, Group, for the period January – March 2022

Cash and cash equivalents at the end of the period amounted to SEK 37.8 M, compared with SEK 53.1 M at the end of 2021. Cash flow for the period amounted to a negative SEK 15.3 M (pos: 65.8). The cash flow from operating activities amounted to a negative SEK 14.7 M (neg: 8.0). Cash flow from investing activities amounted to SEK 0.2 M (0.0) and financing activities amounted to a negative SEK 0.3 M (pos: 73.8) following the rights issue concluded in the first quarter of 2021. The share issue in 2021 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 – March 2022

No sales were recorded during the period. Operating expenses amounted to SEK 15.3 M (9.7). The Parent Company's operating loss for the period was SEK 15.3 M (loss: 9.7). Net financial income amounted to a negative SEK 0.4 M (0.0) and the loss after financial items was SEK 15.7 M (loss: 9.8). Cash and cash equivalents including short-term investments totaled SEK 37.6 M at the end of the period, compared with SEK 52.9 M on January 1, 2022.

## Shareholders' equity

Consolidated shareholders' equity at the end of the period amounted to SEK 31.0 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 73.2 percent, compared with 82.2 percent at year-end 2021. The corresponding figures for the Parent Company, Active Biotech AB, were 11.9 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 361,756 shares (Savings shares) in the market during the applicable time period in the respective incentive programs. Total costs, including social contributions, as of March 31, 2022, amounted to SEK 946 K, whereof SEK 18 K refer to the period January-March, 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 (9), 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 currently holds three projects in its portfolio:

- **tasquinimod**, targeted towards hematological malignancies is in clinical phase Ib/IIa treatment of multiple myeloma and is advancing towards clinical phase IIa study in myelofibrosis funded by Oncode
- **laquinimod**, targeted towards inflammatory eye disorders, is in a clinical phase I trial with a topical ophthalmic formulation, which was initiated in December 2021
- **naptumomab**, a targeted anti-cancer 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 for the coming 12 months and Active Biotech therefore require access to further growth capital within this period to maintain progress of its unpartnered project portfolio. Several sources of financing are being explored, including partnering the company's development programs, directed share issuances to new investors as well as rights issue to current investors. Given the current macro-economic uncertainties and the projected developments of the company's project portfolio, the Board has decided to keep all options open for the time being. The future financing of the company will be firmed up during the coming 6 months.

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 2020.

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 uncertain how global measures against COVID-19, and prioritization of health care resources, may affect timelines of project and the ongoing and planned preclinical and 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.

#### SIGNIFICANT EVENTS DURING THE PERIOD

- Dr. Erik Vahtola appointed Chief Medical Officer (Jan 01)
- First patient dosed in the combination part of the phase Ib/IIa study of **tasquinimod** in multiple myeloma (Feb 07)
- Active Biotech entered into global patent license agreement with Oncode Institute for **tasquinimod** in myelofibrosis (Feb 9)

#### EVENTS AFTER THE END OF THE PERIOD

- **Laquinimod** eye drop phase I single ascending-dose part in healthy volunteers finished with no safety concerns, multiple-dose part started

## CONSOLIDATED PROFIT AND LOSS

SEK M	Jan-Mar		Full Year
	2022	2021	2021
<b>Net sales</b>	-	-	-
Administrative expenses	-3.6	-3.3	-15.2
Research and development costs	-11.7	-6.4	-34.5
<b>Operating profit/loss</b>	<b>-15.3</b>	<b>-9.7</b>	<b>-49.8</b>
Net financial items	-0.4	0.0	0.0
<b>Profit/loss before tax</b>	<b>-15.7</b>	<b>-9.8</b>	<b>-49.8</b>
Tax	-	-	-
<b>Net profit/loss for the period</b>	<b>-15.7</b>	<b>-9.8</b>	<b>-49.8</b>
Comprehensive profit/loss attributable to:			
Parent Company shareholders	-15.7	-9.8	-49.8
Non-controlling interest	-	-	-
<b>Net profit/loss for the period</b>	<b>-15.7</b>	<b>-9.8</b>	<b>-49.8</b>
Comprehensive profit/loss per share before dilution (SEK)	-0.07	-0.05	-0.24
Comprehensive profit/loss per share after dilution (SEK)	-0.07	-0.05	-0.24

## STATEMENT OF PROFIT AND LOSS AND CONSOLIDATED COMPREHENSIVE INCOME

SEK M	Jan-Mar		Full Year
	2022	2021	2021
Net profit/loss for the period	-15.7	-9.8	-49.8
Other comprehensive income	-	-	-
<b>Total comprehensive profit/loss for the period</b>	<b>-15.7</b>	<b>-9.8</b>	<b>-49.8</b>
Total other comprehensive profit/loss for the period attributable to:			
Parent Company shareholders	-15.7	-9.8	-49.8
Non-controlling interest	-	-	-
<b>Total comprehensive profit/loss for the period</b>	<b>-15.7</b>	<b>-9.8</b>	<b>-49.8</b>
Depreciation/amortization included in the amount of	0.3	0.3	1.3
Investments in tangible fixed assets	-	-	-
Weighted number of outstanding common shares before dilution (000s)	217,999	199,322	211,901
Weighted number of outstanding common shares after dilution (000s)	217,999	199,322	211,901
Number of shares at close of the period (000s)	218,055	217,972	217,972

## CONSOLIDATED STATEMENT OF FINANCIAL POSITION

SEK M	Mar 31		Dec 31
	2022	2021	2021
Intangible fixed assets	0.2	–	–
Tangible fixed assets	0.6	1.5	0.9
Long-term receivables	0.0	0.0	0.0
<b>Total fixed assets</b>	<b>0.9</b>	<b>1.5</b>	<b>0.9</b>
Current receivables	3.6	3.5	2.7
Cash and cash equivalents	37.8	92.0	53.1
<b>Total current assets</b>	<b>41.5</b>	<b>95.5</b>	<b>55.9</b>
<b>Total assets</b>	<b>42.3</b>	<b>97.1</b>	<b>56.8</b>
Shareholders equity	31.0	86.5	46.7
Long-term liabilities	0.2	0.4	0.2
Current liabilities	11.1	10.2	9.9
<b>Total shareholders equity and liabilities</b>	<b>42.3</b>	<b>97.1</b>	<b>56.8</b>

## CONSOLIDATED STATEMENT OF CHANGES IN SHAREHOLDERS EQUITY

SEK M	Mar 31		Dec 31
	2022	2021	2021
Opening balance	46.7	22.1	22.1
Loss for the period	-15.7	-9.8	-49.8
Other comprehensive income for the period	–	–	–
<i>Comprehensive profit/loss for the period</i>	<i>-15.7</i>	<i>-9.8</i>	<i>-49.8</i>
Share-based payments that are settled with equity instruments, IFRS2	–	0.0	0.3
New share issue	–	74.1	74.1
<b>Balance at close of period</b>	<b>31.0</b>	<b>86.5</b>	<b>46.7</b>

## CONDENSED CONSOLIDATED CASH-FLOW STATEMENT

SEK M	Jan-Mar		Full Year
	2022	2021	2021
<b>Loss after financial items</b>	<b>-15.7</b>	<b>-9.8</b>	<b>-49.8</b>
Adjustment for non-cash items, etc.	0.3	0.3	1.6
<b>Cash flow from operating activities before changes in working capital</b>	<b>-15.4</b>	<b>-9.4</b>	<b>-48.3</b>
Changes in working capital	0.6	1.5	2.1
<b>Cash flow from operating activities</b>	<b>-14.7</b>	<b>-8.0</b>	<b>-46.2</b>
Investments in intangible assets	-0.2	–	–
<b>Cash flow from investments</b>	<b>-0.2</b>	<b>–</b>	<b>–</b>
New share issue	–	74.1	74.1
Loans raised/amortization of loan liabilities	-0.3	-0.3	-1.0
<b>Cash flow from financing activities</b>	<b>-0.3</b>	<b>73.8</b>	<b>73.1</b>
<b>Cash flow for the period</b>	<b>-15.3</b>	<b>65.8</b>	<b>26.9</b>
<b>Opening cash and cash equivalents</b>	<b>53.1</b>	<b>26.2</b>	<b>26.2</b>
<b>Closing cash and cash equivalents</b>	<b>37.8</b>	<b>92.0</b>	<b>53.1</b>

## KEY FIGURES

	Mar 31		Dec 31
	2022	2021	2021
Shareholders equity, SEK M	31.0	86.5	46.7
Equity per share, SEK	0.14	0.40	0.21
Equity/assets ratio in the Parent Company	11.9%	48.0%	26.4%
Equity/assets ratio in the Group	73.2%	89.0%	82.2%
Average number of annual employees	9	9	8

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

## CONSOLIDATED PROFIT AND LOSS

SEK M	2018				2019				2020				2021				2022
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1
<b>Net Sales</b>	<b>4.8</b>	<b>5.7</b>	<b>4.7</b>	<b>4.8</b>	<b>5.5</b>	<b>1.1</b>	<b>0.9</b>	<b>0.9</b>	<b>0.5</b>	-	-	<b>6.2</b>	-	-	-	-	-
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
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
Other operating expenses/income	-	-	-	-	-	2.2	-2.2	-	-	-	-	-	-	-	-	-	-
<b>Operating profit/loss</b>	<b>-8.5</b>	<b>-7.3</b>	<b>-6.9</b>	<b>-7.1</b>	<b>-6.4</b>	<b>-5.4</b>	<b>-9.3</b>	<b>-11.2</b>	<b>-9.7</b>	<b>-10.1</b>	<b>-8.3</b>	<b>-4.1</b>	<b>-9.7</b>	<b>-12.6</b>	<b>-11.3</b>	<b>-16.1</b>	<b>-15.3</b>
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
<b>Profit/loss before tax</b>	<b>-10.2</b>	<b>-9.1</b>	<b>-8.7</b>	<b>-8.9</b>	<b>-8.1</b>	<b>-5.5</b>	<b>-9.3</b>	<b>-11.2</b>	<b>-10.1</b>	<b>-9.8</b>	<b>-8.2</b>	<b>-4.1</b>	<b>-9.8</b>	<b>-12.6</b>	<b>-11.2</b>	<b>-16.2</b>	<b>-15.7</b>
Tax	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
<b>Net profit/loss for the period</b>	<b>-10.2</b>	<b>-9.1</b>	<b>-8.7</b>	<b>-8.9</b>	<b>-8.1</b>	<b>-5.5</b>	<b>-9.3</b>	<b>-11.2</b>	<b>-10.1</b>	<b>-9.8</b>	<b>-8.2</b>	<b>-4.1</b>	<b>-9.8</b>	<b>-12.6</b>	<b>-11.2</b>	<b>-16.2</b>	<b>-15.7</b>

## ACTIVE BIOTECH PARENT COMPANY – INCOME STATEMENT, CONDENSED

SEK M	Jan-Mar		Full Year
	2022	2021	2021
<b>Net Sales</b>	-	-	-
Administration expenses	-3.6	-3.3	-15.3
Research and development costs	-11.7	-6.4	-34.6
<b>Operating profit/loss</b>	<b>-15.3</b>	<b>-9.7</b>	<b>-49.9</b>
<i>Profit/loss from financial items:</i>			
Interest income and similar income-statement items	-	0.0	0.0
Interest expense and similar income-statement items	-0.4	0.0	0.0
<b>Profit/loss after financial items</b>	<b>-15.7</b>	<b>-9.8</b>	<b>-49.9</b>
Tax	-	-	-
<b>Net profit/loss for the period</b>	<b>-15.7</b>	<b>-9.8</b>	<b>-49.9</b>
<b>Statement of comprehensive income parent company</b>			
Net profit/loss for the period	-15.7	-9.8	-49.9
Other comprehensive income	-	-	-
<b>Total comprehensive profit/loss for the period</b>	<b>-15.7</b>	<b>-9.8</b>	<b>-49.9</b>

## ACTIVE BIOTECH PARENT COMPANY – BALANCE SHEET, CONDENSED

SEK M	Mar 31		Dec 31
	2022	2021	2021
Intangible fixed assets	0.2	-	-
Financial fixed assets	40.5	40.5	40.5
<b>Total fixed assets</b>	<b>40.7</b>	<b>40.5</b>	<b>40.5</b>
Current receivables	3.6	3.5	2.7
Short-term investments	32.4	90.8	50.8
Cash and bank balances	5.2	1.0	2.1
<b>Total current assets</b>	<b>41.3</b>	<b>95.3</b>	<b>55.7</b>
<b>Total assets</b>	<b>82.0</b>	<b>135.8</b>	<b>96.2</b>
Shareholders equity	9.7	65.2	25.4
Current liabilities	72.3	70.6	70.8
<b>Total equity and liabilities</b>	<b>82.0</b>	<b>135.8</b>	<b>96.2</b>

Any errors in additions are attributable to rounding of figures.

**NOTE 1: ACCOUNTING POLICIES**

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

**NOTE 2: FAIR VALUE OF FINANCIAL INSTRUMENTS**

SEK M	Mar 31, 2022 Level 2	Dec 31, 2021 Level 2
Short-term investments	32.4	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: August 4 (Q2), November 3 (Q3)
- Annual General Meeting: May 19, 2022
- Year End Report 2022: February 9, 2023

The reports will be available from these dates at [www.activebiotech.com](http://www.activebiotech.com)

The interim report for the January – March 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 April 21, 2022  
Active Biotech AB (publ)

Helén Tuveßon  
*President and CEO*

This interim report is unaudited.

**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](http://www.activebiotech.com) for more information.