



# ANNUAL REPORT 2015



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## Financial information

Interim report (Q1) April 28, 2016  
Annual General Meeting May 26, 2016  
Interim report (Q2) Aug. 11, 2016  
Interim report (Q3) Nov. 10, 2016  
Year-end report for 2016 Feb. 16, 2017  
Financial information can be requested from Active Biotech AB, PO Box 724, SE-220 07 Lund, Sweden.  
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Information can also be obtained from the company's website [www.activebiotech.com](http://www.activebiotech.com).

*This Annual Report contains forward-looking information regarding Active Biotech. Although we believe that our expectations are based on reasonable assumptions, forward-looking statements could be affected by factors causing the actual outcome and trend to differ materially from the forecast. The forward-looking statements comprise various risks and uncertainties. There are significant factors that could cause the actual outcome to differ considerably from that expressed or implied by these forward-looking statements, some of which are beyond our control. These include the risk that patent rights might expire or be lost, exchange rate movements, the risk that research and development operations do not result in commercially successful new products, competition effects, tax risks, effects resulting from the failure of a third party to deliver products or services, difficulties in obtaining and maintaining official approval for products, and environmental responsibility risks.*

## Annual General Meeting

The Annual General Meeting of Active Biotech AB (publ) is to be held on Thursday, May 26, 2016 at 5:00 p.m. at Elite Hotel Ideon, Scheelevägen 27, Lund, Sweden. Shareholders who wish to participate in the Meeting must (a) be recorded in the register of shareholders maintained by Euroclear Sweden AB on Friday, May 20, 2016, and (b) notify the company of their intention to participate in the Meeting not later than Friday, May 20, 2016.

Shareholders who have trustee-registered shares must temporarily re-register the shares in their own name with Euroclear Sweden to be entitled to participate in the Meeting. This registration must be completed not later than Friday, May 20, 2016. Accordingly, shareholders must inform the trustee of this request in ample time prior to this date.

### Notice of participation

Notice of participation can be made in writing to Active Biotech AB (publ), Attn. Susanne Jönsson, PO Box 724, SE-220 07 Lund, Sweden, by fax on +46 (0)46-19 20 50, by telephone on +46 (0)46-19 20 00 or by e-mail to [susanne.jonsson@activebiotech.com](mailto:susanne.jonsson@activebiotech.com). The notice is to include name, personal/corporate registration number, number of shares held, daytime telephone number and, if applicable, the number of advisers (two at the most) that will accompany the shareholder at the Meeting.

The notice of the Annual General Meeting is available in its entirety on the company's website [www.activebiotech.com](http://www.activebiotech.com).



## Active Biotech in brief

Active Biotech is a company that focuses on pharmaceutical development in medical fields in which the immune system plays a central role. The company's project portfolio primarily includes projects for the development of drugs for the treatment of neurodegenerative/inflammatory diseases and cancer.

Active Biotech currently has one project in clinical phase, laquinimod, which is out-licensed to Teva. In addition, the company conducts commercial activities relating to the tasquinimod, ANYARA and paquinimod projects and the preclinical project SILC.

- **Laquinimod** is an orally administered compound under development for the treatment of neurodegenerative/inflammatory diseases. Clinical studies have shown that laquinimod can slow disability progression and reduce brain tissue loss associated with multiple sclerosis (MS). Combined with a favorable clinical safety profile, laquinimod distinguishes itself from most products in the market. The diseases in which clinical development is ongoing are relapsing remitting multiple sclerosis (RRMS), primary progressive multiple sclerosis (PPMS) and Huntington's disease.

Active Biotech has an agreement with the Israeli pharmaceutical company Teva since 2004 for the development and commercialization of laquinimod. Results from the ongoing pivotal CONCERTO clinical Phase 3 trial are expected in the first half of 2017.

- The results of the 10TASQ10 Phase 3 trial for the **tasquinimod** candidate drug were presented in April 2015. The results showed that, although the primary endpoint of extending progression-free survival was achieved, overall survival among patients was not

extended. Active Biotech and its partner Ipsen made the decision to discontinue all further development of tasquinimod in prostate cancer. In March 2016, it was announced that highly favorable results were achieved in the preclinical models for multiple myeloma. A patent application for treatment of this cancer form using tasquinimod was submitted and the company is actively seeking a collaboration partner for the further development of tasquinimod within this indication.

- **SILC – S100A9 Inhibition by Low molecular weight Compounds** – is a preclinical project aimed at utilizing the company's own results generated around a target molecule, S100A9, and the biological mode of action of quinoline compounds. Efforts have been focused on building up a patent portfolio around the substances that interact with S100 proteins and impede their interaction with their receptors. The company has submitted three priority applications for the purpose of obtaining patent protection for three chemically unrelated substance groups. One of these patent applications has already been granted. Only commercial activities aimed at out-licensing the SILC project will be conducted during 2016.
- The company will also only conduct out-licensing activities for the **ANYARA** and **paquinimod** (57-57) projects. Active Biotech's partner MediGene AG is responsible for the clinical development of **RhuDex®**, which is currently in Phase 2 clinical development.

### Clinical development projects

PROJECT	PRIMARY INDICATION	DISCOVERY PHASE	PRECLINICAL DEV.	CLINICAL PHASE 1	CLINICAL PHASE 2	CLINICAL PHASE 3	PARTNER
Laquinimod	RRMS (Allegro/Bravo)						TEVA
	RRMS (Concerto)						
	PPMS (Arpeggio)						
	Huntington's disease (Legato-HD)						
	Crohn's disease						
	Lupus						

Striped = ongoing

### Out-licensing projects

PROJECT	PRIMARY INDICATION	DISCOVERY PHASE	PRECLINICAL DEV.	CLINICAL PHASE 1	CLINICAL PHASE 2	CLINICAL PHASE 3
Tasquinimod	Prostate cancer					
	Multiple myeloma					
ANYARA	Renal cell cancer					
Paquinimod	Systemic Sclerosis					
SILC	Oncology					

## 2015 – A disappointing year

We had high hopes at the beginning of the year for the tasquinimod project's potential to treat prostate cancer. These hopes were shared by our partner Ipsen and were based on positive results from previous clinical trials. The unblinding of the Phase 3 study in April 2015 showed that the primary endpoint had been achieved, but both we and our partner Ipsen made the assessment that the results were not sufficiently strong for securing marketing authorization. As a consequence, the further development of tasquinimod for the treatment of prostate cancer, and the partnership with Ipsen, were discontinued.



### Financing

We announced on June 1, 2015 that due to the outcome of the tasquinimod study, the operations were to be focused on the laquinimod project. From 2016, only commercial activities will be conducted for our other projects and all proprietary laboratory activities will be terminated. These measures led to extensive employee reductions that were completed in 2015 and are expected to have a full effect on costs in the second half of 2016. The company currently employs 19 people, of whom about half work with operation and maintenance of the property and experiment-related services to tenants. At year-end 2015, we had cash and bank balances totaling approximately SEK 104 million. In addition, the company owns a property in Lund, valued at SEK 325 million. I believe that no additional financial contributions will be required until the results of the ongoing Phase 3 study for the treatment of multiple sclerosis (MS), CONCERTO, are available in the first half of 2017.

### Laquinimod

Active Biotech and our partner Teva were pleased to announce in April 2015 that the first patient had been

enrolled in a Phase 2 study (ARPEGGIO) to evaluate laquinimod's potential for treatment of primary progressive multiple sclerosis (PPMS). PPMS is a form of MS whereby the patient suffers from gradual deterioration of neurological functions, but without pronounced clinical relapses. This form of MS affects 10-15 percent of all patients diagnosed with MS and there is currently no adequate treatment option available for this patient group. Our partner Teva's decision to commence the development of laquinimod to also include PPMS was based on the previous clinical results that we had seen from the Phase 3 trials of ALLEGRO and BRAVO. It was noted that laquinimod had a modest effect on reducing the relapse rate, while the effect on slowing the patients' progression of disability and the development of brain atrophy was robust. This inspires hope that laquinimod may also have an effect on patients with PPMS. It should also be noted the most relevant clinical parameter for all MS patients is slowed disability progression. We expect the results of the ARPEGGIO study to be communicated in 2017.

At the end of June 2015, Active Biotech and our partner Teva announced that patient enrollment for the ongoing

*“I believe that no additional financial contributions will be required until the results of the ongoing Phase 3 study for the treatment of multiple sclerosis (MS), CONCERTO, are available in the first half of 2017.”*

Phase 3 CONCERTO trial in relapsing remitting multiple sclerosis (RRMS) was finalized with 2,199 patients. The primary endpoint of the trial is reducing the time to Confirmed Disability Progression (CDP), as measured by the Expanded Disability Status Scale (EDSS). We also announced at the same time that an agreement had been reached, following new discussions between Teva and the FDA, that the study was to be unblinded when either 260 EDSS events are reached or all patients complete 24 months of study treatment. This means that it will be possible to report the results from the CONCERTO study during the first half of 2017. In addition, Teva also reported results from preclinical studies and clinical extension studies with laquinimod at conferences and symposiums during the year.

Teva is continuing to conduct a Phase 2 trial (LEGATO) in another neurodegenerative disease, namely Huntington's disease. This is a rare hereditary disease for which no active treatment is currently available. This study also has slowed disability progression as the primary endpoint, with results expected at some point in 2018.

In January 2016, Active Biotech and our partner Teva announced that the treatment of patients with higher doses of laquinimod in all ongoing clinical studies was to be discontinued after the occurrence of cardiovascular events, none of which were fatal, in eight patients. No such events were observed in the 0.6 mg daily dose group or placebo group. All studies are progressing according to plan with the 0.6 mg daily dose and an in-depth analysis of the patients who suffered from side effects is underway.

#### **Tasquinimod**

The development of tasquinimod for the treatment of prostate cancer was discontinued in 2015. In the same year, we noted that tasquinimod showed surprising favorable results in preclinical models for a form of blood cancer, multiple myeloma. This disease is relatively rare, meaning that treatments are assigned what is known as orphan drug status. The Orphan Medicinal Product designation is implemented to promote the development of drugs that may provide significant benefit to patients suffering from rare diseases identified as life-threatening or chronically debilitating. Active Biotech has submitted a patent application to use tasquinimod to treat multiple myeloma, which could protect the product until 2035. We intend to submit applications to the EU and the US to obtain orphan drug status for tasquinimod in 2016. We will subsequently seek development partners for the project in this new indication.

#### **Other projects**

All patent applications have been submitted in the SILC project, and one patent has already been granted. For this project, as for ANYARA and the paquinimod project, Active Biotech will focus on seeking commercial partners in the years ahead.

#### **Closing words**

To conclude, I would like to thank all of the shareholders for their support and patience even in difficult times. I would also like to express my gratitude and appreciation to the company's current and former employees.

March 2016,  
Tomas Leanderson, President and CEO

# Directors' Report

The Board of Directors and President & CEO of Active Biotech AB (publ), Corporate Registration Number 556223-9227, hereby submit their Annual Report and consolidated financial statements for the fiscal year January 1, 2015 to December 31, 2015. Active Biotech conducts operations as a limited liability company and has its registered office in Lund, Sweden.

## Operations

Active Biotech is a company that focuses on pharmaceutical research and development in medical fields in which the immune system plays a central role. The company's research portfolio primarily includes projects for the development of drugs for the treatment of neurodegenerative diseases and cancer.

## Group

The Group's legal structure is built around the Parent Company Active Biotech AB, whose operations comprise pharmaceutical development, Group-wide functions and asset management.

In addition, the Group includes the wholly owned subsidiary Active Forskaren 1 KB, Lund, Sweden, which owns the property in which operations are pursued.

## Active Biotech's research operations

Active Biotech's field of expertise mainly comprises knowledge of the human immune system, which is used to develop drugs for the treatment of neurodegenerative diseases and cancer. The company had the laquinimod project in clinical phase at the end of 2015. In this project, the Group is developing – together with Teva – a drug to address neurodegenerative/inflammatory diseases, such as multiple sclerosis (MS) and Huntington's disease.

Results from the clinical Phase 3 trial of tasquinimod for the treatment of prostate cancer were reported in 2015. Since the results were not deemed to be sufficiently strong for marketing authorization, a decision was made to discontinue all further development of tasquinimod for prostate cancer.

In addition to the ongoing clinical project for laquinimod, the company is pursuing one preclinical project, called SILC, aimed at exploring the company's own preclinical results generated around a target molecule for quinoline compounds and its biological mode of action. The project aims to produce new, patentable chemical compounds that interact with one of the quinoline compounds' target molecules.

Only out-licensing activities have been conducted since 2014 for the clinical projects ANYARA for the treatment of renal cell cancer and paquinimod (57-57) for the treatment of systemic sclerosis. Active Biotech's partner MediGene AG is responsible for the clinical development of RhuDex®, for primary biliary cirrhosis and rheumatoid arthritis (RA), which is currently in Phase 2 clinical development.

## Progress of each project:

### Laquinimod – a novel immunomodulatory compound for the treatment of neurodegenerative/inflammatory diseases

#### Significant events during the period 2004 – 2015:

Following the completion of Phase 1 and Phase 2 trials by

Active Biotech on a proprietary basis, an agreement was signed with Teva Pharmaceutical Industries Ltd (Teva) in **June 2004** covering the development and commercialization of laquinimod.

#### Development and commercialization agreement with Teva:

According to the agreement, Teva performs and funds the clinical development of laquinimod. If all the clinical and commercial milestones are achieved, Teva will pay USD 92 M to Active Biotech, of which USD 22 M had been received since the signing of the agreement until year-end 2014.

In addition to milestone payments, Active Biotech will also receive tiered royalty payments on sales. These will start just above 10 percent and end just below 20 percent, with the exception of sales of laquinimod in the Nordic/Baltic regions, where Active Biotech will receive a fixed royalty rate that is more than double that of the highest level in the global agreement.

#### Clinical development:

In **September 2006**, Teva successfully concluded an additional Phase 2 trial ahead of pivotal Phase 3 trials. In 2007, the first clinical Phase 3 study ALLEGRO (assessment of oral laquinimod in preventing progression of multiple sclerosis) commenced, which was a global, pivotal, 24-month, double-blind trial. The purpose was to evaluate the efficacy, safety and tolerability of laquinimod versus placebo in the treatment of relapsing remitting multiple sclerosis (RRMS). In December 2010, Teva announced that the ALLEGRO study, encompassing about 1,100 patients, had achieved its primary endpoint at the same time as a highly favorable clinical safety profile was preserved. Laquinimod showed a statistically significant 23-percent reduction in annualized relapse rate ( $p=0.0024$ ), the primary clinical endpoint, along with a significant 36-percent reduction in the risk of confirmed disability progression, as measured by Expanded Disability Status Scale (EDSS) ( $p=0.0122$ ), compared with placebo. Treatment with laquinimod was also associated with a significant reduction in brain tissue loss, as measured by a 33-percent reduction in progression of brain atrophy ( $p<0.0001$ ). Furthermore, new detailed mode of action data was presented in 2010 demonstrating that laquinimod has both neuroprotective and anti-inflammatory properties. Among other results, the study showed that laquinimod treatment is associated with an increase in brain-derived neurotrophic factor (BDNF), a protein that has a key role in development and protection of nerve fibers. On **August 1, 2011**, the initial results were announced from the Phase 3 study BRAVO (benefit-risk assessment of Avonex® and laquinimod), which was designed to evaluate the efficacy, safety and tolerability of laquinimod compared with placebo and to provide a benefit-risk assessment comparing oral laquinimod and a reference arm of injectable Interferon beta-1a (Avonex®). The BRAVO trial was a 24-month, global, multicenter, randomized, placebo-controlled trial with parallel groups, in which the effects of laquinimod were compared with placebo. The BRAVO findings supported the direct effect of laquinimod in the central nervous system (CNS) and were in line with the results of the first laquinimod Phase 3 trial, ALLEGRO. The BRAVO study demonstrated a



trend of reducing the annualized relapse rate in laquinimod-treated patients compared to placebo, the primary endpoint of the study, but did not reach statistical significance ( $p=0.075$ ). The reduction of disability progression measured by EDSS also showed a trend in favor of laquinimod without reaching statistical significance. Furthermore, a significant reduction was observed in brain tissue loss in connection with treatment with laquinimod compared to placebo. The randomization process for BRAVO was adequately performed and according to the study protocol; however, placebo and treatment study groups showed dissimilarity in two baseline magnetic resonance imaging (MRI) characteristics. When this imbalance was corrected according to a standard and pre-specified sensitivity analysis included within the original statistical analysis plan (SAP), laquinimod demonstrated a significant reduction in the annualized relapse rate (21.3 percent,  $p=0.026$ ), as well as a significant reduction in the risk of disability progression measured by EDSS (33.5 percent,  $p=0.044$ ). Also in this analysis, laquinimod demonstrated a significant reduction of brain atrophy (27.5 percent,  $p<0.0001$ ). Additionally, as in ALLEGRO, the BRAVO study showed that laquinimod has a very favorable safety and tolerability profile. In **November 2011**, Teva announced that, following discussions with the US Food and Drug Administration (FDA), it had decided to carry out one additional clinical study prior to filing a new drug application (NDA) in the US. The FDA offered its assistance to cooperate with Teva in the design of this study.

In **March 2012**, results from the ALLEGRO study were published in The New England Journal of Medicine. Data from the completed Phase 3 trial showed that laquinimod reduced inflammatory disease activity as measured by clinical relapses and Magnetic Resonance Imaging (MRI), slowed disability progression and decreased brain tissue loss, while maintaining a favorable safety and tolerability profile in RRMS patients. On **July 17, 2012**, it was announced that the European Medicines Agency (EMA) accepted the marketing authorization application (MAA) for laquinimod for treatment of RRMS and that the scientific review had thus commenced. This acceptance of the EMA filing for review triggered a milestone payment of USD 5 M from Teva. The marketing authorization application submission was supported by a pooled analysis of data from the ALLEGRO and BRAVO trials involving more than 2,400 patients treated over a period of two years.

#### Effect compared to placebo (p value)

	ALLEGRO Laq vs. placebo	BRAVO* Laq vs. placebo	Integrated analysis Laq vs. placebo
Rate of relapse	23% (0.0024)	21% (0.03)	21.4% (0.0005)
Disability progression (3 months CDP)	36% (0.0122)	33.5% (0.04)	34.2% (0.0017)
Brain atrophy	32.8% ( $<0.0001$ )	27.4% (0.0001)	30% ( $<0.0001$ )

\* After corrections according to the predefined statistical analysis plan

In **August 2012**, Teva announced that a third Phase 3 laquinimod trial for the treatment of RRMS would be launched. The trial, CONCERTO, is evaluating two doses

of laquinimod (0.6mg and 1.2mg) and encompasses about 2,100 patients being treated for up to 24 months. The primary outcome measure of the study is confirmed disability progression as measured by EDSS. The design of this trial has been prepared by Teva in collaboration with the FDA under a Special Protocol Assessment (SPA) process. This means that an agreement has been concluded between the parties that entails that the study's design meets the current scientific and regulatory requirements for a registration application. On **October 22, 2012**, positive Phase 2 clinical data was announced for laquinimod for the treatment of active Crohn's disease (CD) at the 20th United European Gastroenterology (UEG) Week Conference. The findings demonstrated that treatment with orally administered laquinimod 0.5 mg per day resulted in a robust, early and consistent effect on remission (48.3 percent vs. 15.9 percent of patients, respectively) and response rates (62.1 percent vs 34.9 percent of patients, respectively) in patients with moderate-to-severe CD versus placebo.

On **March 3, 2013**, it was announced that the first patient had been enrolled in the CONCERTO study – the third Phase 3 placebo-controlled study designed to evaluate the efficacy, safety and tolerability of laquinimod in patients with RRMS. On **March 21, 2013**, data was presented at the 65th Annual Meeting of the American Academy of Neurology (AAN) showing that early treatment with laquinimod demonstrated significant benefit in terms of slowing disability progression compared to delayed treatment. The data presented was based on an extension of the Phase 3 ALLEGRO trial, which compared the effectiveness of laquinimod in patients who received 36 months (early-start) versus those who received 24 months of laquinimod treatment after 12 months on placebo (delayed-start).

Of the 864 RRMS patients who participated in the ALLEGRO trial, 97 percent participated in the extension study and 87 percent completed one year of the extension phase. Throughout the study, the progression-free survival for early-start patients was longer than those with a delayed start (11.8 percent risk of confirmed disability progression vs. 16.7 percent, HR = 0.62,  $p < 0.0038$ ). The study also supported a favorable safety and tolerability profile of laquinimod. On **June 12, 2013**, positive results from Phase 2a study of laquinimod in active lupus nephritis were reported. The study was designed to assess safety, tolerability and clinical efficacy of laquinimod in 46 patients with active lupus nephritis. The clinical trial was a multicenter, double-blind, placebo-controlled, exploratory study of 46 patients with active lupus nephritis that evaluated laquinimod (0.5 and 1.0 mg per day) versus placebo in combination with standard of care treatment. The study showed that at 24 weeks, 62.5 percent of patients who received 0.5 mg per day of laquinimod achieved renal response, compared to 33.3 percent of patients who were administered placebo. Reported adverse events (AEs) were comparable in both the active treatment and placebo patient groups. In **October 2013**, a pre-planned analysis of over 1,000 patients was published online in the Journal of Neurology, Neurosurgery & Psychiatry (JNNP) demonstrating the benefits of laquinimod on neurodegeneration. Laquinimod-treated patients accumulated significantly less brain tissue damage caused by neurodegeneration, compared to

placebo in MRI analyses. On **October 4**, it was announced that post-hoc analyses of the Phase 3 studies ALLEGRO and BRAVO were presented at the 29th Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS). Pooled data analyses of the above studies supports that laquinimod may have an effect on both inflammation and the broader underlying mechanisms associated with disease progression in RRMS. On **November 4, 2013**, it was announced that Teva planned to initiate a further clinical trial, LIBRETTO, to evaluate the efficacy, safety and tolerability of two doses of oral laquinimod (0.6 and 1.2 mg per day), compared to interferon beta-1a, in patients with RRMS. The primary endpoint of the study was brain atrophy. On **January 24, 2014**, laquinimod received a negative opinion by the Committee for Medicinal Products for Human Use ("CHMP") of the EMA. The CHMP's opinion was based on the view that laquinimod's positive effect on reducing relapses did not outweigh the potential risks. Although the CHMP found that laquinimod has a positive effect on slowing disability in MS patients, this finding did not alter the decision. In the risk assessment, the CHMP focused on findings in animal studies, performed in parallel with the pivotal clinical trials, relating to the potential risk of fetal damage and the potential increased risk of cancer. None of these effects have been observed in the comprehensive patient material, comprising 7,490 patient years in total, with some patients being exposed for more than seven years and tolerated treatment well. Teva requested a re-examination of the CHMP's opinion. On **February 19, 2014**, it was announced that Teva had decided not to proceed with the randomization stage of the planned LIBRETTO trial for the treatment of RRMS since the design was no longer aligned with the regulatory strategy.

On **May 23, 2014**, it was announced that CHMP of the EMA confirmed its January 24, 2014 risk-benefit opinion and therefore recommended against approval for the treatment of RRMS in the EU at this time. Active Biotech and Teva remain fully committed to the laquinimod clinical development program for treatment of multiple sclerosis and are continuing to evaluate the CHMP feedback to determine potential adjustments and additions to the current clinical development program. On **August 18, 2014**, it was announced that Teva will initiate a Phase 2 clinical trial to evaluate the efficacy and safety of laquinimod for the treatment of Huntington's disease. On **September 12, 2014**, follow-up data was presented evaluating the clinical safety of laquinimod in RRMS patients who were treated with laquinimod in Phase 2, Phase 3 and open-label extension studies for two or more years. In the pooled safety analysis, rates of adverse events (AEs) and serious AEs were lower in the open-label extensions than in the core studies and less than 3 percent of patients discontinued treatment due to AEs during these extensions. On **November 4, 2014**, it was announced that Teva will expand the clinical development program for laquinimod by initiating the ARPEGGIO study that will evaluate the potential of laquinimod for the treatment of primary progressive multiple sclerosis (PPMS). It was also announced that the first patient had been screened in the LEGATO-HD study that will evaluate laquinimod in Huntington's disease.

On **April 23, 2015**, it was announced that the first patient had been enrolled in the Phase 2 study ARPEGGIO.

The study evaluates two doses of laquinimod (0.6 mg and 1.5 mg per day) compared with placebo in patients with PPMS. The study includes about 375 patients in the US, Canada and Europe. The primary endpoint of the study is brain atrophy, defined as the percentage brain volume change as measured with MRI. On **June 25, 2015**, it was announced that the Phase 3 study, CONCERTO, had been fully enrolled and that study completion would occur when either 260 EDSS events are reached or all patients complete 24 months of study treatment. The results of the study are expected to be available in the first half of 2017.

#### **Tasquinimod – an immunomodulatory, anti-metastatic substance for the treatment of prostate cancer**

##### *Significant events during the period 2004 – 2015:*

In the tasquinimod project, Active Biotech is developing an immunomodulatory anti-metastatic substance, tasquinimod, which indirectly affects the tumor's ability to grow and spread. Tasquinimod was primarily developed to be orally administered for the treatment of prostate cancer, among other indications. Following the conclusion of an initial clinical Phase 1 trial involving healthy volunteers in 2004, a clinical Phase 1 dose-escalation program with prostate cancer patients commenced in the latter part of the same year, with the objective of studying the safety of tasquinimod. Patients continued treatment in a follow-up study that aimed to document long-term tolerance and safety. The US Food and Drug Administration's (FDA) review of the investigational new drug (IND) application was completed in August 2007 and a Phase 2 proof-of-concept study was initiated later in the same year. This study was a 2:1 randomized, placebo-controlled, double-blind Phase 2 study of 1 mg per day of tasquinimod versus placebo. It comprised 206 symptom-free patients in the US, Canada and Sweden with metastatic, castrate-resistant prostate cancer. The primary clinical endpoint of this study was to reduce the proportion of patients displaying disease progression after six months of tasquinimod therapy compared with placebo. A secondary clinical endpoint of importance for this group of patients included time to clinical progression. It was announced in **December 2009** that these endpoints had been achieved. The results from the trial were presented at the 46th Annual Meeting of the American Society of Clinical Oncology (ASCO) held on June 4-8, 2010. Results from the study showed that disease progression was 31 percent for patients treated with tasquinimod compared with 66 percent for placebo-treated patients ( $p < 0.0001$ ). The median progression-free survival (PFS) was 7.6 months for the tasquinimod group, compared with 3.2 months for the placebo group ( $p = 0.0009$ ). A pivotal Phase 3 trial was initiated in March 2011. The study (10TASQ10) is a global, randomized, double-blind, placebo-controlled Phase 3 trial in patients with metastatic castrate-resistant prostate cancer (CRPC). The aim of the study is to confirm tasquinimod's effect on the disease, with radiological progression-free survival (PFS) as the primary clinical endpoint and overall survival (OS) as secondary clinical endpoint.

On **April 18, 2011**, it was announced that Active Biotech had entered into a broad partnership with Ipsen to co-develop and commercialize tasquinimod.

In **September 2011**, the Journal of Clinical Oncology



published the complete results from the Phase 2 study of tasquinimod. Tasquinimod significantly slows disease progression and improves PFS in patients with CRPC, alongside a retained favorable side effect profile. Of 201 evaluable patients, the six-month progression-free proportion for tasquinimod and placebo treatment groups were 69 percent and 37 percent, respectively ( $p < 0.0001$ ), with a median PFS of 7.6 vs. 3.3 months ( $p = 0.0042$ ).

In **January 2012**, Active Biotech announced the launch of an investigator-sponsored clinical Phase 1 trial (CATCH), led by Dr. Andrew Armstrong at Duke Cancer Institute, US. The primary objective for the trial is to determine the recommended dose of tasquinimod in combination with cabazitaxel (Jevtana) in patients with CRPC. Secondary objectives include efficacy as measured by PFS and OS. The study includes about 30 patients.

In **February 2012**, Active Biotech and Ipsen reported long-term safety data from the Phase 2 study of tasquinimod at the European Association of Urology (EAU) Congress. Treatment side effects were mild to moderate, manageable and less frequent after two months of therapy. On **May 21, 2012**, it was reported that 600 patients were randomized in the Phase 3 trial of tasquinimod in patients with CRPC. Under the agreement, Active Biotech received a milestone payment from Ipsen amounting to EUR 10 M. In **June 2012**, Active Biotech and Ipsen reported survival data from the Phase 2 study of tasquinimod at the 2012 ASCO Annual Meeting. The results showed that overall survival times after treatment with tasquinimod were longer than previously reported in this patient group. Median OS was 33.4 vs. 30.4 months (tasquinimod vs. placebo). A preliminary sub-group analysis showed that the median OS observed in patients with bone metastases was 34.2 vs. 27.1 months (tasquinimod vs. placebo). In **October 2012**, data on biomarkers from the Phase 2 study of tasquinimod was presented at the ESMO 2012 congress. The results support an effect of tasquinimod on both immunomodulation and angiogenesis, which positions tasquinimod as a potentially unique therapeutic approach. On **October 3, 2012**, Ipsen announced the launch of a switch maintenance Phase 2 trial with tasquinimod in CRPC patients and, on **October 19**, the company announced its intention to initiate a proof-of-concept study into four cancer forms: advanced or metastatic hepatocellular, ovarian, renal cell and gastric carcinomas. On **December 10, 2012**, Active Biotech and Ipsen announced that the tasquinimod Phase 3 trial had been fully enrolled, encompassing a total of 1,245 patients at about 250 hospitals in 37 countries, which triggered a contractual milestone payment from Ipsen of EUR 10 M. On **April 25, 2013**, Active Biotech and Ipsen announced that the analysis plan for the ongoing Phase 3 study (10TASQ10) had been updated. In the updated analysis plan, the companies plan to conduct the primary PFS analysis for the 10TASQ10 trial in 2014, at the same time as the first interim OS analysis. On **June 3, 2013**, Dr Andrew J. Armstrong from the Duke Cancer Institute presented follow-up data from the completed Phase 2 trial of tasquinimod in prostate cancer at the 2013 ASCO Annual Meeting held in Chicago, in the US. Using automated software for analysis of the bone scan index (BSI), a quantitative measure of tumor burden in bone, the relation of the BSI with other prognostic biomarkers and overall survival were analyzed in a data set from the

previously concluded Phase 2 tasquinimod study. A delay in objective radiographic bone scan progression with tasquinimod using the BSI analysis was observed, and this delay may be associated with improvements in survival. On **October 9, 2013**, it was announced that Active Biotech, under the terms of the co-development and commercialization agreement on the candidate drug tasquinimod, had received a milestone payment of EUR 12 M from Ipsen. In **February 2014**, Ipsen launched a randomized, double-blind, placebo-controlled Phase 3 study of tasquinimod in chemo-naïve CRPC patients in Asia. On **September 27, 2014**, Ipsen announced the preliminary results of the clinical Phase 2 proof-of-concept study in four cancer indications. The study for the treatment of hepatocellular carcinoma is continuing with results expected in 2015. The results do not support the further development of tasquinimod for the treatment of patients with advanced ovarian, renal cell or gastric carcinomas. The primary endpoint of the study was progression-free survival (PFS) at a predefined time for each cohort.

The results of the 10TASQ10 study in tasquinimod were presented on **April 24, 2015**. The study showed that tasquinimod reduced the risk of radiographic cancer progression or death compared to placebo (rPFS, HR=0.69, CI 95%: 0.60 - 0.80) in patients with metastatic castration resistant prostate cancer who have not received chemotherapy. However, tasquinimod did not extend overall survival (OS, HR=1.09, CI 95%: 0.94 - 1.28). Efficacy results together with preliminary safety data did not support positive benefit risk balance in this population. Therefore, Active Biotech and Ipsen decided to discontinue all studies in prostate cancer. On **September 28, 2015**, the final results from the tasquinimod Phase 3 trial were presented at the European Cancer Congress (ECC 2015). Tasquinimod treatment resulted in a prolonged radiographic progression-free survival (rPFS), 7.0 vs. 4.4 months (central assessment), similar to an earlier Phase 2 study. However, the positive effect on rPFS did not translate into an improved OS (HR 1.097, 95% CI: 0.938-1.282). Tasquinimod safety was in general manageable and similar to what was observed during the earlier Phase 2 study.

#### **ANYARA – fusion protein for immunological treatment of renal cell cancer**

In the ANYARA project, Active Biotech developed an immunological targeted treatment of cancer that stimulates the immune system to eradicate tumor cells.

#### *Significant events 2006–2015:*

In 2006, three clinical Phase 1 studies of ANYARA for the treatment of advanced non-small cell lung cancer, renal cell carcinoma and pancreatic cancer were successfully concluded. The median survival of 26.2 months observed for patients with advanced renal cell cancer and treated with ANYARA was longer than expected. Results from two Phase 1 studies of ANYARA were published in the Journal of Clinical Oncology, where ANYARA was studied both as a single agent (monotherapy) and in combination with an established tumor therapy (Taxotere). The results showed that ANYARA was well tolerated both as monotherapy and in co-administration. In **July 2007**,

ANYARA was granted orphan medicinal product status, for the indication renal cell cancer, by the European Medicines Agency's (EMA) expert committee. A combined Phase 2/3 trial for the treatment of renal cell cancer was initiated at the end of 2006 at about 50 clinics in Europe. The trial was a randomized study of ANYARA in combination with interferon-alpha, compared with only interferon-alpha, in patients with advanced renal cell cancer. The primary endpoint for this study was prolonged overall survival (OS) and it included 513 patients. In **May 2008**, following the enrollment of approximately 250 patients in the trial, an interim analysis was conducted with positive results. The study was fully enrolled in June 2009. In **January 2013**, the initial results were presented from the concluded Phase 2/3 clinical study. The results showed that the ANYARA Phase 2/3 study did not achieve its primary endpoint of showing a prolonged OS in the intention to treat (ITT) population. A subgroup, comprising about 25 percent of the patients with low/normal levels of base line IL-6 and expected antibody levels against the anti-superantigen element of ANYARA, showed a statistically significant treatment advantage on both OS and progression-free survival (PFS). OS was 63.3 months for the group that received ANYARA combined with interferon-alpha vs. 31.1 months for the group that received interferon-alpha alone ( $p=0.020$ ,  $HR=0.59$ ) and PFS 13.7 vs. 5.8 months ( $p=0.016$ ,  $HR=0.62$ ). In North America and Western Europe, this subgroup accounts for 40-50 percent of the total number of advanced renal cell cancer patients. The safety profile was favorable and in line with that observed earlier. On **June 3, 2013**, it was announced that data from the completed Phase 2/3 study in ANYARA had been presented by the coordinating investigator Professor Robert Hawkins at the 2013 ASCO Annual Meeting in Chicago, US. On **September 12, 2013**, it was announced that Professor Tim Eisen, Department of Oncology, Cambridge University Hospitals NHS Foundation Trust, UK, had presented a new and more detailed analysis at the European Cancer Congress 2013 (ECCO) held in Amsterdam, the Netherlands, that provides further support to the previous findings that low baseline levels of pre-formed antibodies against ANYARA or low levels of the cytokine IL-6, independently predict anti-tumor efficacy after ANYARA+Interferon-alpha treatment. The analysis showed clear trends of increased OS in patients with decreasing IL-6 or anti-ANYARA antibodies. Based on the results of the completed Phase 3 study in which ANYARA displayed a survival benefit in a subgroup of patients, Active Biotech discussed the continued development of ANYARA with the FDA and EMA in 2013.

The company will not commence the further clinical development of ANYARA on an independent basis and only commercial activities aimed at out-licensing ANYARA are being conducted.

## Paquinimod – novel oral immunomodulatory compound for the treatment of systemic sclerosis

### *Significant events 2004–2015:*

The first clinical Phase 1 dose-escalation study, comprising 30 healthy volunteers, was started at the Karolinska University Hospital in Stockholm, Sweden, at the end of 2004 and was successfully completed in 2005. The results showed that paquinimod is well tolerated at all of the tested dosage levels in single and multiple doses and that the compound is suitable to be administered as an oral, daily treatment. The clinical development program continued with a Phase 1b trial in systemic lupus erythematosus (SLE) patients, which commenced in December 2005. The study primarily documented safety and pharmacokinetic properties, but also monitored a number of biological markers to determine the effect of paquinimod on disease progression.

The study was concluded in 2008 and data from the trial confirmed the previously reported favorable safety profile, and demonstrated effects on markers for the SLE disease. During 2008 and 2009, follow-up data from the concluded Phase 1b trial was presented at scientific conferences. In November 2011, the article "Pharmacokinetics, tolerability, and preliminary efficacy of ABR-215757, a new quinoline-3-carboxamide derivative, in murine and human SLE" was published in the online edition of the *Arthritis & Rheumatism* journal (2012 May; 64(5):1579-88). The explorative clinical study that commenced in 2009 comprising 13 SLE patients in Sweden and Denmark was concluded in 2010 and a reduction in disease activity was observed in several patients. In 2010, Active Biotech decided to initiate development of paquinimod to address the indication systemic sclerosis, a rare autoimmune disease for which paquinimod was granted orphan medicinal product status in February 2011 in Europe. An explorative clinical study in systemic sclerosis was initiated in **December 2011** and included nine patients. The primary endpoint of the study was the effect on biomarkers that correlate with disease activity. The clinical study in systemic sclerosis was concluded in the latter part of 2012.

Evaluation of the clinical trial in systemic sclerosis demonstrated a favorable safety profile and effects on disease-related biomarkers in line with paquinimod's mode of action. The next step in clinical development is to verify these effects in a controlled Phase 2 study that can form the basis for a pivotal study in this patient group. On **January 17, 2014**, paquinimod, for the treatment of systemic sclerosis, was granted orphan drug status by the US Food and Drug Administration (FDA). Orphan drug status in the US provides advantages such as market exclusivity for a period of seven years upon approval.

The company will not commence the further clinical development of paquinimod on an independent basis and only commercial activities to out-license paquinimod are being conducted.

### RhuDex® – a novel oral treatment for autoimmune diseases

RhuDex is an orally active compound for the treatment of autoimmune diseases and originates from Active Biotech's patented CD80 antagonists, out-licensed in 2002 to MediGene AG (MediGene). MediGene is responsible for the development and carries the related costs of the clinical program.

#### Significant events 2004–2015:

Following successful preclinical development work, a candidate drug was selected in 2004 under the name of RhuDex, an orally administered small molecule primarily intended for the treatment of rheumatoid arthritis (RA). Phase 1 studies of RhuDex commenced during the spring of 2005, yielding a small milestone payment for Active Biotech. In **March 2006**, the company could report that MediGene had successfully concluded two Phase 1 studies in which safety, tolerability and pharmacokinetic properties had been studied in healthy volunteers. A Phase 2a dose-escalation study in 35 RA patients was initiated in 2007 and, in 2008, positive data from the trial was reported. Further preclinical trials were completed in 2010. In 2013, a clinical Phase 1a study was initiated for treatment of primary biliary cirrhosis (PBC), a chronic liver disease. This is being carried out to confirm the mode of action of RhuDex in autoimmune diseases and facilitate the continued development of the drug. In **March 2014**, MediGene signed an agreement with the company Dr. Falk Pharma GmbH for the development and commercialization of RhuDex in hepatology and gastroenterology.

### SILC – preclinical project based on the mode of action of quinoline compounds

#### Significant events during the period 2008 – 2015:

Active Biotech's SILC project was initiated in 2008. Previous work has shown that quinoline compounds inhibit the interaction between a defined target molecule, S100A9, and at least two pro-inflammatory receptors. An in-house library and commercially available libraries of compounds have been screened for binding to the target molecule. Interesting, non-quinoline compounds in several different classes have been identified and developed. The objective of the SILC project is to develop new, patentable small molecule compounds that bind to the same target molecule but with superior pharmacological properties compared with the existing quinoline compounds. In 2014, project work focused on building up a strong patent portfolio around the substances that interact with S100 proteins and impede their interaction with their receptors. The company submitted three priority applications for the purpose of obtaining patent protection for three, chemically unrelated, substance groups. One of these has been approved.

Only commercial activities aimed at out-licensing the SILC project are conducted.

#### Comments on the income statement

The Group's net sales amounted to SEK 16.3 M (10.4) and included service and rental revenues.

#### Specification of net sales (SEK million)

	2015 Jan-Dec	2014 Jan-Dec	2013 Jan-Dec
Revenue from out-licensing and partnership agreements	0.0	0.0	104.1
Rental revenues	9.2	7.3	7.0
Other revenues	7.0	3.1	4.9
Total	16.3	10.4	116.0

At year-end, the clinical development program comprised a total of five projects, of which laquinimod and RhuDex were fully financed by partners, while tasquinimod, ANYARA and paquinimod and the preclinical SILC project were fully or partially financed by Active Biotech on an independent basis.

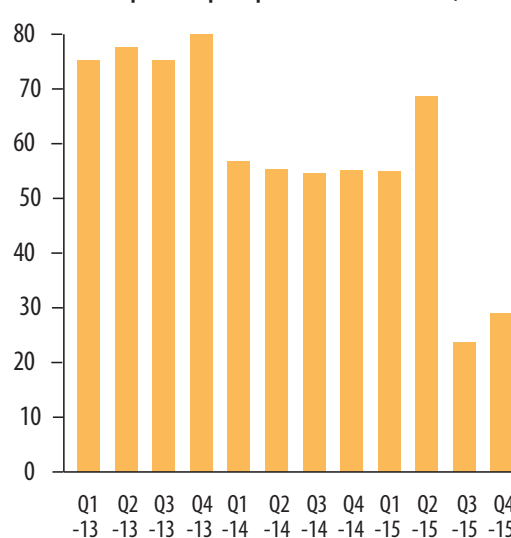
Of the total of SEK 176.2 M (221.9) in research expenses in 2015, the cost of purchased services from companies specialized in conducting clinical development, manufacturing clinical material, and so forth, amounted to SEK 81.5 M (133.7) and costs for personnel, premises, consumables in operations, etc. to SEK 94.9 M (88.2). The decrease of SEK 45.7 million in costs between 2015 and 2014 is entirely attributable to the planned lower costs in the Phase 3 study of tasquinimod in prostate cancer, since the study was concluded in 2015. The cost outcome for 2015 includes SEK 9.0 million in costs for redundancies.

#### Specification of purchased research services in 2012–2015 (SEK M)

Of a total of SEK 176.2 M in research expenses, tasquinimod's share in 2015 represented 61 percent, compared with 68 percent in 2014. The development program for tasquinimod was comprehensive and involved a global Phase 3 trial that was launched in 2011 and the trial results were reported in April 2015.

Enrollment in the study was completed in December 2012 and included a total of 1,245 patients at 240 hospitals in 37 countries. Costs for the study peaked in 2012 and have subsequently declined as patients reach the end of their treatment.

#### Research expenses per quarter 2013–2015 (SEK M)

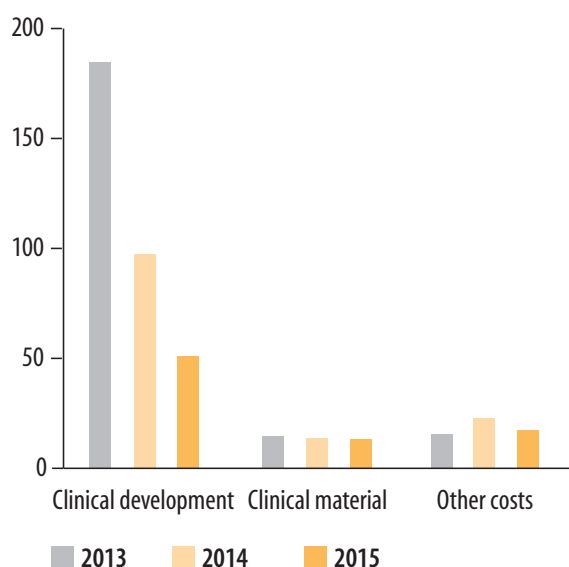




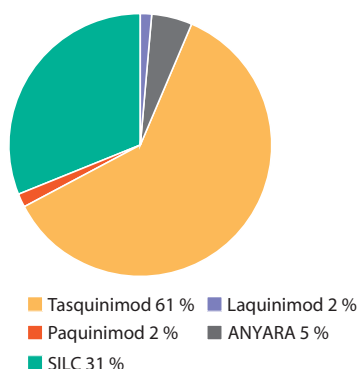
Active Biotech's development and partnership agreement with Ipsen was signed in 2011 and discontinued in 2015. Under the agreement, Ipsen makes milestone payments on fulfillment of predefined clinical, regulatory and commercial goals. Until year-end 2015, an initial payment upon signing of the contract and three milestone payments totaled EUR 57 M (SEK 505 M).

The scientific activities for the ANYARA and paquinimod projects were concluded during the latter part of 2014, which was the reason for only 4.9 percent and 1.6 percent, respectively, of total research expenses in 2015 being allocated to these projects. In addition to the clinical development program, the company also pursues the preclinical research project SILC, the aim of which is to utilize Active Biotech's own research results generated around a target molecule for the quinoline compounds and their biological mode of action. During 2015, the project focused on strengthening the patent portfolio surrounding the substances that interact with S100 proteins. The increased allocation of resources to the SILC project in 2015 was reflected in a higher share of total research expenses from 23.2 percent in 2014 to 31.0 percent in 2015.

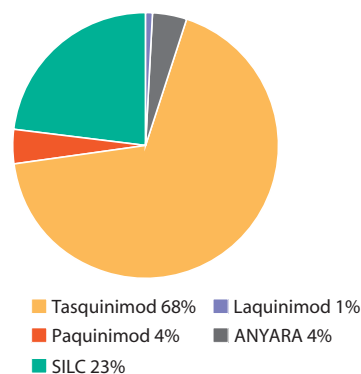
#### Specification of purchased research services in 2013–2015 (SEK M)



#### Specification of research and development costs 2015



#### Specification of research and development costs 2014



Administrative expenses amounted to SEK 18.0 million (17.0). The consolidated operating loss amounted to SEK 177.9 M (loss: 228.5). The improvement in earnings was attributable to lower costs of SEK 44.7 M and higher service and rental revenues of SEK 5.9 M in 2015 compared with 2014. Consolidated net financial items amounted to an expense of SEK 6.8 M (expense: 5.3), of which financial income amounted to SEK 0.2 M (6.8). Of financial expenses totaling SEK 7.0 M (12.0), interest expenses accounted for SEK 7.0 M (11.7), and exchange rate changes for SEK 0 M (0.3).

#### Comments on the balance sheet

At year-end 2015, the Group's total assets amounted to SEK 449.4 M (722.5), of which tangible fixed assets accounted for SEK 329.8 M (381.6). The market value of the company's property Forskaren 1, amounted to SEK 325.0 M (375.0). The value of equipment, tools, fixtures and fittings totaled SEK 4.8 M (6.6). At year-end, cash and cash equivalents and financial investments totaled SEK 103.6 M (328.5).

#### Comments on the cash-flow statement

The Group's cash flow for full-year 2015 was negative SEK 224.8 M (neg: 47.7). The negative cash flow from operating activities amounted to SEK 217.9 M (neg: 267.1). Cash flow from investing activities amounted to SEK 0 million (neg: 1.9) and the cash flow from financing activities amounted to a negative SEK 7.0 million (pos: 221.3). A rights issue comprising 14,736,623 shares was carried out in the year-earlier period, raising proceeds of approximately SEK 223.6 M. Investments in tangible fixed assets amounted to SEK 0.2 M (2.8), of which SEK 0.2 M (0.9) was financed through financial leasing agreements.

#### Cash and cash equivalents and financial position

At year-end, cash and cash equivalents totaled SEK 103.6 M (328.5). The Board of Active Biotech has established a policy for the investment of the Group's cash and cash equivalents, which stipulates that these be invested at low credit risk, primarily in short-term Swedish securities, commercial papers and fixed-income and bond funds with high liquidity. At year-end, cash and cash equivalents totaling SEK 76.6 M were invested in short-term Swedish securities. Interest-bearing liabilities amounted to SEK 222.8 M (229.5), of which SEK 220.1 M (225.4) is repre-

sented by a property loan and SEK 2.7 M (4.1) by liabilities to leasing companies. At year-end, consolidated shareholders' equity amounted to SEK 180.6 M (405.3). At the end of the year, the equity/assets ratio for the Group was 40.2 percent, compared with 56.1 percent at year-end 2014.

### The Active Biotech share

#### *Share capital and ownership structure*

At year-end 2015, Active Biotech AB's share capital amounted to SEK 338.9 M distributed among 89,908,298 shares. The company has one class of share. All shares carry equal rights to participation in the company's assets and dividends. For information concerning the company's major shareholders, see page 41 of this Annual Report.

#### *Corporate governance*

Active Biotech AB's Articles of Association stipulate that the election of the Board is to always take place at the Annual General Meeting. Apart from this, the Articles of Association do not contain any stipulations governing how Board members are to be appointed or dismissed, or regarding changes to the Articles of Association. Shareholders can vote for the full number of shares held or represented at General Meetings of Active Biotech. Shares that have been issued are freely transferable without restrictions pursuant to legislation or Active Biotech's Articles of Association. The company is not aware of any agreements among shareholders that can entail restrictions on the entitlement to transfer shares in the company. For a more detailed description of how Active Biotech manages corporate governance issues and information on mandates granted by the General Meeting, refer to the Corporate Governance Report on pages 44–47.

### Parent Company

The operations of the Parent Company Active Biotech AB comprise the Group's research operations, Group coordinative administrative functions and asset management. The Parent Company's net sales for the year amounted to SEK 26.0 M (18.0). Operating expenses for the year amounted to SEK 226.8 M (270.1). Investments in tangible fixed assets amounted to SEK 0.0 M (0.1) for the year. At year-end, the Parent Company's cash and cash equivalents, including short-term investments, amounted to SEK 88.6 M, compared with SEK 319.7 M at the beginning of the year. The loss after tax was SEK 200.7 M (loss: 250.0).

### Risk factors

A research company such as Active Biotech is characterized by a high operational and financial risk, since the majority of the projects in which the company is involved are at the clinical phase, and there are a number of factors that have an impact on the likelihood of commercial success. The earlier in the development chain the project is, the higher the risk, while the risk decreases and the likelihood of reaching the market increases as each project completes the various specified development phases. The risk level of projects must be weighed against the potential that the projects will result in the development of a drug in the major indication areas that they aim to address. Active Biotech specializes in the development of pharmaceuticals. However, none of the company's products have yet been approved for sale, and operations to date have therefore been loss-making. It will be 2018 at the earliest before

there is a possibility of these products being registered and approved for sale. As a result, Active Biotech might continue to recognize operating losses for several years to come, and there is a risk that the company may never report a profit.

### Risks in operations

The process of research and pharmaceutical development until an approved product is registered is, to a great extent, both risky and capital-intensive. There are no guarantees that the requisite clinical studies will produce results that are sufficiently positive to secure approval. Most projects that are started will never achieve the stage of market registration. Neither are there any guarantees that the company will find necessary partners or that these partnerships will achieve the planned outcome. If approval is obtained, there is no guarantee that the approved product will achieve sales success. Competing products with better properties could be launched in the market or the company may prove incapable of marketing its product, either by itself or via partners. While Active Biotech is constantly working to improve patent protection for its compounds, methods and applications, there is no guarantee that the patents will in fact provide the necessary protection or that competitors will not somehow circumvent the patents or in some other manner use the research findings or other intellectual rights that the company has built up. Both the extent and timing of the Group's future capital requirements will depend on a number of factors, such as possibilities to enter into partnership agreements and the degree of success for development projects.

### Official requirements

Active Biotech currently holds all the permits required to conduct its operations. Operations are conducted in accordance with applicable legislation, and also meet high environmental and ethical standards. However, there is no guarantee that new requirements introduced by authorities will not make it more difficult to conduct operations. Neither is there any guarantee that the currently applicable permits will be renewed on the same terms or that the Group's insurance cover, which is deemed adequate today, will prove adequate.

### Financial risks

The Group has a currency exposure since operations are conducted in Sweden and research services are purchased internationally. Earnings are exposed to exchange rate changes with regard to the procurement of clinical trial services, research services and production of clinical materials. Operating expenses amounted to SEK 194.2 M during the fiscal year, of which about 40 percent corresponded to costs in foreign currencies. The proportion of costs in foreign currencies, principally in USD and EUR, may fluctuate as projects enter later phases of clinical development with more clinical studies potentially being conducted abroad. Since the Group does not make use of forward contracts or options to hedge foreign-exchange risk, exchange rate effects may impact the income statement. The company's credit risks are marginal, since its operations are only subject to low invoicing levels by virtue of the fact that it currently engages primarily in research and development. For further information on financial risks, see Note 18 on pages 33–34.

### Organization

The average number of employees in the Group amounted to 55 (58), of whom 28 (28) were women. The average age of the employees was 54 (53) with an average employment period of 22 years (19.8). The education level of the personnel is high; 18 hold a PhD and 22 have university/college education. During the year, the Group incurred average education costs of SEK 3,712 per employee. At year-end 2015, the number of employees was 50 (56), of whom 38 (45) were active in research and development operations.

### Incentive program

There are no outstanding incentive programs.

### Environmental information

Active Biotech conducts its operations in accordance with the permits issued for the company by the authorities. The company has, for example, a permit from the Swedish Radiation Protection Institute for the handling of radioactive materials, and from the Swedish Board of Agriculture and the Swedish Work Environment Authority regarding genetically modified organisms. In accordance with the Swedish Environmental Code, the company has registered its operations with the County Administrative Board. Inspections by the Swedish Work Environment Authority, the Lund Municipal Environmental Administration and the Swedish Radiation Protection Institute all achieved satisfactory results. Active Biotech has a well-developed program for the sorting of waste at source and for the destruction of environmentally hazardous waste, and works actively to minimize energy consumption and the use of environmentally hazardous substances. Active Biotech is not involved in any environmental disputes.

### Proposed appropriation of the company's accumulated loss

The Board of Directors and the President propose that no dividend be paid for the 2015 fiscal year. The proposed appropriation of the company's accumulated loss is detailed on page 15.

### Report on the work of the Board

The Board decides on the Group's overall strategy, the Group's organization and management in accordance with the Swedish Companies Act. At year-end, the Board comprised four members elected by the Annual General Meeting, two employee representatives and two deputy employee representatives. Other white-collar employees in the company participate in Board meetings in a reporting capacity or in administrative functions. During the year, seven meetings were held at which minutes were taken. The President & CEO continuously informed the Chairman of the Board and the other Board members of developments in the company. Important issues addressed by the Board included:

- Financing of the operation
- Development of research projects
- Business development projects
- Strategic focus
- Information concerning financial statements
- Budgets and forecasts for the operation
- Partnership strategy and partnership discussions

The work of the Board and governance of Active Biotech is described in detail in the "Corporate Governance Report" section on pages 44–47. With regard to the Group's and Parent Company's results and financial position, refer to the subsequent income statements and balance sheets with the accompanying notes to the financial statements.

### The Board's proposed guidelines for remuneration of senior executives

The Board proposes that the Annual General Meeting to be held on May 26, 2016 decides on the following guidelines for remuneration of senior executives. These guidelines essentially conform to those applied to date within the company. Senior executives are defined as the President & CEO and other members of Group management. The guidelines are to apply to employment contracts entered into subsequent to the Board's decision on guidelines and in those instances amendments are made in existing terms and conditions following the Board's decision.

Active Biotech is to offer total remuneration on market terms, facilitating the recruitment and retention of competent senior executives. Remuneration of senior executives is to comprise fixed salary, any variable salary, pensions and other benefits. If the Board also determines that new share-based incentives should be introduced (e.g. employee stock options), a motion concerning this is to be submitted to the General Meeting for resolution. The guidelines applied in 2015 and the remuneration paid are described in Note 5 on pages 23–24.

#### *Fixed salary*

The fixed salary is to take into consideration the individuals' area of responsibility and experience. This is to be reviewed on an annual basis.

#### *Variable salary*

The variable salary is to, where applicable, depend on the individuals' fulfillment of quantitative and qualitative goals. Variable salary may not exceed 50 percent of fixed salary for the President & CEO. For other senior executives, the variable salary is to amount to not more than 25 percent of fixed salary, whereby the highest level should be based on such factors as the position held by the specific individual.

#### *Pension*

Pension benefits are to comprise defined-contribution schemes. For senior executives covered by the ITP plan, the pension premium is to correspond to the stipulations of the ITP plan. For other senior executives, the pension premium is to not exceed 25 percent of fixed salary.

#### *Severance pay, etc.*

The period of termination notice for senior executives is to not exceed 12 months. No severance amounts will be payable. However, the President & CEO is entitled to extra remuneration of not more than four annual salaries in the event of an ownership change that entails that the company, in its entirety, is acquired or taken over by another party.

#### *Other benefits*

Senior executives may be awarded otherwise customary benefits, such as a company car, company healthcare, etc.



#### *Preparation and approval*

The President & CEO's remuneration is to be prepared and approved by the Board. Other senior executives' remuneration is to be prepared by the President & CEO, who is to submit a proposal to the Board for approval. The Board is entitled to deviate from the above principles if it deems that there are particular grounds for doing so in individual cases.

#### *Previously approved remuneration*

The President & CEO is entitled to extra remuneration such as that referred to above under the heading "Severance pay, etc." In other respects, there are no earlier adopted remuneration packages that have not fallen due for payment.

#### **Events after the end of the fiscal year**

On **January 4, 2016**, it was announced that the high dose groups of laquinimod in studies in multiple sclerosis (MS) (CONCERTO and ARPEGGIO) would be discontinued after the occurrence of cardiovascular events, none of which were fatal, in eight patients. The change came at the recommendation of the data monitoring committee (DMC) overseeing the two active clinical studies in MS. The DMC identified an imbalance in the number of cardiovascular events in the studies. Seven events were observed in patients receiving laquinimod daily at 1.2 mg for treatment of relapsing remitting MS (RRMS) in the Phase 3 CONCERTO trial. No events occurred in the 0.6 mg or placebo groups. CONCERTO has 2,199 patients with 3,070 years of patient experience. One event was observed in the 1.5 mg daily-dose arm of the Phase 2 ARPEGGIO trial in primary-progressive MS (PPMS). ARPEGGIO has enrolled 191 patients and has 35 years of patient experience. Teva notified trial sites to discontinue the higher doses immediately in both trials and will encourage participants to continue follow ups.

Both trials, CONCERTO and ARPEGGIO, are continuing the lower-dose arms (0.6 mg daily), and participants in the trials will be provided with an update to confirm re-consent for participation. The DMC did not identify a cardiovascular signal with the lower dose but recommended long-term monitoring. Teva has previously carried out comprehensive studies of laquinimod at 0.6 mg per day and long-term extension studies with this dose are ongoing with any indications of cardiovascular events being noted.

On **January 11, 2016**, it was also announced that Teva would amend the trial design of the Phase 2 study of laquinimod in Huntington's disease. The amendment consists of dropping the highest of three doses (1.5 mg per day) in the trial while keeping two remaining active doses (0.5 and 1 mg per day) unchanged. This is a precautionary measure in the interest of patient safety being suggested by Teva to the Data Safety Monitoring Board (DSMB) for the LEGATO-HD trial.

The DSMB accepted the recommendation after reviewing data which observed cardiovascular incidents in patients receiving the high doses of laquinimod in two multiple sclerosis trials as reported on January 4, 2016. No cardiovascular events have been observed for any dose of the LEGATO-HD trial. Teva will continue in its commitment to study laquinimod in Huntington's disease.

Currently the mechanism of the cardiovascular events in the MS trials remains unknown. Although no specific time-to-event patterns have been identified, cardiovascular risk factors and demographics may play a role.

The results of the **tasquinimod** project were presented at the ASCO GU (American Society of Clinical Oncology,

GenitoUrinary) Symposium on **January 21-23, 2016**. An expanded analysis of the secondary endpoints for the Phase 3 study 10TASQ10 was presented alongside results from the Phase 2 study with tasquinimod as a maintenance therapy following docetaxel treatment, which was carried out by Active Biotech's partner Ipsen. Results from the investigator-sponsored clinical Phase 1 trial CATCH, in which tasquinimod was combined with the cytostatic agent cabazitaxel, were also presented.

Analysis of the secondary endpoints for the Phase 3 study 10TASQ10 showed that, with regard to tasquinimod, the results from both radiographic and PSA-based endpoints were favorable. However, as previously communicated, overall survival (OS) was not extended, prompting the discontinuation of all further development within prostate cancer.

Results from the Phase 2 study of tasquinimod to evaluate the clinical efficacy of tasquinimod used as maintenance therapy in patients with metastatic castrate-resistant prostate cancer (mCRPC) who have not progressed after a first-line docetaxel-based chemotherapy showed extended progression-free survival (median rPFS 7.32 months versus 5.24 months for placebo). The objective of the investigator-sponsored clinical Phase 1 study CATCH was to determine the recommended dose of tasquinimod in combination with cabazitaxel in patients with mCRPC. The results demonstrated that the recommended dose of tasquinimod in combination with cabazitaxel is 0.5 mg per day.

On **March 23, 2016**, it was announced that the company plans to develop tasquinimod for the treatment of multiple myeloma. It is the company's opinion that the existing medical need and the possibility for combination treatments makes tasquinimod, with its unique mode of action, a strong development candidate within this indication. The company intends to actively seek a collaboration partner for further development.

#### **Outlook for 2016**

Active Biotech's ability to develop pharmaceutical projects to the point at which partnership agreements can be concluded 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. Payments from existing agreements, the development and commercialization agreement with Teva regarding laquinimod, existing cash and cash equivalents and real assets, is expected to fund the operation. Since the timing for the signing of additional partnership agreements and the receipt of milestone payments from existing agreements cannot be specified, no earnings forecast is being issued for the 2016 fiscal year.

#### **Proposed appropriation of the company's accumulated loss**

The following amount stated in SEK is at the disposal of the Annual General Meeting:

Share premium reserve	167,096,523
Loss brought forward	-310,449,126
Loss for the year	-200,712,615
Total	-344,065,217

The Board of Directors proposes that the above loss of SEK 344,065,217 be carried forward.

## Consolidated income statement

JANUARY 1 – DECEMBER 31				
SEK thousands	Note	2015	2014	
Net sales	2	16,275	10,399	
Administrative expenses	3,4	-17,974	-16,974	
Research and development costs	3	-176,228	-221,885	
<b>Operating loss</b>	<b>5</b>	<b>-177,927</b>	<b>-228,460</b>	
Financial income		166	6,784	
Financial expenses		-6,978	-12,044	
<b>Net financial expense</b>	<b>6</b>	<b>-6,812</b>	<b>- 5,260</b>	
<b>Loss before tax</b>		<b>-184,739</b>	<b>-233,720</b>	
Tax	7	-8,792	2,208	
<b>Loss for the year</b>		<b>-193,531</b>	<b>-231,512</b>	
<b>Loss for the year attributable to:</b>				
Parent Company's shareholder		-193,531	-231,512	
Non-controlling interests		–	–	
<b>Earnings per share</b>	<b>13</b>			
before dilution (SEK)		-2.15	-3.02	
after dilution (SEK)		-2.15	-3.02	

## Statement of consolidated comprehensive income

JANUARY 1 – DECEMBER 31			
SEK thousands		2015	2014
<b>Loss for the year</b>		<b>-193,531</b>	<b>-231,512</b>
<b>Other comprehensive income</b>			
<b>Items that cannot be reclassified into profit or loss for the year</b>			
Change in revaluation reserve		-42,821	7,179
Tax attributable to other comprehensive income		9,421	-1,579
<b>Other comprehensive income/loss for the year</b>		<b>-33,400</b>	<b>5,600</b>
<b>Comprehensive loss for the year</b>		<b>-226,931</b>	<b>-225,912</b>
<b>Comprehensive loss for the year attributable to:</b>			
Parent Company's shareholders		-226,931	-225,912
Non-controlling interests		–	–

## Consolidated statement of financial position

AT DECEMBER 31			
SEK thousands	Note	2015	2014
<b>ASSETS</b>			
Land and buildings	9	325,000	375,000
Equipment, tools, fixtures and fittings	9	4,802	6,636
Long-term receivables		1	1
<b>Total fixed assets</b>		<b>329,803</b>	<b>381,637</b>
Accounts receivable		529	462
Tax assets		2,457	2,457
Other receivables	10	10,251	6,118
Prepaid expenses			
and accrued income	11	2,783	3,391
Cash and cash equivalents	21	103,617	328,455
<b>Total current assets</b>		<b>119,637</b>	<b>340,883</b>
<b>TOTAL ASSETS AT DECEMBER 31</b>		<b>449,440</b>	<b>722,520</b>

## Consolidated statement of cash flows

JANUARY 1 – DECEMBER 31			
SEK thousands	Note 21	2015	2014
<b>Operating activities</b>			
Loss before tax		-184,739	-233,720
Adjustments for non-cash items		12,45	12,257
<b>Cash flow from operating activities before changes in working capital</b>		<b>-172,694</b>	<b>-221,463</b>
<b>Cash flow from changes in working capital</b>			
Increase(-)/Reduction(+) in operating receivables		-3,592	-1,851
Increase(-)/Reduction(+) in operating liabilities		-41,601	-43,776
<b>Cash flow from operating activities</b>		<b>-217,887</b>	<b>-267,090</b>
<b>Investing activities</b>			
Acquisition of tangible fixed assets		–	-1,901
<b>Cash flow from investing activities</b>		<b>–</b>	<b>-1,901</b>
<b>Financing activities</b>			
New share issue		–	224,771
Issue expenses		–	-1,192
Loans raised		–	5,000
Amortization of loans		-5,380	-5,255
Amortization of leasing liabilities		-1,571	-2,073
<b>Cash flow from financing activities</b>		<b>-6,951</b>	<b>221,251</b>
<b>Cash flow for the year</b>		<b>-224,838</b>	<b>-47,740</b>
<b>Cash and cash equivalents, January 1</b>		<b>328,455</b>	<b>376,195</b>
<b>CASH AND CASH EQUIVALENTS AT YEAR-END</b>		<b>103,617</b>	<b>328,455</b>

AT DECEMBER 31			
SEK thousands	Note	2015	2014
<b>SHAREHOLDERS' EQUITY</b>			
Share capital		338,895	282,413
New share issue in progress		–	56,482
Other capital contributed		3,237,363	3,237,363
Reserves		80,489	113,889
Loss brought forward including loss for the year		-3,476,144	- 3,284,841
<b>Total shareholders' equity</b>	<b>12</b>	<b>180,603</b>	<b>405,306</b>
<b>LIABILITIES</b>			
Liabilities to credit institutions	14	214,688	220,068
Other long-term interest-bearing liabilities	14	1,584	2,571
<b>Total long-term liabilities</b>		<b>216,272</b>	<b>222,639</b>
Short-term interest-bearing liabilities	14	6,490	6,898
Accounts payable		6,625	24,432
Tax liabilities		34	34
Other liabilities	15	2,064	2,304
Accrued expenses and deferred income	16	37,352	60,907
<b>Total short-term liabilities</b>		<b>52,565</b>	<b>94,575</b>
<b>TOTAL LIABILITIES</b>		<b>268,837</b>	<b>317,214</b>
<b>TOTAL SHAREHOLDERS' EQUITY AND LIABILITIES</b>		<b>449,440</b>	<b>722,520</b>

For information pertaining to pledged assets and contingent liabilities, see Note 19.

## Statement of changes in consolidated equity

SEK thousands	Note 12	Share capital	New share issue in progress	Other capital contributed	Revaluation reserve	Profit/loss brought forward incl. loss for the year	Total shareholders' equity
Opening shareholders' equity, January 1, 2014		282,413	—	3 070,266	108,289	- 3,055,557	405,411
Comprehensive income/loss for the year		—	—	—	5,600	-231,512	-225,912
Transfer from revaluation reserve		—	—	—	—	2,228	2,228
New share issue in progress <sup>1)</sup>		—	56,482	167,097	—	—	223,579
Closing shareholders' equity, December 31, 2014		282,413	56,482	3,237,363	113,889	-3,284,841	405,306
Opening shareholders' equity, January 1, 2015		282,413	56,482	3,237,363	113,889	-3,284,841	405,306
Comprehensive income loss for the year		—	—	—	-33,400	-193,531	-226,931
Transfer from revaluation reserve		—	—	—	—	2,228	2,228
New share issue in progress		56,482	-56,482	—	—	—	—
Closing shareholders' equity, December 31, 2015		338,895	—	3,237,363	80,489	-3,476,144	180,603

1) The new share issue amount for 2014 was recognized net after deductions for transaction costs of SEK 1,192 thousand.

## Parent Company income statement

JANUARY 1 – DECEMBER 31			
SEK thousands	Note	2015	2014
Net sales	2	26,042	18,014
Administrative expenses	3,4	-35,611	-34,602
Research and development costs	3	-191,189	-235,463
<b>Operating loss</b>	<b>5</b>	<b>-200,758</b>	<b>-252,051</b>
<i>Profit/loss from financial items</i>			
Interest income and similar items	6	166	2,430
Interest expense and similar items	6	-120	-353
<b>Loss after financial items</b>		<b>-200,712</b>	<b>-249,974</b>
<b>Loss before tax</b>		<b>-200,712</b>	<b>-249,974</b>
Tax	7	—	—
<b>Loss for the year</b>		<b>-200,712</b>	<b>-249,974</b>

## Statement of comprehensive income, Parent Company

JANUARY 1 – DECEMBER 31		
SEK thousands	2015	2014
Loss for the year	-200,712	-249,974
Other comprehensive income	—	—
<b>Comprehensive loss for the year</b>	<b>-200,712</b>	<b>-249,974</b>

## Cash flow statement for the Parent Company

JANUARY 1 – DECEMBER 31			
SEK thousands	Note 21	2015	2014
<i>Operating activities</i>			
Loss after financial items		-200,712	-249,974
Adjustments for non-cash items		16,214	16,270
<b>Cash flow from operating activities before changes in working capital</b>		<b>-184,498</b>	<b>-233,704</b>
<i>Cash flow from changes in working capital</i>			
Increase(-)/Reduction(+) in operating receivables		-5,087	-1,425
Increase(-)/Reduction(+) in operating liabilities		-41,489	-39,199
<b>Cash flow from operating activities</b>		<b>-231,074</b>	<b>-274,328</b>
<i>Investing activities</i>			
Acquisition of tangible fixed assets		—	-61
<b>Cash flow from investing activities</b>		<b>—</b>	<b>-61</b>
<i>Financing activities</i>			
New share issue		—	224,771
Issue expenses		—	-1,192
<b>Cash flow from financing activities</b>		<b>—</b>	<b>223,579</b>
<b>Cash flow for the year</b>		<b>-231,074</b>	<b>-50,810</b>
<b>Cash and cash equivalents, January 1</b>		<b>319,694</b>	<b>370,504</b>
<b>CASH AND CASH EQUIVALENTS AT YEAR-END</b>		<b>88,620</b>	<b>319,694</b>



## Parent Company balance sheet

AT DECEMBER 31			
SEK thousands	Note	2015	2014
<b>ASSETS</b>			
<b>Fixed assets</b>			
<i>Intangible fixed assets</i>			
Goodwill	8	80,748	96,898
<b>Total intangible fixed assets</b>		<b>80,748</b>	<b>96,898</b>
<i>Tangible fixed assets</i>			
Equipment, tools, fixtures and fittings	9	493	557
<b>Total tangible fixed assets</b>		<b>493</b>	<b>557</b>
<i>Financial fixed assets</i>			
Participations in Group companies	19	40,550	40,550
Other long-term receivables		1	1
<b>Total financial fixed assets</b>		<b>40,551</b>	<b>40,551</b>
<b>Total fixed assets</b>		<b>121,792</b>	<b>138,006</b>
<b>Current assets</b>			
<i>Short-term receivables</i>			
Accounts receivable		441	260
Receivables from Group companies		12,461	11,080
Tax assets		2,457	2,457
Other receivables	10	10,250	6,117
Prepaid expenses and accrued income	11	2,783	3,391
<b>Total short-term investments</b>		<b>28,392</b>	<b>23,305</b>
Short-term investments	21	76,555	76,666
Cash and bank balances	21	12,065	243,028
<b>Total current assets</b>		<b>117,012</b>	<b>342,999</b>
<b>TOTAL ASSETS</b>		<b>238,804</b>	<b>481,005</b>

AT DECEMBER 31			
SEK thousands	Note	2015	2014
<b>SHAREHOLDERS' EQUITY AND LIABILITIES</b>			
<b>Shareholders' equity</b>			
<i>Restricted equity</i>			
Share capital		338,895	282,413
Revaluation reserve		80,748	96,898
Statutory reserve		118,871	118,871
New share issue in progress		—	56,483
<i>Unrestricted equity</i>			
Share premium reserve		167,097	167,097
Loss brought forward		-310,449	-76,625
Loss for the year		-200,712	-249,974
<b>Total shareholders' equity</b>	12	<b>194,450</b>	<b>395,162</b>
<b>Short-term liabilities</b>			
Accounts payable		6,624	24,432
Other liabilities	15	980	1,123
Accrued expenses and deferred income	16	36,750	60,288
<b>Total short-term liabilities</b>		<b>44,354</b>	<b>85,843</b>
<b>TOTAL SHAREHOLDERS' EQUITY AND LIABILITIES</b>		<b>238,804</b>	<b>481,005</b>

### Pledged assets and contingent liabilities for the Parent Company

AT DECEMBER 31			
SEK thousands	Note	2015	2014
Assets pledged	19	36,679	34,902
Contingent liabilities	19	220,068	225,448

## Statement of changes in Parent Company's equity

SEK thousands	Note 12	Restricted equity			Share premium reserve	Unrestricted equity		Total shareholders' equity
		Share capital	Revaluation reserve	Statutory reserve		Profit/loss brought forward	Loss for the year	
Opening shareholders' equity, January 1, 2014		282,413	113,048	118,871	—	-112,629	-227,281	421,557
New share issue in progress <sup>1)</sup>		—	—	—	56,482	—	—	223,579
Transfer between restricted and unrestricted equity <sup>2)</sup>		—	-16,150	—	—	16,150	—	—
Comprehensive income for the year		—	—	—	—	—	-249,974	-249,974
Treatment of profit/loss in preceding year		—	—	—	—	19,854	227,281	—
Closing shareholders' equity, December 31, 2014		282,413	96,898	118,871	56,482	-76,625	-249,974	395,162

Opening shareholders' equity, January 1, 2015	282,413	96,898	118,871	56,482	167,097	-76,625	-249,974	395,162
New share issue in progress	56,482	—	—	-56,482	—	—	—	—
Transfer between restricted and unrestricted equity <sup>2)</sup>	—	-16,150	—	—	—	16,150	—	—
Comprehensive loss for the year	—	—	—	—	—	—	-200,712	-200,712
Treatment of profit/loss in preceding year	—	—	—	—	—	-249,974	249,974	—
Closing shareholders' equity, December 31, 2015	338,895	80,748	118,871	—	167,097	-310,449	-200,712	194,450

<sup>1)</sup> The new share issue amount for 2014 was recognized net after deductions for transaction costs of SEK 1,192 thousand.

<sup>2)</sup> The transfer between restricted and unrestricted equity that took place in 2014 and 2015 was attributable to amortization of goodwill arising from the purchase of the net assets of a business.

# Notes to the financial statements

## Note 1 • Accounting policies

### Conformity with standards and legislation

The consolidated financial statements were prepared in accordance with the International Financial Reporting Standards (IFRS) published by the International Accounting Standards Board (IASB), as adopted by the European Union. In addition, the Group applied the recommendation of the Swedish Financial Reporting Board RFR 1 Supplementary Accounting Rules for Groups.

The Parent Company applies the same accounting policies as the Group, except in the instances specified below in the section "Accounting policies of the Parent Company."

The Annual Report and the consolidated financial statements were approved for issue by the Board and the President on April 27, 2016.

The consolidated income statement and statement of financial position and the Parent Company's income statement and balance sheet will be subject for adoption by the Annual General Meeting on May 26, 2016.

### Conditions for preparing the Parent Company's and Group's financial statements

The Parent Company's functional currency is Swedish kronor, which is also the presentation currency for the Parent Company and the Group. Accordingly, the financial statements are presented in Swedish kronor, SEK. All amounts, unless otherwise stated, are rounded off to the nearest thousand. Assets and liabilities are recognized at historical acquisition value (cost), except for the Group's property Forskaren 1, and certain financial assets and liabilities, which are measured at fair value. Financial assets and liabilities measured at fair value comprise derivatives and short-term investments.

The preparation of financial statements in accordance with IFRS requires company management to make assessments and estimates that affect the application of the accounting policies and the recognized amounts of assets, liabilities, revenues and expenses. The actual outcome may deviate from these estimates and assessments. The estimates and assumptions are reviewed regularly. Changes to the estimates are recognized in the period in which the change is made if it is the only period affected by the change, but if it also affects future periods, it is recognized in the period the change is made and in future periods.

Assessments made by company management when applying IFRS that may considerably influence the financial statements together with estimates made that may entail significant adjustments to financial statements in forthcoming years are described in more detail in Note 22.

The accounting policies for the Group detailed below were applied consistently in all periods presented in the consolidated financial statements, unless otherwise specified below. The Group's accounting policies were applied consistently in the reporting and consolidation of the Parent Company and subsidiaries.

### Changed accounting policies

In 2015, no revisions of IFRS with application as of 2015 had any material impact on the Group's reporting. A number of new or revised IFRS will come into effect in forthcoming fiscal years but were not applied prospectively when preparing these financial statements. The Group does not plan to prematurely apply new standards or amendments to standards with prospective application. The company's assessment is that published new or revised standards with prospective application will not have any material impact on the Group's reporting.

### Segment reporting

An operating segment is a part of the Group that conducts operations from which it can generate revenues and incur costs and from which independent financial information is available. In addition, an operating segment's results are followed up by the company's chief operating decision-maker to assess earnings and to be able to allocate resources to the operating segment. Since operations within the Active Biotech Group are organized as a cohesive unit, with similar risks and opportunities for the products and services produced, the Group's entire operation comprises a single operating segment. All operations are conducted in Sweden.

### Classification, etc.

Fixed assets and long-term liabilities in the Parent Company and Group essentially consist of amounts that are expected to be recovered or paid more than 12 months after the balance sheet date. Current assets and short-term liabilities in the Parent Company and Group primarily consist of amounts that are expected to be recovered or paid within 12 months from the balance sheet date.

### Consolidation principles

#### Subsidiaries

A subsidiary is a company in which Active Biotech AB has a controlling influence. Controlling influence entails a direct or indirect right to formulate a company's financial and operative strategies with the aim of obtaining financial benefits. When determining if a controlling influence exists, consideration is given to potential shares that carry voting rights, which can be utilized or converted without delay.

### Transactions to be eliminated at consolidation

Intra-Group receivables and liabilities, revenues and expenses and unrealized gains or losses that arise from transactions between Group companies are eliminated in their entirety when preparing the consolidated financial statements.

### Foreign currency

#### Transactions in foreign currency

Transactions in foreign currency are translated to the functional currency at the exchange rate prevailing on the transaction date. Monetary assets and liabilities in foreign currencies are translated to the functional currency at the exchange rate prevailing on the balance sheet date. Exchange rate differences that arise in translation are recognized in profit or loss. Non-monetary assets and liabilities that are recognized at historical cost are translated at the exchange rate prevailing at the date of the transaction. Non-monetary assets and liabilities that are recognized at fair value are translated to the functional currency at the exchange rate prevailing at the date of measurement at fair value.

### Recognition of revenues

Active Biotech currently receives revenues for out-licensing of research projects, for performing research services and from rental revenues.

Revenues for out-licensing of research projects comprise a licensing fee, milestone payments and royalties from the sale of the pharmaceuticals. An up-front payment is received when the partnership agreement is entered into. This payment is recognized in full at the date of entering into the agreement on condition that the company has fulfilled all commitments under the agreement. Any milestone payments are recognized as revenue if and when the parties to the agreement meet the agreed criteria and agreement has been reached with the counterparty. Any future royalty revenues are recognized as revenue in accordance with the financial content of the agreement.

Research services are recognized as revenue in the accounting period during which the work was performed.

Rental revenues are recognized in accordance with the terms of the rental agreement.

### Operating expenses and financial income and expenses

#### Operational leasing agreements

Costs pertaining to operational leasing agreements are recognized straight-line in profit or loss over the leasing period.

#### Financial leasing agreements

Minimum lease payments are divided between interest expenses and amortization of the outstanding liability. The interest expense is divided over the leasing period so that each accounting period is charged with an amount that corresponds to a fixed interest rate for the recognized liability in each period. Variable fees are expensed in the periods in which they arise.

#### Financial income and expenses

Financial income and expenses include interest income on bank deposits and receivables, interest expenses on loans, exchange rate differences and unrealized and realized gains from financial investments and value changes in derivatives.

Interest income on receivables and interest expenses on liabilities are calculated using the effective interest method. Effective interest is the interest that discounts estimated future receipts and payments during a financial instrument's anticipated duration to the financial asset's or liability's recognized net value. The interest component in financial leasing payments is recognized in profit or loss through the application of the effective interest method. Interest income includes the allocated amounts of transaction expenses and any discounts, premiums and other differences between the original value of the receivable and the amount received at maturity.

Interest is not included in the net gain or net loss on financial instruments measured at fair value in profit or loss.

Exchange rate gains and losses are netted.

### Financial instruments

Financial instruments recognized in the asset side of the statement of financial position include cash and cash equivalents, accounts receivable, shares and other equity instruments, loan receivables and bond receivables. Liabilities include accounts payable, loan liabilities and derivatives with a negative fair value.

### Recognition in, and derecognition from, the statement of financial position

A financial asset or financial liability is recognized in the statement of financial position when the company is party to the contractual conditions of the instrument. Accounts receivable are recognized in the statement of financial position when the invoice has been sent. Liabilities are recognized when the other contracting party has fulfilled its obligations and payment is due, although the invoice has not yet been received. Accounts payable are recognized when the invoice is received.

A financial asset is derecognized from the statement of financial position when the contractual rights are realized, mature or the company loses control over them. This also applies to parts of financial assets. A financial liability is derecognized from the statement of financial position when the contractual obligation is met. This also applies to parts of financial liabilities. Acquisition and divestment of financial assets are recognized on the transaction date, which is the date the company commits to the acquisition or divestment of the asset.

Cash and cash equivalents comprise liquid funds and immediately accessible balances in banks and corresponding institutes, as well as short-term liquid investments that have a maturity of three months or less from the acquisition date, which are exposed to only an insignificant risk of fluctuation in value.

#### *Classification and measurement*

Financial instruments are initially recognized at cost representing the fair value of the instrument, with transaction costs added for all financial instruments, except those defined as financial assets and measured at fair value in profit or loss, which are measured at fair value excluding transaction expenses. Accordingly, the recognition of financial instruments depends on the manner in which they have been classified, which is specified below.

#### Loan and accounts receivables

Loan and accounts receivables are financial assets, which do not comprise derivatives, with fixed or determinable payments that are not quoted on an active market. Assets in this category are measured at amortized cost. Amortized cost is based on the effective interest calculated at the date of acquisition. Assets with a short duration are not discounted. This category comprises accounts receivable, long-term receivables, other receivables, and cash and bank. Accounts receivable are recognized at the amount that is expected to be received, that is, after the deduction of doubtful receivables, which are determined individually. Impairment of accounts receivable is recognized in operating expenses. Other receivables are classified as long-term receivables if the duration is longer than one year, and if it is shorter, as other receivables. Any impairment of long-term loan receivables is recognized as a financial item.

#### Investments held to maturity

Investments held to maturity comprise financial assets that encompass interest-bearing securities with fixed or determinable payments and fixed maturities that the company has an express intention and ability to hold to maturity. Assets in this category are measured at amortized cost.

#### Financial assets and liabilities at fair value in profit or loss

This category consists of the sub-group Financial assets and liabilities held for trading and contains the Group's derivatives with positive or negative fair values and other financial instruments continuously measured at fair value with the changes in the value recognized in profit or loss.

#### Other financial liabilities

Loans and other financial liabilities, such as accounts payable, are included in this category. Liabilities are measured at amortized cost. Accounts payable have a short expected duration and are measured without discounting to the nominal amount. Long-term liabilities have an expected duration of more than one year, while short-term liabilities have a duration of less than one year.

#### Derivatives and hedge accounting

The Group's derivative instruments have been acquired to financially hedge the risk of interest-rate exposure experienced by the Group. To hedge the risk in highly probable forecast interest-rate flows of loans with floating interest rates, interest-rate swaps are used in which the company receives floating interest-rate payments and pays fixed-interest rates. Derivatives are initially measured at fair value, meaning that the transaction costs are charged to earnings for the period. The Group has chosen not to apply hedge accounting, which means that current changes in the fair value of derivatives are recognized in profit or loss.

Interest coupons on interest-rate swaps are recognized as interest income or interest expenses depending on whether the interest is received or paid, while other changes in value are included in the net gain or the net loss on financial assets and financial liabilities measured at fair value in profit or loss.

#### **Tangible fixed assets**

##### *Owned assets*

The Group measures tangible fixed assets using the cost method, with the exception of the Group's property, which is measured using the revaluation method. Tangible fixed assets that are recognized using the cost method are recognized in the consolidated accounts at cost, less a deduction for accumulated depreciation and any impairment losses. The cost includes the purchase price and expenses directly attributable to the asset to bring the asset to the site and in the working condition for its intended use. Examples of directly attributable expenses included in the cost are delivery and handling costs, installation, acquisition registration, consultancy services and legal services.

The Group's property is measured at fair value less deductions for accumulated depreciation and adjustments due to revaluation. Revaluation is conducted with the regularity that is required to ensure that the carrying amount is not to significantly deviate from what is established as the fair value on the balance sheet date. The fair value of the property is based on the valuation conducted by independent external appraisers. When an asset's carrying amount increases, the appreciation is recognized directly in other comprehensive income and accumulated in a separate component in shareholders' equity termed "Revaluation reserve." If the increase entails a reversal of the previously recognized value impairment with regard to the same asset, the reduction is recognized as a reduced expense in profit or loss. When the carrying amount of an asset is reduced as a result of a revaluation, the reduction is recognized as an expense in profit or loss. If there is a balance in the revaluation reserve attributable to the asset, the value decline is recognized in other comprehensive income as a reduction in the revaluation reserve.

The difference between depreciation based on the revaluation value and depreciation using the original cost is transferred from the revaluation reserve to profit/loss brought forward.

Accumulated depreciation at the time of revaluation is eliminated against the asset's cost (or, where appropriate, in the revalued cost) after which the remaining net amount is adjusted to achieve conformity with the amount to which the asset was revalued (the asset's fair value). When an asset is divested, the revaluation reserve is transferred to profit/loss brought forward with no impact on profit or loss or other comprehensive income.

Tangible fixed assets comprising components with varying useful lifetimes are treated as separate components of tangible fixed assets.

The carrying amount of a tangible fixed asset is derecognized from the statement of financial position when it is disposed of, divested, or when no future financial benefits are expected from the disposal/divestment of the asset. Profit or loss arising from divestment or disposal of an asset comprises the difference between the sale price and the asset's carrying amount, less deductions for direct selling expenses. Profit or loss is recognized as other operating revenues/expenses.

#### *Leased assets*

Leases are classified in the consolidated financial statements as either financial leases or operational leases. Financial leases exist when the financial risks and benefits associated with ownership are essentially transferred to the lessee. If this is not the case, the lease is considered to be an operational lease.

Assets leased through financial leasing agreements are recognized as assets in the consolidated statement of financial position. The commitment to pay future leasing fees is recognized as long-term and short-term liabilities. These assets are depreciated over the contractual leasing period while leasing fees are recognized as interest and amortization of liabilities.

Leasing fees for operational leases are expensed straight-line over the term of the lease based on the value in use, which may differ from that which has actually been paid as a leasing fee during the year.

#### *Additional expenses*

Additional expenses are added to the cost only if it is probable that the company will recover the future financial benefits associated with the assets and the cost can be calculated in a reliable manner. All other additional expenses are recognized as expenses in the period in which they arise.

Pivotal in the assessments of when an additional expense is added to the cost is whether the expense refers to the replacement of identifiable components or parts thereof, which is when such expenses are capitalized. Expenses are also added to cost when new components are created. Any undepreciated carrying amounts of replacement components, or parts of components, are disposed of and expensed in connection with the replacement. Repairs are expensed on an ongoing basis.

#### *Depreciation principles*

Depreciation is calculated using the straight-line method over the estimated useful life of the assets. The Group applies component depreciation, which means that the estimated useful life of the components is the basis for depreciation.

Estimated useful life of:

– Buildings, owner-occupied properties	35 – 100 years
– Equipment, tools, fixtures and fittings	3 – 10 years

The owner-occupied properties comprise a number of components, whose useful life varies. The main category is land and buildings. No depreciation is recognized for the component land, since its useful life has been determined as unlimited. However, a building comprises a number of components whose useful life varies.

The useful life of these components has been estimated to vary between 35 and 100 years.



The following main categories of components have been identified and form the basis for the depreciation of buildings:

– Framework	100 years
– Non-structural elements, interior walls, etc.	50 years
– Glass roof	40 years
– Fire seal	40 years
– Installations; heating, electricity, plumbing, ventilation, etc.	50 years
– Elevators	35 years

Assessment of an asset's residual value, useful life and depreciation method is conducted annually.

### Intangible assets

#### Research and development

Expenses for research with the purpose of acquiring new scientific or technical knowledge are expensed when they arise.

Expenses for developments, in which the research result or other knowledge is applied to produce new or improved products or processes, is recognized as an asset in the statement of financial position, if the product or process is technically and commercially useful and the company has adequate resources to pursue development and thereafter use and sell the intangible asset. Other expenses for development are recognized in profit or loss as a cost as they arise.

Since the period in which the company's research and development projects are expected to be registered is some way off in the future, there is considerable uncertainty as to when any financial benefits will accrue to the company. Development costs are capitalized only on the condition that it is technically and financially possible to complete the asset, that the intention is, and the conditions exist, for the asset to be used in operations or sold and that it can be calculated in a reliable manner. Expenses pertaining to patents, technology and trademark rights and other similar assets that are part of the research and development operations are not capitalized, but are offset against earnings on an ongoing basis.

No assets of this character were acquired.

### Impairment

Carrying amounts of Group assets are tested at each balance sheet date to establish whether there are any impairment indicators.

#### Impairment testing of tangible and intangible assets and participations in subsidiaries and associated companies

If there is an indication that an impairment requirement exists, the asset's recoverable amount (see below) is calculated in accordance with IAS 36. If it is not possible to establish fundamentally independent cash flows attributable to a specific asset, when testing for impairment, the assets are to be grouped at the lowest level whereby it is possible to identify fundamentally independent cash flows — a so-called cash-generating unit. An impairment loss is recognized when an asset's or cash-generating unit's (group of units) carrying amount exceeds the recoverable amount. An impairment loss is charged to profit or loss. An impairment loss in assets attributable to a cash-generating unit (group of units) is first allocated to goodwill. Thereafter, a proportional impairment is conducted of other assets included in the cash-generating unit (group of units).

The recoverable amount is the highest of fair value less selling expenses and value in use. In calculating value in use, future cash flows are discounted at an interest rate that takes into account the market's assessment of risk-free interest and risk related to the specific asset.

#### Impairment testing of financial assets

At each reporting occasion, the company assesses if there is objective evidence that an impairment requirement exists for a financial asset or group of financial assets. Objective evidence comprises observable events that have taken place that have had a negative impact on the prospect of recovering the cost.

The recoverable amount for assets included in the loan receivables and accounts receivable category, which are recognized at amortized cost, is calculated as the present value of future cash flows discounted by the effective interest rate that applied when the asset was initially recognized. Assets with a short duration are not discounted. An impairment loss is charged to profit or loss.

#### Reversal of impairment

An impairment loss is reversed if there is both an indication that the impairment requirement no longer exists and if there has been a change in the assumptions that formed the basis for the calculation of the recoverable amount. However, impairment of goodwill is never reversed. Reversal of impairment is only conducted to the extent that the asset's carrying amount after the reversal does not exceed the carrying amount that would have been recognized, less depreciation, where applicable, had no impairment taken place.

Impairment of investments held to maturity or loan receivables and accounts receivable that are recognized at amortized cost is reversed if a later increase of the recoverable amount can be attributed to an event that occurred after the impairment was conducted.

### Employee remuneration

#### Post-retirement benefits

Both defined-benefit and defined-contribution pension plans exist within the Group. For defined-benefit plans, remuneration of current and former employees is based on their salary at the time of retirement as well as the number of years of service. The Group assumes responsibility for ensuring that promised remuneration is paid. For defined-contribution plans, the company pays pension premiums to separate legal entities and has no legal commitment or informal obligation to pay further premiums (if these should lack the assets necessary to provide the promised benefits). The company's obligations relating to fees for defined-contribution plans are expensed in profit or loss as they are accrued due to the employee performing services for the company over a period.

All defined-benefit pension plans are secured through insurance with Alecta, which is a multi-employer defined-benefit plan. For the 2015 and 2014 fiscal years, the company did not have access to information that would make it possible to recognize this plan as a defined-benefit plan. Accordingly, pension plans conforming to ITP and secured through an Alecta insurance policy are recognized as a defined-contribution plan.

#### Severance pay

An expense for remuneration in connection with termination of employment of personnel is recognized only if the company is unquestionably obligated, without any realistic possibility of withdrawal, by a formal detailed plan to eliminate a position in advance of when that position would normally expire. When remuneration is paid as an offer to encourage voluntary termination of employment, a cost for this is recognized if it is probable that the offer will be accepted and the number of employees that will accept the offer can be reliably estimated.

#### Current employee remuneration

Current remuneration to employees is calculated without discounting and is recognized as an expense when the related services are received.

A provision is recognized for the anticipated cost for bonus payments when the Group has an applicable legal or informal obligation to make such payments, as a result of services received from employees, and the obligation can be reliably estimated.

### Recognition of earnings per share

The calculation of earnings per share is based on profit/loss for the year in the Group attributable to the Parent Company's shareholders and on the weighted average number of shares outstanding during the year. There were no potential ordinary shares that could give rise to any dilution effects during the reported periods.

### Provisions

A provision is recognized in the statement of financial position when the Group has an existing legal or constructive obligation resulting from past events and it is probable that an outflow of financial resources will be required to settle the obligation and the amount can be reliably estimated. When the effect of the timing of when the payment will be made is significant, provisions are calculated by discounting the anticipated future cash flows to an interest rate before tax that reflects the actual market estimate of the money's value over time and, if applicable, the risks that are associated with the liability.

### Taxes

Income taxes comprise current tax and deferred tax. Income taxes are recognized in profit or loss except where the underlying transaction is recognized in other comprehensive income or in shareholders' equity, whereby the associated tax effect is recognized in other comprehensive income or shareholders' equity.

Current tax is tax that is to be paid or recovered in relation to the current year, applying tax rates determined or announced at the balance sheet date. Adjustment to current tax relating to previous periods is also recognized here.

Deferred tax is calculated using the balance sheet method based on the temporary differences between the carrying amount and the value for tax purposes of assets and liabilities. The following temporary differences are not recognized: temporary differences are not recognized in consolidated goodwill or for the difference that arises during initial recognition of assets and liabilities that do not constitute a business combination which, at the time of the transaction, do not have an impact on recognized or taxable earnings. Furthermore, temporary differences are not recognized that are attributable to shares in subsidiaries and participations in associated companies that are not expected to be reversed in the foreseeable future. Estimates of deferred tax are based on how carrying amounts of assets and liabilities are expected to be realized or

settled. Deferred tax is calculated applying tax rates and legislation determined or announced at the balance sheet date.

Deferred tax assets pertaining to deductible temporary differences and loss carryforwards are recognized to the extent that it is probable that they will be utilized. The carrying amount of deferred tax assets is reduced when it is no longer judged probable that they will be utilized. Any additional income tax arising from dividends is recognized at the same date as when the dividend was recognized as a liability.

#### **Contingent liabilities**

A contingent liability is recognized when a possible commitment exists arising from events that have occurred, the validity of which can only be confirmed by the occurrence or absence of one or more future events, or where there is a commitment not recognized as a liability or provision due to the low probability that an outflow of resources will be required.

#### **Parent Company's accounting policies**

The Parent Company prepared its annual financial statements in accordance with the Annual Accounts Act (1995:1554) and the recommendations of the Swedish Financial Reporting Board RFR 2, Accounting for Legal Entities. Statements issued by the Swedish Financial Reporting Board concerning listed companies were also applied. RFR 2 entails that in the annual accounts for a legal entity, the Parent Company is to apply all of the IFRS regulations and statements approved by the European Union to the greatest possible extent, within the framework of the Annual Accounts Act, the Pension Obligations Vesting Act and with consideration given to the relationship between accounting and taxation. The recommendation stipulates what exceptions and additions are to be made to IFRS.

#### **Changed accounting policies**

The Parent Company's accounting policies for 2015 were unchanged compared with the preceding year.

#### **Differences between the Group's and the Parent Company's accounting policies**

The differences between the Group's and the Parent Company's accounting policies are presented below. The accounting policies presented below for the Parent Company were applied consistently in all periods presented in the Parent Company's financial statements.

#### **Classification and presentation forms**

The presentation of the Parent Company's income statement and balance sheet is in line with the arrangement specified in the Annual Accounts Act. The difference in relation to IAS 1 Presentation of financial statements, which is applied in the preparation of the consolidated financial statements, is primarily the recognition of financial income and expenses, shareholders' equity and the occurrence of provisions as a separate heading in the balance sheet.

#### **Subsidiaries**

Participations in subsidiaries are recognized by the Parent Company using the cost method. This implies that transaction costs are included in the carrying amount of participations in subsidiaries. In the consolidated financial statements, transaction expenses attributable to subsidiaries are recognized immediately in profit or loss when these arise. The Parent Company always recognizes dividends from subsidiaries as revenue in profit or loss.

#### **Financial guarantee contracts**

The Parent Company's financial guarantee contracts mainly comprise guarantees for the benefit of subsidiaries. Financial guarantees mean that the company has an obligation to compensate the holder of a promissory instrument for losses that it incurs because a specific debtor fails to pay by the due date in accordance with the terms and conditions of the agreement. For recognition of financial guarantee contracts, the Parent Company applies one of the regulations permitted by the Swedish Financial Reporting Board that entails a relaxation compared with IAS 39 as regards financial guarantee contracts issued for the benefit of subsidiaries. The Parent Company records financial guarantee contracts as a provision in the balance sheet when the company has an obligation for which it is probable that payment will be required to settle the obligation.

#### **Tangible fixed assets**

##### *Owned assets*

Tangible fixed assets in the Parent Company are recognized at cost less deductions for accumulated depreciation and any impairment losses in the same manner as for the Group, but with the addition of any revaluations.

##### *Leased assets*

In the Parent Company, all leasing agreements are recognized in accordance with the regulations for operational leasing.

#### **Intangible fixed assets**

##### *Research and development*

In the Parent Company, all expenses for development are recognized as expenses in profit or loss.

##### *Depreciation principles*

Amortization is conducted on a straight-line basis over the estimated useful life of the asset, which corresponds to the period during which it will be used. For goodwill, the useful life is ten years.

#### **Taxes**

Untaxed reserves include deferred tax liabilities when recognized in the Parent Company. However, in the consolidated financial statements, untaxed reserves are divided into deferred tax liability and shareholders' equity.

## Note 2 • Distribution of sales

SEK thousands	Group		Parent Company	
	2015	2014	2015	2014
Research services	4,474	2,265	4,474	2,265
Service and rental revenues	10,332	8,134	1,087	795
Property services	–	–	19,012	14,954
Other	1,469	–	1,469	–
<b>Total</b>	<b>16,275</b>	<b>10,399</b>	<b>26,042</b>	<b>18,014</b>

## Note 3 • Operating expenses distributed by type of cost

SEK thousands	Group		Parent Company	
	2015	2014	2015	2014
Personnel costs	68,851	61,514	68,851	61,514
Depreciation/amortization	12,046	12,256	16,213	16,270
Operating expenses	11,128	10,819	11,125	10,814
Property expenses	16,874	15,759	45,308	42,956
Administrative expenses	1,713	1,328	1,713	1,328
External R&D expenses	81,368	133,709	81,368	133,709
Other external services	2,222	3,474	2,222	3,474
<b>Total</b>	<b>194,202</b>	<b>238,859</b>	<b>226,800</b>	<b>270,065</b>

## Note 4 • Auditors' fees

SEK thousands	Group and Parent Company	
	2015	2014
KPMG AB		
Auditing assignment	439	434
Audit activities other than auditing assignment	–	8
Tax consultancy services	38	–
Other assignments	–	–

Auditing assignments relate to the auditing of the annual report and accounts, including the Board's and the President & CEO's administration, and other assignments that the company's auditors are required to perform (including reviews of interim reports).

## Note 5 • Employee and personnel costs, and remuneration of senior executives

Costs for remuneration of employees		Group		Parent Company	
SEK thousands		2015	2014	2015	2014
Salaries and remuneration, etc. <sup>3)</sup>		41,941	38,063	41,941	38,063
Pension costs, defined-contribution plans <sup>1) 2)</sup> (see below)		9,866	9,910	9,866	9,910
Social-security costs <sup>3)</sup>		13,741	10,246	13,741	10,246
Non-monetary remuneration		2,344	2,349		
<b>Total</b>		<b>67,892</b>	<b>60,568</b>	<b>65,548</b>	<b>58,219</b>

<sup>1)</sup> Of the Parent Company's pension costs, SEK 2,814 thousand (2,614) pertains to the Board of Directors and President & CEO.

<sup>2)</sup> The Group's pension costs include SEK 2.7 M (2.6) pertaining to the ITP plan financed in Alecta. See the section "Post-retirement benefits" for further information.

<sup>3)</sup> Salaries and remuneration, etc. and social-security costs include expenses for redundancies of a total of SEK 9.0 M.

Gender distribution in management	2015	2014
	Of whom, women	
<b>Parent Company</b>		
Board of directors	25%	38%
Other senior executives	33%	33%
<b>Group total</b>		
Board of Directors	25%	38%
Other senior executives	33%	33%

2015			2014			
	Senior executives (7 individuals)	Other employees	Total	Senior executives (9 individuals)	Other employees	Total
SEK thousands						
Salaries and other remuneration						
Sweden	6 678	35,263	41,941	6,953	31,110	38,063
(of which, bonus and similar)	—	—	—	—	—	—
<b>Total Parent Company</b>	6,678	35,263	41,941	6,953	31,110	38,063
(of which, bonus and similar)	—	—	—	—	—	—
Social-security costs <sup>1)</sup>	6,461	17,146	23,607	6,315	13,842	20,157
<sup>1)</sup> of which, pension costs	4,139	5,727	9,866	3,923	5,987	9,910

for senior executive in the Group	2015	2014
Group	Senior executives	Senior executives
SEK thousands	(7 individuals)	(9 individuals)
Salaries and other remuneration (of which, bonus and similar)	6,678 —	6,953 —
Pension costs	4,139	3,923

No agreement exists covering severance pay or loans to Board members. The company and the President & CEO are subject to a mutual period of termination notice of 12 months. No severance pay will be issued and no loans exist. The company and other senior executives are to be subject to a mutual period of termination notice of not more than 12 months. No severance pay will be issued and no loans exist. However, the President & CEO is entitled to extra remuneration of not more than four annual salaries in the event of an ownership change that entails that the company, in its entirety, is acquired or taken over by another party.

**Defined-benefit plans**

Retirement pension and family pension obligations for salaried workers in Sweden are secured through insurance with Alecta, which is a multi-employer, defined-benefit plan. For the 2015 and 2014 fiscal years, the company did not have access to information that would make it possible to recognize this plan as a defined-benefit plan. Accordingly, pension plans conforming to ITP and secured through an Alecta insurance policy are recognized as a defined-contribution plan. The year's fees for pension insurance subscribed to in Alecta totaled SEK 2.7 M (2.6) and for 2016 the premiums will amount to SEK 2.6 M. Alecta's surplus can be allocated to the policyholders and/or the insured. At year-end 2015, Alecta's surplus at the collective funding ratio amounted to 153 percent (143). The collective funding ratio comprises the market value of Alecta's assets as a percentage of insurance obligations based on Alecta's actuarial calculations, which do not conform to IAS 19. Active Biotech's share of total savings premiums for ITP2 with Alecta amounted to 0.011 percent for 2015 and the share of the total actively insured in ITP2 amounted to 0.0092 percent in December 2015.



### Remuneration of senior executives

*Guidelines adopted at the Annual General Meeting on June 11, 2015*

Active Biotech is to offer total remuneration on market terms, facilitating the recruitment and retention of competent senior executives. Remuneration of senior executives is to comprise fixed salary, any variable salary, pensions and other benefits. If the Board also determines that new share-based incentives should be introduced (e.g. employee stock options), a motion concerning this is to be submitted to the General Meeting for resolution.

#### Fixed salary

The fixed salary is to take into consideration the individuals' area of responsibility and experience. This is to be reviewed on an annual basis.

#### Variable salary

The variable salary is to, where applicable, depend on the individuals' fulfillment of quantitative and qualitative goals. Variable salary may not exceed 50 percent of fixed salary for the President & CEO. For other senior executives, the variable salary is to amount to not more than 25 percent of fixed salary, whereby the highest level should be based on such factors as the position held by the specific individual.

#### Pension

Pension benefits are to comprise defined-contribution schemes. For senior executives covered by the ITP plan, the pension premium is to correspond to the stipulations of

the ITP plan. For other senior executives, the pension premium is to not exceed 25 percent of fixed salary.

#### Severance pay, etc.

The period of termination notice for senior executives is to not exceed 12 months. No severance amounts will be payable. However, the President & CEO is entitled to extra remuneration of not more than four annual salaries in the event of an ownership change that entails that the company, in its entirety, is acquired or taken over by another party.

#### Other benefits

Senior executives may be awarded otherwise customary benefits, such as a company car, company healthcare, etc.

#### Preparation and approval

The President & CEO's remuneration is to be prepared and approved by the Board. Other senior executives' remuneration is to be prepared by the President & CEO, who is to submit a proposal to the Board for approval. The Board is entitled to deviate from the above principles if it deems that there are particular grounds for doing so in individual cases.

#### Previously approved remuneration

The President & CEO is entitled to extra remuneration such as that referred to above under the heading "Severance pay, etc." In other respects, there are no earlier adopted remuneration packages that have not fallen due for payment.

### Remuneration and other benefits during 2015

SEK thousands	Basic salary /Board fee	Variable remuneration	Salary exchange	Pension costs	Share-based remuneration	Other remuneration	Total
Chairman of the Board; Mats Arnhöj <sup>1)</sup>	250	—	—	—	—	—	250
Board member; Magnhild Sandberg-Wollheim <sup>1)</sup>	125	—	—	—	—	—	125
Board member; Peter Sjöstrand <sup>1)</sup>	125	—	—	—	—	—	125
Board member; Peter Thelin <sup>1)</sup>	125	—	—	—	—	—	125
President & CEO, Tomas Leanderson	3,291	—	1,530	1,284	—	—	6,105
Other senior executives (2 individuals)	2,762	—	457	868	—	—	4,087
<b>Total</b>	<b>6,678</b>	<b>—</b>	<b>1,987</b>	<b>2,152</b>	<b>—</b>	<b>—</b>	<b>10,817</b>

<sup>1)</sup> Apart from Board fees, no additional remuneration was paid to Board members.

### Remuneration and other benefits during 2014

SEK thousands	Basic salary /Board fee	Variable remuneration	Salary exchange	Pension costs	Share-based remuneration	Other remuneration	Total
Chairman of the Board; Mats Arnhöj <sup>1)</sup>	250	—	—	—	—	—	250
Board member; Magnhild Sandberg-Wollheim <sup>1)</sup>	125	—	—	—	—	—	125
Board member; Rolf Kiessling <sup>1)</sup>	125	—	—	—	—	—	125
Board member; Peter Sjöstrand <sup>1)</sup>	125	—	—	—	—	—	125
Board member; Peter Hofvenstam <sup>1)</sup>	125	—	—	—	—	—	125
Board member; Peter Thelin <sup>1)</sup>	125	—	—	—	—	—	125
President & CEO, Tomas Leanderson	3,393	—	1,403	1,211	—	—	6,007
Other senior executives (2 individuals)	2,685	—	422	887	—	—	3,994
<b>Total</b>	<b>6,953</b>	<b>—</b>	<b>1,825</b>	<b>2,098</b>	<b>—</b>	<b>—</b>	<b>10,876</b>

<sup>1)</sup> Apart from Board fees, no additional remuneration was paid to Board members.

## Note 6 • Net financial items

	Group		Parent Company	
SEK thousands	2015	2014	2015	2014
Interest income				
- Interest income from bank balances	–	92	–	62
- Other interest income	11	8	11	8
Net gain on financial assets and liabilities measured at fair value in profit or loss				
- Held for trading: Interest-rate swaps	–	4 324	–	–
- Held for trading: Short-term investments	–	2 360	–	2,360
Net exchange rate changes	155	–	155	–
<b>Financial income/Interest income and similar profit/loss items</b>	<b>166</b>	<b>6,784</b>	<b>166</b>	<b>2,430</b>
Interest expenses				
- Interest expenses relating to bank loans	-6,764	-7,453	–	–
- Interest expenses relating to financial leasing	-94	-177	–	–
- Coupon interest on interest-rate swaps	–	-4,061	–	–
- Other interest expenses	-9	-13	-9	-13
Net loss on financial assets and liabilities measured at fair value in profit or loss				
- Held for trading: Short-term investments	-111	–	-111	–
Net exchange rate changes	–	-340	–	-340
<b>Financial expenses/Interest expenses and similar profit/loss items</b>	<b>-6,978</b>	<b>-12,044</b>	<b>-120</b>	<b>-353</b>
<b>Net financial items</b>	<b>-6,812</b>	<b>-5,260</b>	<b>46</b>	<b>2,077</b>
Of which:				
Interest income from instruments measured at amortized cost	–	92		
Interest expenses from instruments measured at amortized cost	-6 867	-7 643		
Exchange rate differences that impacted earnings				
Exchange rate differences that impacted operating loss	15	-141	15	-141
Financial exchange rate differences	155	-340	155	-340
<b>Total</b>	<b>170</b>	<b>-481</b>	<b>170</b>	<b>-481</b>

## Note 7 • Taxes

	Group		Parent Company	
SEK thousands	2015	2014	2015	2014
Recognized in profit or loss				
Current tax expense (-)/tax income (+)				
Tax expense/tax income for the period	–	–	–	–
Tax adjustments brought forward from earlier years	–	–	–	–
Deferred tax expense (-)/tax income (+)				
Deferred tax expense as a result of the utilization of loss carryforwards previously capitalized	-629	-629	–	–
Deferred tax income in tax loss carryforwards capitalized during the year	–	2,208	–	–
Deferred tax income attributable to reassessment of capitalized loss carryforwards	-8,792	–	–	–
Deferred tax income attributable to depreciation of revaluation of property	629	629	–	–
<b>Total recognized tax expense/income</b>	<b>-8,792</b>	<b>2,208</b>	<b>–</b>	<b>–</b>

	Group		Parent Company	
SEK thousands	2015	2014	2015	2014
Reconciliation of effective tax				
Loss before tax	-184,739	-233,720	-200,713	-249,974
Tax on the Parent Company according to current rates, 22%	40,643	51,418	44,157	54,995
Non-deductible expenses	-1,311	-331	-1,311	-331
Non-taxable revenues	149	134	149	134
Increase in loss carryforwards without equivalent capitalization of deferred taxes	-42,995	-54,798	-42,995	-54,798
Deductible expenses/taxable revenues not recognized in earnings	3,553	3,553	–	–
Increase/decrease in temporary differences for which deferred tax is not recognized	-39	24	–	–
Revaluation of deferred tax	-8,792	2,208	–	–
<b>Recognized effective tax</b>	<b>-8,792</b>	<b>2,208</b>	<b>–</b>	<b>–</b>

Tax items recognized directly in other comprehensive income	Group		Parent Company	
SEK thousands	2015	2014	2015	2014
Tax attributable to change in revaluation reserve	9,421	-1,579	–	–

Tax items recognized directly in equity	Group		Parent Company	
SEK thousands	2015	2014	2015	2014
Tax attributable to change in revaluation reserve	-629	-629	–	–

Recognized in statement of financial position	Deferred tax assets		Deferred tax liabilities		Net	
Deferred tax assets and liabilities	Group		Group		Group	
SEK thousands	2015	2014	2015	2014	2015	2014
Tangible fixed assets	–	–	-22,701	-32,122	-22,701	-32,122
Loss carryforwards	22,701	32,122	–	–	22,701	32,122
Tax assets/liabilities	22,701	32,122	-22,701	-32,122	–	–
Offsetting	-22,701	-32,122	22,701	32,122	–	–
<b>Tax assets/liabilities, net</b>	<b>–</b>	<b>–</b>	<b>–</b>	<b>–</b>	<b>–</b>	<b>–</b>

#### Change in deferred tax in temporary differences and loss carryforwards

SEK thousands	Balance at Jan. 1, 2015	Recognized in profit or loss	Recognized in other comprehensive income	Recognized in equity	Balance at Dec. 31, 2015
Tangible fixed assets	-32,122	629	9,421	-629	-22,701
Loss carryforwards	32,122	-9,421	–	–	22,701
	–	-8,792	9,421	-629	–
SEK thousands	Balance at Jan. 1, 2014	Recognized in profit or loss	Recognized in other comprehensive income	Recognized in equity	Balance at Dec. 31, 2014
Tangible fixed assets	-30,543	629	-1,579	-629	-32,122
Loss carryforwards	30,543	1,579	–	–	32,122
	–	2,208	-1,579	-629	–

Due to the Group's activities with considerable research and development costs, it is not liable for tax. At the end of 2015, the Group's accumulated loss carryforwards amounted to SEK 3,122 M and was attributable to the Group's Swedish companies. The Parent Company's loss carryforwards amounted to SEK 3,121 M. Since the time at which the Parent Company and the Swedish subsidiaries may be expected to generate revenues cannot yet be specified, only the portion of the taxable effects of the loss carryforwards corresponding to the deferred tax liability was recognized. The loss carryforwards for which deferred tax receivables are not recognized amounted to SEK 3,019 M (2,781).

## Note 8 • Intangible fixed assets

### Parent Company

SEK thousands	Goodwill	Total
<b>Cost</b>		
Opening balance, January 1, 2014	161,497	161,497
Other acquisitions	–	–
Closing balance, December 31, 2014	161,497	161,497
Opening balance, January 1, 2015	161,497	161,497
Other acquisitions	–	–
Closing balance, December 31, 2015	161,497	161,497

### Parent Company

SEK thousands	Goodwill	Total
<b>Amortization and impairment losses</b>		
Opening balance, January 1, 2014	-48,449	-48,449
Amortization for the year	-16,150	-16,150
Closing balance, December 31, 2014	-64,599	-64,599
Opening balance, January 1, 2015	-64,599	-64,599
Amortization for the year	-16,150	-16,150
Closing balance, December 31, 2015	-80,749	-80,749
<b>Carrying amounts</b>		
January 1, 2014	113,048	113,048
December 31, 2014	96,898	96,898
January 1, 2015	96,898	96,898
December 31, 2015	80,748	80,748

## Note 9 • Tangible fixed assets

### Group

SEK thousands	Land and buildings	Equipment, tools fixtures and fittings	Total
	Recognition based on revaluation method	Recognition based on cost method	
<b>Cost</b>			
Opening balance, January 1, 2014	449,197	143,249	592,446
Other acquisitions	–	2,823	2,823
Disposal	–	-630	-630
Revaluation	10,036	–	10,036
Closing balance, December 31, 2014	459,233	145,442	604,675
Opening balance, January 1, 2015	459,233	145,442	604,675
Other acquisitions	–	175	175
Disposal	–	-93,821	-93,821
Revaluation	-39,964	–	-39,964
Closing balance, December 31, 2015	419,269	51,796	471,065
<b>Depreciation and impairment losses</b>			
Opening balance, January 1, 2014	-74,197	-137,215	-211,412
Depreciation for the year	-7,179	-2,221	-9,400
Disposal	–	630	630
Revaluation	-2,857	–	-2,857
Closing balance, December 31, 2014	-84,233	-138,806	-223,039
Opening balance, January 1, 2015	-84,233	-138,806	-223,039
Depreciation for the year	-7,179	-2,009	-9,188
Disposal	–	93,821	93,821
Revaluation	-2,857	–	-2,857
Closing balance, December 31, 2015	-94,269	-46,994	-141,263

## Group

SEK thousands	Land and buildings	Equipment, tools fixtures and fittings		
	Recognition based on revaluation method	Recognition based on cost method	Total	
<b>Carrying amounts</b>				
January 1, 2014	375,000	6,034	381,034	
December 31, 2014	375,000	6,636	381,636	
January 1, 2015	375,000	6,636	381,636	
December 31, 2015	325,000	4,802	329,802	
<b>Tax assessment values</b>				
Group	Dec. 31, 2015	Dec. 31, 2014		
Tax assessment value, buildings (Forskaren 1, Municipality of Lund)	68,400	6,400		
Tax assessment value, land (Forskaren 1, Municipality of Lund)	13,652	13,652		
<b>Buildings and land recognized based on revaluation method</b>	Historical carrying amount Dec. 31, 2015	Carrying amount after revaluations Dec. 31, 2015	Historical carrying amount Dec. 31, 2014	Carrying amount after revaluations Dec. 31, 2014
Cost	296,461	419,269	296,461	459,233
Accumulated depreciation	-74,651	-94,269	-67,472	-84,233
Carrying amount	221,810	325,000	228,989	37,000

**Valuation of the Forskaren 1 property**

The Group recognizes the property at market value. At December 31, 2015, the property was valued by Thomas Ahlbeck Fastighetsekonomi AB at SEK 325 M. The value assessment assumes that on December 31, 2015 Active Biotech utilizes approximately 65 percent of the premises for its own operations and that the remaining 35 percent are leased to external tenants. The value of the laboratory equipment and other special equipment was not considered in the valuation. The value assessment was conducted using a market simulation via yield-based market value assessment and via the local market price method.

## Conditions and assumptions for valuation:

- Inflation assumption of 2.0 percent for the calculation period of 15 years
- Rental increases for rented premises in accordance with agreed rental terms
- Rental increases for internal premises, 100 percent of CPI
- Annual increase of operation/maintenance, 100 percent of CPI
- Direct yield last year's net operating income, 7.5 percent
- Nominal cost of capital, 9.6 percent

**Financial leasing in the Group**

The Group leases machines and other technical facilities under various financial leasing agreements in which the main terms of the agreement are as follows: rental period 36-60 months, final residual value 10 percent of the cost and an interest rate linked to a floating market interest rate. Property leased through the above-mentioned agreements is recognized in the consolidated balance sheet under equipment, tools, fixtures and fittings. At December 31, 2015, the carrying amount of property covered by financial leasing agreements was SEK 2,169 thousand. See also Note 14 Interest-bearing liabilities.

**Operational leasing in the Group**

The Group has operational leasing agreements for cars, telephone switchboard and photocopying machines. Payments pertaining to these operational leasing agreements are due as follows: within one year SEK 914 thousand, between one and five years SEK 1,380 thousand, and after five years SEK 0.

## Parent Company

SEK thousands	Equipment, tools, fixtures and fittings	Total
<b>Cost</b>		
Opening balance, January 1, 2014	138,487	138,487
Other acquisitions	61	61
Disposal	-630	-630
Closing balance, December 31, 2014	137,918	137,918
Opening balance, January 1, 2015	137,918	137,918
Other acquisitions	–	–
Disposal	-116,135	-116,135
Closing balance, December 31, 2015	21,783	21,783
<b>Depreciation and impairment losses</b>		
Opening balance, January 1, 2014	-137,871	-137,871
Depreciation for the year	-120	-120
Disposal	630	630
Closing balance, December 31, 2014	-137,361	-137,361
Opening balance, January 1, 2015	-137,361	-137,361
Depreciation for the year	-64	-64
Disposal	116,135	116,135
Closing balance, December 31, 2015	-21,290	-21,290
<b>Carrying amounts</b>		
January 1, 2014	616	616
December 31, 2014	557	557
January 1, 2015	557	557
December 31, 2015	493	493



## Note 10 • Other receivables

	Group		Parent Company	
SEK thousands	2015	2014	2015	2014
Not paid, subscribed issue proceeds	–	3,721	–	3,721
Receivables from suppliers	8,603	–	8,603	–
Tax account	776	687	776	687
VAT	868	1,047	868	1,047
Other receivables	4	663	3	662
<b>Total</b>	<b>10,251</b>	<b>6,118</b>	<b>10,250</b>	<b>6,117</b>

## Note 11 • Prepaid expenses and accrued income

	Group		Parent Company	
SEK thousands	2015	2014	2015	2014
Prepaid rent	27	27	27	27
Prepaid insurance	1,143	1,209	1,143	1,209
Accrued income	688	337	688	337
Prepaid clinical trials	–	206	–	206
Other prepaid expenses and accrued income	925	1,612	925	1,612
<b>Total</b>	<b>2,783</b>	<b>3,391</b>	<b>2,783</b>	<b>3,391</b>

## Note 12 • Shareholders' equity

### Consolidated shareholders' equity

#### Specification of shareholders' equity item Reserves

##### Revaluation reserve

SEK thousands	2015	2014
Revaluation reserve, January 1	113,889	108,289
Revaluation of property	-39,964	10,036
Tax effect of property revaluation	8,792	-2,208
Loss brought forward	-2,857	-2,857
Tax effect of transfer to loss brought forward	629	629
Revaluation reserve, December 31	80,489	113,889

##### Share capital

##### Ordinary shares

Thousands of shares	2015	2014
Issued at January 1	89,908	74,924
Issued at December 31 – registered	89,908	74,924

At December 31, 2015, the registered share capital comprised 89,908,298 ordinary shares with a quotient value of SEK 3.77 issued in one series. Holders of ordinary shares are entitled to dividends determined successively and the shareholding entitles the holder to voting rights at the Annual General Meeting of one vote per share.

### Other capital contributed

Refers to shareholders' equity contributed by the owners in addition to share capital. This includes the share premium reserves transferred to the statutory reserve at December 31, 2005. Effective January 1, 2006 and onward, allocations to the statutory reserve will also be recognized as contributed capital.

### Reserves

#### Revaluation reserve

The revaluation reserve includes value changes attributable to tangible fixed assets.

### Profit/loss brought forward including profit/loss for the year

Loss brought forward including loss for the year includes accumulated earnings/losses in the Parent Company and its subsidiaries and associated companies. Earlier provisions to statutory reserves, excluding transferred share premium reserves, are included in this equity item.

### Dividend

The Board of Directors proposes that no dividend be paid for the 2015 fiscal year.

### Capital management

In accordance with the Board's policy, the Group's financial objective is to maintain a solid capital structure and financial stability, thereby retaining the confidence of investors and credit providers in the market, and to function as a platform for the continued development of the business operation. Capital is defined as total shareholders' equity. With reference to the focus of the operation, no specific target for the debt/equity ratio has been defined. Neither the Parent Company nor any of its subsidiaries are subject to any external capital requirements.

### Parent Company's shareholders' equity

#### Restricted funds

Restricted funds may not be reduced through the distribution of profits.

#### Statutory reserve

The purpose of the statutory reserve is to retain a portion of net profit that is not used to cover losses brought forward. Amounts that were allocated to the share premium reserve before January 1, 2006 have been transferred and are now included in the statutory reserve.

#### Unrestricted equity

In addition to profit/loss for the year, the following funds comprise unrestricted equity, meaning the amount that is available for distribution to shareholders.

#### Share premium reserve

When shares are issued at a premium, that is, payment is required for the shares in excess of their quotient value, an amount corresponding to the proceeds received in excess of the shares' quotient value is to be transferred to the share premium reserve. Amounts allocated to the share premium reserve from January 1, 2006 are included in unrestricted equity.

#### Profit/loss brought forward

Profit/loss brought forward comprises the preceding year's profit/loss brought forward, less any dividends paid during the year.

## Not 13 • Earnings per share

	Before dilution		After dilution	
SEK	2015	2014	2015	2014
Earnings per share	-2.15	-3.02	-2.15	-3.02

Calculation of the numerator and the denominator used in the above calculation of earnings per share is specified below.

### Earnings per share before dilution

The calculation of earnings per share in 2015 was based on loss for the year attributable to the Parent Company's ordinary shareholders amounting to SEK 193,531 thousand (loss: 231,512) and on a weighted average number of shares outstanding during 2015 totaling 89,908,298 (76,754,591). The two components were calculated in the following manner:

#### Loss attributable to the Parent Company's ordinary shareholders, before dilution

SEK thousands	2015	2014
Loss attributable to the Parent Company's shareholders	-193,531	-231,512

#### Weighted average number of outstanding ordinary shares, before dilution

Thousands of shares	2015	2014
Total number of ordinary shares at January 1	74,924	74,924
Effect of new share issues	14,984	1,831
Weighted average number of ordinary shares during the year, before dilution	89,908	76,755

### Earnings per share after dilution

Earnings and the number of shares in the calculation of earnings per share after dilution are the same as for the calculation of earnings per share before dilution since there are no potential ordinary shares that could give rise to a dilutive effect.

**Note 14 • Interest-bearing liabilities**

	Group	
SEK thousands	2015	2014
<b>Long-term liabilities</b>		
Bank loans	214,688	220,068
Financial leasing liabilities	1,584	2,571
<b>Total</b>	<b>216,272</b>	<b>222,639</b>
<b>Short-term liabilities</b>		
Short-term portion of bank loan	5,380	5,380
Short-term portion of financial leasing liabilities	1,110	1,518
<b>Total</b>	<b>6,490</b>	<b>6,898</b>

**Financial leasing**

The portion of long-term interest-bearing liabilities that pertains to financial leasing agreements in the Group comprises future leasing fees attributable to agreements under financial leasing. The obligations pertaining to financial leasing mature as follows:

SEK thousands	Amortization	Interest	Total payment
Within one year	1,110	77	1,187
Between one and five years	1,584	87	1,671
Later than five years	—	—	—
	<b>2,694</b>	<b>164</b>	<b>2,858</b>

Amortization due within one year is recognized as a short-term liability. Interest on financial leasing agreements is linked to the floating market interest rates. For further information concerning interest and maturity structures, see Note 18.

**Note 15 • Other short-term liabilities**

	Group		Parent Company	
SEK thousands	2015	2014	2015	2014
Personnel tax at source	980	1,067	980	1,067
VAT	1,084	1,181	—	—
Other short-term liabilities	—	56	—	56
<b>Total</b>	<b>2,064</b>	<b>2,304</b>	<b>980</b>	<b>1,123</b>

**Note 16 • Accrued expenses and deferred income**

	Group		Parent Company	
SEK thousands	2015	2014	2015	2014
Accrued vacation liability, including social-security costs	6,894	6,908	6,894	6,908
Accrued employer's contributions	673	719	673	719
Other accrued personnel costs	2,782	2,855	2,782	2,855
Accrued Board fees, including social-security costs	756	1,058	756	1,058
Accrued auditors' fees	300	300	300	300
Accrued interest	602	619	—	—
Accrued expenses, clinical trials	15,097	47,272	15,097	47,272
Accrued property expenses	916	899	916	899
Accrued costs, redundancies	8,996	—	8,996	—
Other items	336	277	336	277
<b>Total</b>	<b>37,352</b>	<b>60,907</b>	<b>36,750</b>	<b>60,288</b>

## Note 17 • Categories of financial assets and liabilities and disclosures regarding fair value

In Active Biotech's opinion, the carrying amount comprises a reasonable approximation of the fair value of all of the Group's financial assets and liabilities. The Group's liabilities to credit institutions and liabilities pertaining to financial leasing bear floating interest rates, which means that the value of the liabilities is not affected by changes in the base interest rate. Also, Active Biotech does not believe that credit margins have changed to any extent that could significantly impact the fair value of liabilities. The Group's short-term investments and derivatives are measured at fair value in the statement of financial position, which means that the carrying amount is the same as the fair value of these items. In addition to short-term investments, the Group's financial assets essentially comprise cash and bank balances and receivables with short-term maturities that are recognized after deductions for any impairment. Accordingly, the carrying amount is considered to be a reasonable approximation of the fair value also for these items. The tables below state the carrying amounts for financial assets and financial liabilities by measurement category.

### Group 2015

SEK thousands	Accounts and loan receivables	Financial assets/ liabilities at fair value in profit or loss	Other financial liabilities	Total carrying amount
Other long-term receivables	1	–	–	1
Accounts receivable	529	–	–	529
Accrued income	–	–	–	–
Short-term investments	–	76 555	–	76 555
Cash and bank balances	27 062	–	–	27 062
<b>Total</b>	<b>27 592</b>	<b>76 555</b>	<b>–</b>	<b>104 147</b>
Long-term interest-bearing liabilities	–	–	216 272	216 272
Short-term interest-bearing liabilities	–	–	6 490	6 490
Accounts payable	–	–	6 625	6 625
Accrued expenses	–	–	602	602
Other liabilities	–	–	–	–
<b>Total</b>	<b>–</b>	<b>–</b>	<b>229 989</b>	<b>229 989</b>

### Group 2014

SEK thousands	Accounts and loan receivables	Financial assets/ liabilities at fair value in profit or loss	Other financial liabilities	Total carrying amount
Other long-term receivables	1	–	–	1
Accounts receivable	462	–	–	462
Accrued income	–	–	–	–
Short-term investments	–	76,666	–	76,666
Cash and bank balances	251,789	–	–	251,789
<b>Total</b>	<b>252,252</b>	<b>76,666</b>	<b>–</b>	<b>328,918</b>
Long-term interest-bearing liabilities	–	–	222,639	222,639
Current interest-bearing liabilities	–	–	6,898	6,898
Accounts payable	–	–	24,432	24,432
Accrued expenses	–	–	619	619
Other liabilities	–	–	–	–
<b>Total</b>	<b>–</b>	<b>–</b>	<b>254,588</b>	<b>254,588</b>

### Disclosure regarding the determination of fair value

#### Group 2015

	Level 1	Level 2	Level 3	Total
Short-term investments – on a par with cash and cash equivalents		76,555		76,555
Short-term liability, derivatives		–		–

#### Group 2014

	Level 1	Level 2	Level 3	Total
Short-term investments – on a par with cash and cash equivalents		76,666		76,666
Short-term liability, derivatives		–		–

Level 1: according to quoted prices on an active market for the same instrument

Level 2: based on directly or indirectly observable market inputs other than those included in Level 1

Level 3: according to inputs not based on observable market data

### Calculation of fair value

#### Short-term investments

Short-term investments comprise units in a short-term fixed-income fund. The value of the units is based on a valuation obtained from the institute that administers the fund.



## Parent Company 2015

SEK thousands	Accounts and loan receivables	Financial assets/ liabilities at fair value in profit or loss	Other financial liabilities	Total carrying amount
Long-term receivables	1	–	–	1
Accounts receivable	441	–	–	441
Accrued income	–	–	–	–
Short-term investments	–	76,555	–	76,555
Cash and bank balances	12,065	–	–	12,065
<b>Total</b>	<b>12,507</b>	<b>76,555</b>	<b>–</b>	<b>89,062</b>
Accounts payable	–	–	6,625	6,625
<b>Total</b>	<b>–</b>	<b>–</b>	<b>6,625</b>	<b>6,625</b>

## Parent Company 2014

SEK thousands	Accounts and loan receivables	Financial assets/ liabilities at fair value in profit or loss	Other financial liabilities	Total carrying amount
Long-term receivables	1	–	–	1
Accounts receivable	260	–	–	260
Accrued income	–	–	–	–
Short-term investments	–	76,666	–	76,666
Cash and bank balances	243,028	–	–	243,028
<b>Total</b>	<b>243,289</b>	<b>76,666</b>	<b>–</b>	<b>319,955</b>
Accounts payable	–	–	24,432	24,432
<b>Total</b>	<b>–</b>	<b>–</b>	<b>24,432</b>	<b>24,432</b>

## Note 18 • Financial risks and financial policies

Through its operations, the Group is exposed to various forms of financial risk. Financial risk denotes fluctuations in the company's earnings and cash flow resulting from changes in exchange rates, interest rates, refinancing and credit risks.

The Group's financial policy for the management of financial risk has been formulated by the Board and acts as a framework of guidelines and regulations in the form of risk mandates and limits for financing activities. Responsibility for the Group's financial transactions and risks is managed centrally by the Parent Company's finance department. The overriding objective for the finance function is to provide cost-efficient financing and to minimize negative effects on the Group's earnings from market fluctuations. The Board of Active Biotech has established a policy for the investment of the Group's cash and cash equivalents, which, in view of the operational risks associated with the business, stipulates a conservative investment policy. The Group's cash and cash equivalents are to be invested in liquid assets with low credit risk, primarily in short-term Swedish securities, commercial papers and fixed-income and bond funds with high liquidity.

### Interest-rate risk

#### *Interest-rate risk relating to cash and cash equivalents*

The Group's liquidity, which amounted to SEK 103,617 thousand (328,455) at December 31, was invested at a floating interest rate, which fluctuated between -0.1-0.0 percent (0.0-2.3) during the year. Liquidity risk is defined as the risk that the Group could experience problems in fulfilling its obligations associated with financial liabilities. For its short-term planning, the Group has a rolling 12-month liquidity plan that is regularly updated. For its medium-term planning, future revenue and expense flows are regularly forecast based on the anticipated development phase of the projects. In addition, a long-term liquidity forecast is presented to the Board on a regular basis.

#### *Interest-rate risk relating to borrowings*

The interest-rate risk relates to the risk that Active Biotech's exposure to fluctuations in market interest rates can have a negative impact on net earnings. The fixed-interest term on the Group's financial assets and liabilities is the most significant factor that influences the interest-rate risk. Active Biotech's view is that a short fixed-interest term is, in terms of risk, consistent with the company's operative position. However, the Board can choose to extend the period of fixed interest with the aim of limiting the effect of any rise in interest rates. The company's loans have a fixed-interest period of three months.

The Group's financing sources mainly comprise shareholders' equity, bank loans for financing of property holdings and liabilities for financial leasing commitments. Outstanding interest-bearing liabilities are recognized in Note 14 and a term analysis for financial liabilities is presented below.

Sensitivity analysis: A change in the interest rate of plus/minus 1 percentage point would impact net interest income in the amount of plus/minus SEK 0.2 M (0.2).

### Financing risk

Financing risk relates to the risk that financing of Active Biotech's capital requirements and refinancing of loans outstanding may be made more difficult or more expensive. Since Active Biotech has loans that mature on different dates, the financing risk can be reduced.

The liabilities comprise a long-term property loan, a small bank loan and financial leasing liabilities. The company has no short-term loan financing in the form of overdraft facilities. Active Biotech secures short-term access to funds by maintaining good access to liquid funds.

The term analysis below presents the agreed, undiscounted cash flows for the Group's financial liabilities divided among the stated time intervals. The term of the bank loan for the property is until further notice, although the credit provider can terminate the agreement and demand payment with a two-month notice period. Pursuant to the requirements stipulated in IFRS 7, the liability has thus been assigned a time interval of one to three months. However, the company does not expect to be forced to repay the loan within this time frame.

#### Group 2015

SEK thousands	Nominal amount original currency	Total	Within 1 month	1–3 months	3 months – 1 year	1 – 5 years	5 years and longer
Bank loans, SEK		220,068	–	216,068	375	3,625	–
Financial leasing liabilities, SEK		2,858	96	190	901	1,671	–
Accounts payable, SEK		4,018	3,595	423	–	–	–
Accounts payable, EUR	172	1,576	1,576	–	–	–	–
Accounts payable, USD	123	1,031	845	186	–	–	–
<b>Total</b>		<b>229,551</b>	<b>6,112</b>	<b>216,867</b>	<b>1,276</b>	<b>5,296</b>	<b>–</b>

#### Group 2014

SEK thousands	Nominal amount original currency	Total	Within 1 month	1–3 months	3 months – 1 year	1 – 5 years	5 years and longer
Bank loans, SEK		225,448	–	220,948	375	4,125	–
Financial leasing liabilities, SEK		4,452	125	250	1,279	2,798	–
Accounts payable, SEK		5,728	5,581	147	–	–	–
Accounts payable, EUR	1,840	17,506	16,564	942	–	–	–
Accounts payable, NOK	6	6	6	–	–	–	–
Accounts payable, USD	153	1,192	1,087	105	–	–	–
<b>Total</b>		<b>254,332</b>	<b>23,363</b>	<b>222,392</b>	<b>1,654</b>	<b>6,923</b>	<b>–</b>

### Currency risks

Currency risk comprises the risk that changes in exchange rates will have a negative impact on the consolidated income statement, balance sheet and/or cash flow.

The Group has a currency exposure, since operations are primarily conducted in Sweden. Earnings are exposed to fluctuations in exchange rates since both revenues and costs largely comprise foreign currencies, primarily EUR and USD. In 2015, 11 percent of revenues comprised foreign currencies and the equivalent figure for operating expenses was 40 percent.

Sensitivity analysis: A change in exchange rates of plus/minus 10 percent would impact the Group's earnings in the amount of plus/minus SEK 7 M (10) in relation to EUR and plus/minus SEK 1 M (1) in relation to USD.

### Credit risks

The Group is exposed to the risk of not receiving payment from customers. The Group's credit risks are marginal for its operating activities, since the business has a low invoicing level due to the fact that the business activities currently comprise mainly research and development. The credit risk for receivables related to payments from

#### Maturity analysis, due but unimpaired accounts receivable

	2015	2014
	Carrying amount unimpaired receivable	Carrying amount unimpaired receivable
SEK thousands	Collateral	Collateral
Accounts receivable, not due	300	116
Accounts receivable, due 0 – 30 days	198	346
Accounts receivable, due >30 days – 90 days	31	–
Accounts receivable, due >90 days – 180 days	–	–
Accounts receivable, due >360 days	–	–
	<b>529</b>	<b>462</b>

concluded partnership agreements is considered low. Credit losses or impairment of possible credit losses were charged against earnings in the amount of SEK 0.0 M (0.0).

Credit risks also arise when investing cash and cash equivalents.

Cash and cash equivalents are principally invested in short-term Swedish securities, commercial papers and fixed-income and bond funds with high liquidity in well-established banks.

## Note 19 • Pledged assets, contingent liabilities and contingent assets

Pledged assets		Group		Parent Company	
SEK thousands	2015	2014	2015	2014	
<i>In the form of assets pledged for own liabilities and provisions</i>					
Property mortgage	260,000	260,000	–	–	
Assets with ownership reservation	4,445	5,841	4,445	5,841	
<b>Total</b>	<b>264,445</b>	<b>265,841</b>	<b>4,445</b>	<b>5,841</b>	
<i>Other collateral provided and pledged assets</i>					
Pension insurances	32,234	29,061	32,234	29,061	
<b>Total pledged assets</b>	<b>296,679</b>	<b>294,902</b>	<b>36,679</b>	<b>34,902</b>	
Contingent liabilities		Group		Parent Company	
SEK thousands	2015	2014	2015	2014	
Guarantees for the benefit of Group companies	–	–	220,068	225,448	
<b>Total contingent liabilities</b>	<b>–</b>	<b>–</b>	<b>220,068</b>	<b>225,448</b>	

## Note 20 • Group companies

### Holdings in subsidiaries

(SEK thousands)	Corp. Reg. No.	Registered office	No. of shares/percentage	Nominal value	Carrying amount Dec. 31, 2015	Carrying amount Dec. 31, 2014
Active Forskaren 1 KB	969646-4677	Lund			40,000	40,000
Actinova AB	556532-8860	Lund	1 000 / 100%	100	100	100
Active Security Trading AB	556092-7096	Lund	400 / 100%	400	450	450
<b>Total</b>					<b>40,550</b>	<b>40,550</b>

### Change in carrying amount of shares in subsidiaries

SEK thousands	2015	2014
Cost, January 1	40,550	40,550
Accumulated cost, December 31	40,550	40,550
Carrying amount, December 31	40,550	40,550

## Note 21 • Supplementary data to the cash-flow statement

		Group		Parent Company	
SEK thousands		2015	2014	2015	2014
<b>Interest paid and dividends received</b>					
Interest received	11	2,460	10	2,430	
Interest paid	-6,995	-12,138	-120	-14	
<b>Total</b>	<b>-6,984</b>	<b>-9,678</b>	<b>-110</b>	<b>2,416</b>	
<b>Adjustments for non-cash items</b>					
Depreciation/amortization and impairment of assets	12,045	12,257	16,214	16,270	
<b>Total</b>	<b>12,045</b>	<b>12,257</b>	<b>16,214</b>	<b>16,270</b>	
<b>Transactions not involving payment</b>					
Acquisition of assets through financial leasing	175	922			
<b>Cash and cash equivalents</b>					
Cash and cash equivalents consist of the following components:					
Cash and bank balances	27,062	251,789	12,065	243,028	
Short-term investments	76,555	76,666	76,555	76,666	
<b>Total</b>	<b>103,617</b>	<b>328,455</b>	<b>88,620</b>	<b>319,694</b>	

## Note 22 • Important estimates and assessments

Carrying amounts are based partly on assessments and estimates. The area in which estimates and assessments could imply adjustments to carrying amounts in forthcoming fiscal years is primarily the valuation of the Forskaren 1 property where the company's operations are conducted. On assignment from the company, Thomas Ahlbeck Fastighetsekonomi AB performed a valuation of the property at the end of 2015 (see Note 9). The estimated market value is based on assumptions on future revenues, expenses, vacancy levels and the value trend of similar properties. At December 31, 2015, the property's market value was estimated at SEK 325 M.

## Note 23 • Events after the balance sheet date

On January 4, 2016, it was announced that the high dose groups of laquinimod in studies in multiple sclerosis (MS) (CONCERTO and ARPEGGIO) would be discontinued after the occurrence of cardiovascular events, none of which were fatal, in eight patients. The change came at the recommendation of the data monitoring committee (DMC) overseeing the two active clinical studies in MS. The DMC identified an imbalance in the number of cardiovascular events in the studies. Seven events were observed in patients receiving laquinimod daily at 1.2 mg for treatment of relapsing remitting MS (RRMS) in the Phase 3 CONCERTO trial. No events occurred in the 0.6 mg or placebo groups. CONCERTO has 2,199 patients with 3,070 years of patient experience. One event was observed in the 1.5 mg daily-dose arm of the Phase 2 ARPEGGIO trial in primary-progressive MS (PPMS). ARPEGGIO has enrolled 191 patients and has 35 years of patient experience. Teva notified trial sites to discontinue the higher doses immediately in both trials and will encourage participants to continue follow ups.

Both trials, CONCERTO and ARPEGGIO, are continuing the lower-dose arms (0.6 mg daily), and participants in the trials will be provided with an update to confirm re-consent for participation. The DMC did not identify a cardiovascular signal with the lower dose but recommended long-term monitoring. Teva has previously carried out comprehensive studies of laquinimod at 0.6 mg per day and long-term extension studies with this dose are ongoing with any indications of cardiovascular events being noted.

On January 11, 2016, it was also announced that Teva would amend the trial design of the Phase 2 study of laquinimod in Huntington's disease. The amendment consists of dropping the highest of three doses (1.5 mg/day) in the trial while keeping two remaining active doses (0.5 and 1 mg/day) unchanged. This is a precautionary measure in the interest of patient safety being suggested by Teva to the Data Safety Monitoring Board (DSMB) for the LEGATO-HD trial.

The DSMB accepted the recommendation after reviewing data which observed cardiovascular incidents in patients receiving the high doses of laquinimod in two multiple sclerosis trials as reported on January 4, 2016. No cardiovascular events have been observed for any dose of the LEGATO-HD trial. Teva will continue in its commitment to study laquinimod in Huntington's disease.

Currently the mechanism of the cardiovascular events in the MS trials remains unknown. Although no specific time-to-event patterns have been identified, cardiovascular risk factors and demographics may play a role.

The results of the tasquinimod project were presented at the ASCO GU (American Society of Clinical Oncology, GenitoUrinary) Symposium on January 21-23, 2016.

An expanded analysis of the secondary endpoints for the Phase 3 study 10TASQ10 was presented alongside results from the Phase 2 study with tasquinimod as a maintenance therapy following docetaxel treatment, which was carried out by Active Biotech's partner Ipsen. Results from the investigator-sponsored clinical Phase 1 trial CATCH, in which tasquinimod was combined with the cytostatic agent cabazitaxel, were also presented.

Analysis of the secondary endpoints for the Phase 3 study 10TASQ10 showed that, with regard to tasquinimod, the results from both radiographic and PSA-based endpoints were favorable.

However, as previously communicated, overall survival (OS) was not extended, prompting the discontinuation of all further development within prostate cancer.

Results from the Phase 2 study of tasquinimod to evaluate the clinical efficacy of tasquinimod used as maintenance therapy in patients with metastatic castrate-resistant prostate cancer (mCRPC) who have not progressed after a first-line docetaxel-based chemotherapy showed extended progression-free survival (median rPFS 7.32 months versus 5.24 months for placebo). The objective of the investigator-sponsored clinical Phase 1 study CATCH was to determine the recommended dose of tasquinimod in combination with cabazitaxel in patients with mCRPC. The results demonstrated that the recommended dose of tasquinimod in combination with cabazitaxel is 0.5 mg per day.

On March 23, 2016, it was announced that the company plans to develop tasquinimod for the treatment of multiple myeloma. It is the company's opinion that the existing medical need and the possibility for combination treatments makes tasquinimod, with its unique mode of action, a strong development candidate within this indication. The company intends to actively seek a collaboration partner for further development.

## Note 24 • Related-party transactions

### Close relationships

With regard to the Group's and Parent Company's subsidiaries, see Note 20.

The composition of the Board and information relating to senior executives is presented on pages 48 and 49.

### Related-party transactions

During the year, no transactions with shareholders or members of the Board took place apart from the remuneration concerning Board fees presented in Note 5.

For information concerning transactions with key individuals in managerial positions, see Note 5.

In 2015, the Parent Company's sales of services to Group companies totaled SEK 19,012 thousand (14,954). The Parent Company's purchases of services from subsidiaries amounted to SEK 27,179 thousand (25,357) in 2015. The Parent Company's receivables and liabilities relative to the subsidiaries as per December 31, 2015 are presented in the Parent Company's balance sheet.

## Note 25 • Information relating to the Parent Company

Active Biotech AB is a Swedish-registered limited liability company with its registered office in Lund, Sweden. The Parent Company's shares are listed on Nasdaq Stockholm.

The address of the head office is Scheelevägen 22, Lund, Sweden. The consolidated financial statements for the 2015 fiscal year comprise the Parent Company and its subsidiaries, referred to jointly as the Group.



### Approval and adoption

The Annual Report and the consolidated financial statements were approved for issue on April 27, 2016. The consolidated income statement, statement of comprehensive income and statement of financial position and the Parent Company's income statement and balance sheet will be subject to adoption by the Annual General Meeting on May 26, 2016.

### Statement by the Board of Directors

The Board of Directors and the President & CEO affirm that the Annual Report was prepared in accordance with generally accepted accounting principles in Sweden and that the consolidated financial statements were prepared in accordance with the international accounting standards referred to in regulation (EC) No. 1606/2002 of the European Parliament and the Council dated July 19, 2002 governing the application of international accounting standards. The annual accounts and the consolidated financial statements provide a true and fair view of the Group's and Parent Company's financial position and results of operations. The Directors' Report for the Group and the Parent Company provides a true and fair view of the Group's and the Parent Company's operations, position and results, and describes significant risks and uncertainties that the Parent Company and Group companies face.

Lund, April 27, 2016

The Board of Directors of Active Biotech AB (publ)

MATS ARNHÖG  
Chairman

MAGNHILD SANDBERG-WOLLHEIM  
Board member

PETER SJÖSTRAND  
Board member

PETER THELIN  
Board member

TOMAS LEANDERSON  
President & CEO

We submitted our Audit Report on April 27, 2016

KPMG AB

DAVID OLOW  
Authorized Public Accountant

# Auditor's report

To the annual meeting of the shareholders of Active Biotech AB, corp. id 556223-9227

## Report on the annual accounts and consolidated accounts

We have audited the annual accounts and consolidated accounts of Active Biotech AB for the year 2015. The annual accounts and consolidated accounts of the company are included in the printed version of this document on pages 6–37.

### *Responsibilities of the Board of Directors and the Managing Director for the annual accounts and consolidated accounts*

The Board of Directors and the Managing Director are responsible for the preparation and fair presentation of these annual accounts in accordance with the Annual Accounts Act and of the consolidated accounts in accordance with International Financial Reporting Standards, as adopted by the EU, and the Annual Accounts Act, and for such internal control as the Board of Directors and the Managing Director determine is necessary to enable the preparation of annual accounts and consolidated accounts that are free from material misstatement, whether due to fraud or error.

### *Auditor's responsibility*

Our responsibility is to express an opinion on these annual accounts and consolidated accounts based on our audit. We conducted our audit in accordance with International Standards on Auditing and generally accepted auditing standards in Sweden. Those standards require that we comply with ethical requirements and plan and perform the audit to obtain reasonable assurance about whether the annual accounts and consolidated accounts are free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the annual accounts and consolidated accounts. The procedures selected depend on the auditor's judgment, including the assessment of the risks of material misstatement of the annual accounts and consolidated accounts, whether due to fraud or error. In making those risk assessments, the auditor considers internal control relevant to the company's preparation and fair presentation of the annual accounts and consolidated accounts in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the company's internal control. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of accounting estimates made by the Board of Directors and the Managing Director, as well as evaluating the overall presentation of the annual accounts and consolidated accounts.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinions.

### *Opinions*

In our opinion, the annual accounts have been prepared in accordance with the Annual Accounts Act, and present fairly, in all material respects, the financial position of the parent company as of 31 December 2015 and of their financial performance and cash flows for the year then ended in accordance with the Annual Accounts Act. The consolidated accounts have been prepared in accordance with the Annual Accounts Act and present fairly, in all material respects, the financial position of the group as of 31 December 2015 and

of their financial performance and cash flows for the year then ended in accordance with International Financial Reporting Standards, as adopted by the EU, and in accordance with the Annual Accounts Act. The statutory administration report is consistent with the other parts of the annual accounts and consolidated accounts.

We therefore recommend that the annual meeting of shareholders adopt the income statement and balance sheet for the parent company and the income statement and statement of financial position for the group.

## Report on other legal and regulatory requirements

In addition to our audit of the annual accounts and consolidated accounts, we have also audited the proposed appropriations of the company's profit or loss and the administration of the Board of Directors and the Managing Director of Active Biotech AB for the year 2015.

### *Responsibilities of the Board of Directors and the Managing Director*

The Board of Directors is responsible for the proposal for appropriations of the company's profit or loss, and the Board of Directors and the Managing Director are responsible for administration under the Companies Act.

### *Auditor's responsibility*

Our responsibility is to express an opinion with reasonable assurance on the proposed appropriations of the company's profit or loss and on the administration based on our audit. We conducted the audit in accordance with generally accepted auditing standards in Sweden.

As basis for our opinion on the Board of Directors proposed appropriations of the company's profit or loss we examined whether the proposal is in accordance with the Companies Act.

As basis for our opinion concerning discharge from liability, in addition to our audit of the annual accounts and consolidated accounts, we examined significant decisions, actions taken and circumstances of the company in order to determine whether any member of the Board of Directors or the Managing Director is liable to the company. We also examined whether any member of the Board of Directors or the Managing Director has, in any other way, acted in contravention of the Companies Act, the Annual Accounts Act or the Articles of Association.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinions.

### *Opinions*

We recommend to the annual meeting of shareholders that the loss be dealt with in accordance with the proposal in the statutory administration report and that the members of the Board of Directors and the Managing Director be discharged from liability for the financial year.

Malmö 27 April 2016  
KPMG AB

David Olow  
Authorized Public Accountant

# Summary of financial development

SEK M	2015	2014	2013	2012	2011
<b>Income statement</b>					
Net sales	16.3	10.4	116.0	227.9	234.6
Operating expenses (of which, depreciation/amortization)	-194.2 -12.0	-238.8 -12.3	-325.0 -13.0	-391.1 -12.9	-335.5 -12.0
<b>Operating loss</b>	<b>-177.9</b>	<b>-228.4</b>	<b>-209.0</b>	<b>-163.2</b>	<b>-100.9</b>
Net financial expense	-6.8	-5.3	-5.3	-8.7	-2.6
<b>Loss before tax</b>	<b>-184.7</b>	<b>-233.7</b>	<b>-214.3</b>	<b>-171.9</b>	<b>-103.5</b>
Tax	-8.8	2.2	2.2	-3.1	9.0
<b>Loss for the year</b>	<b>-193.5</b>	<b>-231.5</b>	<b>-212.1</b>	<b>-175.0</b>	<b>-94.5</b>
<b>Balance sheet</b>					
Tangible fixed assets	329.8	381.6	381.0	381.5	382.7
Financial fixed assets	0.0	0.0	0.0	0.0	0.0
Other current assets	16.0	12.4	10.6	98.5	10.6
Cash and cash equivalents	103.6	328.5	376.2	216.7	465.2
<b>Total assets</b>	<b>449.4</b>	<b>722.5</b>	<b>767.8</b>	<b>696.7</b>	<b>858.5</b>
Shareholders' equity	180.6	405.3	405.4	339.9	502.0
Interest-bearing provisions and liabilities	222.8	229.5	230.9	236.5	242.8
Non interest-bearing provisions and liabilities	46.0	87.7	131.5	120.3	113.7
<b>Total shareholders' equity and liabilities</b>	<b>449.4</b>	<b>722.5</b>	<b>767.8</b>	<b>696.7</b>	<b>858.5</b>
<b>Condensed cash-flow statement</b>					
Cash flow from operating activities before changes in working capital	-172.7	-221.5	-201.4	-159.1	-91.6
Change in working capital	-45.2	-45.6	99.1	-81.3	44.6
Cash flow from investing activities	—	-1.9	0.0	0.0	-0.5
Cash flow from financing activities	-6.9	221.3	261.8	-8.1	381.5
<b>Cash flow for the year</b>	<b>-224.8</b>	<b>-47.7</b>	<b>159.5</b>	<b>-248.5</b>	<b>334.0</b>
<b>Key figures</b>					
Capital employed (SEK M)	403.4	634.8	636.3	576.4	744.8
Net indebtedness (SEK M)	119.2	-99.0	-145.3	19.8	-222.4
Surplus value in short-term investments (SEK M)	—	—	—	—	—
Return on shareholders' equity (%)	-66	-57	-57	-42	-28
Return on capital employed (%)	-34	-35	-33	-24	-15
Equity/assets ratio (%)	40	56	53	49	58
Proportion of risk-bearing capital (%)	40	56	53	49	58
Net debt/equity ratio (multiple)	0.66	neg	neg	0.06	neg
Interest-coverage ratio (multiple)	neg	neg	neg	neg	neg
Research and development costs (SEK M)	-176.2	-221.9	-308.0	-375.3	-318.6
Average number of employees	55	58	61	76	80
Salary expenses, incl. social-security costs (SEK M)	-68.9	-61.5	-65.0	-80.6	-70.0
<b>Data per share</b>					
Loss per share (SEK)	-2.15	-3.02	-2.81	-2.54	-1.38
Shareholders' equity (SEK)	2.01	5.41	5.41	4.93	7.28
Net worth (SEK)	2.01	5.41	5.41	4.93	7.28
Unrestricted liquidity (SEK)	1.15	4.38	5.02	3.14	6.75
Market price of share at year-end (SEK)	13.80	18.80	69.50	55.0	22.10
Dividends (SEK)	0	0	0	0	0
Share price/shareholders' equity (%)	687	348	1,285	1,116	304
Share price/net worth (%)	687	348	1,285	1,116	304
Number of shares at end of period (thousands)	89,908	74,924	74,924	68,924	68,924
Weighted average number of ordinary shares before dilution (thousands)	89,908	76,755	75,433	68,924	68,597
Maximum number of shares upon exercise of outstanding warrants (thousands)	89,908	76,755	75,433	68,924	68,597

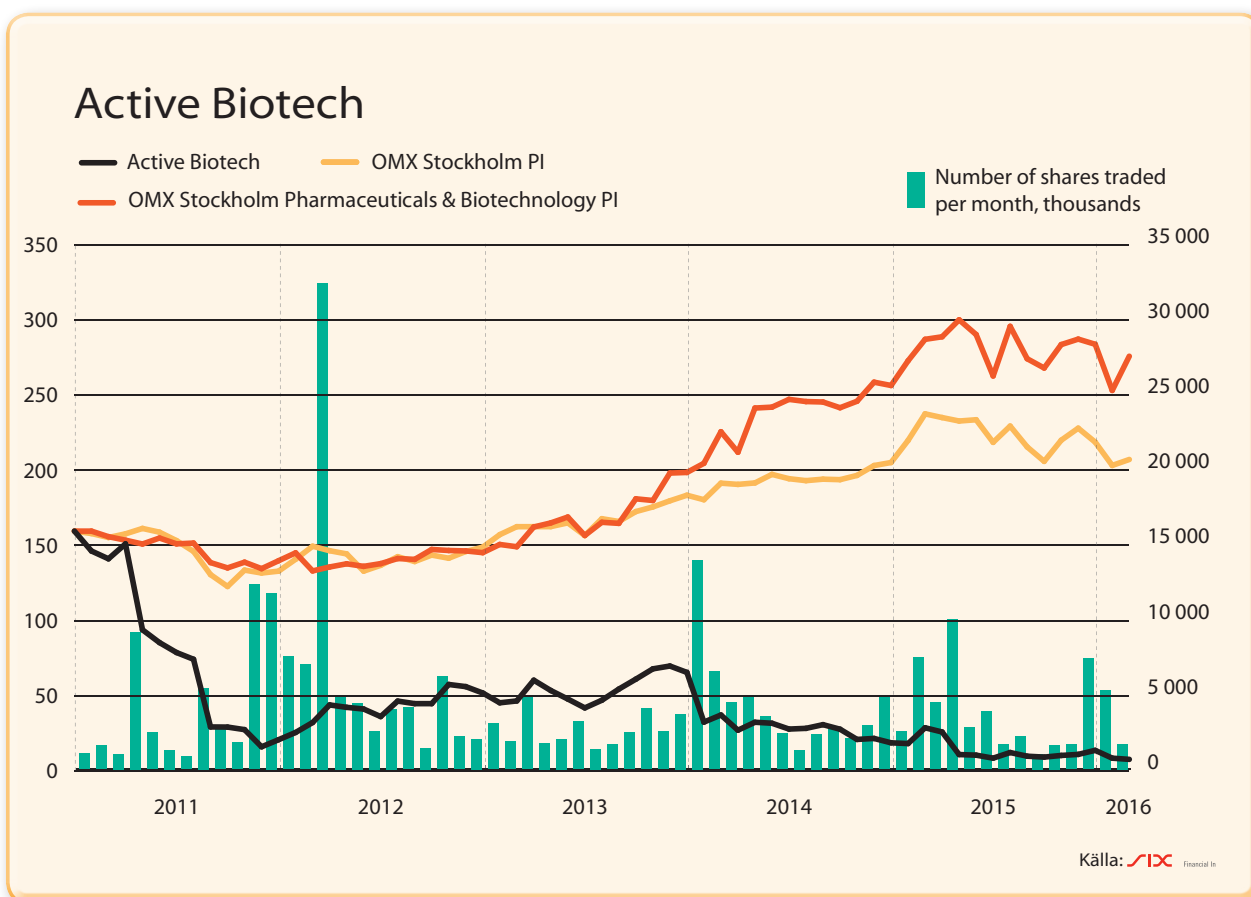
# The share

## General information about the Active Biotech share

Shares in Active Biotech AB are listed on Nasdaq Stockholm (Mid Cap). The share was originally listed on December 1, 1986, on what was then known as the O-list of the Stockholm Stock Exchange. The company was converted into a dedicated biotechnology company in 1997. The latest price information is available on Nasdaq's website under the ticker ACTI. The Active Biotech share is included in Nasdaq Stockholm's Pharmaceuticals, Biotech & Life Science index. The diagram in this section shows the price trend for the Active Biotech share for the period January 2011–February 2016.

## Share capital

The company's share capital is quoted in SEK and distributed among the shares issued by the company with a quotient value that is also expressed in SEK. At December 31, 2015, the share capital in Active Biotech amounted to approximately 338,895,183 distributed among 89,908,298 shares. The share's quotient value is approximately SEK 3.77.



### Share price development

On the final day of trading in December 2014, the share price was SEK 18.80, while at the same date in 2015, it was SEK 13.80. The highest price paid for the share during the year was SEK 30.45 (March 2, 2015).

### Changes in share capital

The table on the next page shows the changes in Active Biotech's share capital from 2000 to January 2016.

### Dividend policy

In view of Active Biotech's financial position and negative earnings, the Board of Directors does not intend to propose that any dividends be paid for the next few years. The company's financial assets will be principally used to finance existing and new research programs.

### Shareholders

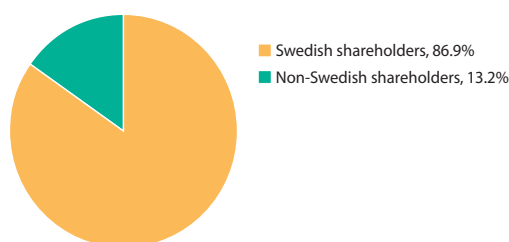
On February 29, 2016, the number of shareholders in Active Biotech amounted to 11,319.

### Shareholders

The following reflects circumstances as known to the company at February 29, 2016.

Owner	No. of shares	Holding, %
MGA Holding AB	23,271,555	25.9
Nordstjernan AB	11,820,994	13.2
Investor	7,200,000	8.0
Third Swedish National Pension Fund	3,000,000	3.3
Avanza Pension	2,798,453	3.1
Fourth Swedish National Pension Fund	1,999,454	2.2
Euroclear	1,736,100	1.9
Credit Suisse	1,624,012	1.8
SEB	1,200,000	1.3
Rhenman Healthcare Fund	1,014,184	1.1
<b>Total, ten largest owners</b>	<b>55,664,752</b>	<b>61.9</b>
<b>Total</b>	<b>89,908,298</b>	<b>100</b>

### Shareholder specification



### Shareholder statistics, February 29, 2016

Shareholding interval	No. of shareholders	% of all shareholders	No. of shares	% of all share capital	Average per shareholder
1 – 1 000	8,310	73.4	2,339,948	2.6	286
1 001 – 10 000	2,595	22.9	7,634,040	8.5	2,942
10 001 – 100 000	354	3.1	9,414,579	10.5	26,595
100 001 –	60	0.5	70,519,731	78.4	1,175,329
<b>Total</b>	<b>11,319</b>	<b>100.0</b>	<b>89,908,298</b>	<b>100.0</b>	<b>7,943</b>



## Changes in share capital

Year	Transaction	Change in number of shares	Change in share capital	Total no. of shares		Total share capital, SEK	Quotient value, SEK
				Class A shares	Class B shares		
	Opening balance			1,963,745	9,282,547	281,157,300	25.00
2000	Reclassification A to B	0	0	1,287,531	9,958,761	281,157,300	25.00
2001	Reclassification A to B	0	0	1,169,691	10,076,601	281,157,300	25.00
2002	Reclassification A to B	0	0	1,145,024	10,101,268	281,157,300	25.00
2003	Reduction of share capital (June)	0	-168,694,380	1,145,024	10,101,268	112,462,920	10.00
2003	Rights issue (June)	22,492,584	224,925,840	1,145,024	32,593,852	337,388,760	10.00
2003	Reclassification A to B	0	0	1,128,174	32,610,702	337,388,760	10.00
2003	Reorganization as a single share class (Dec.)	0	0	33,738,876		337,388,760	10.00
2005	Conversion (Jan.-May)	1,681	16,810	33,740,557		337,405,570	10.00
2005	Rights issue (June/July)	5,623,426	56,234,260	39,363,983		393,639,830	10.00
2005	Conversion (Aug.-Sep.)	228,241	2,282,410	39,592,224		395,922,240	10.00
2006	Conversion (Jan.-May)	160,644	1,606,440	39,752,868		397,528,680	10.00
2006	Reduction of share capital (May)	0	-247,686,499	39,752,868		149,842,181	3.77
2006	Conversion (June-Dec.)	42,553	160,397	39,795,421		150,002,578	3.77
2007	Conversion (Jan.)	204,579	771,128	40,000,000		150,773,706	3.77
2007	Rights issue (Feb.)	4,000,000	15,077,371	44,000,000		165,851,077	3.77
2007	Conversion (March)	3,300,115	12,439,264	47,300,115		178,290,341	3.77
2008	Rights issue (June)	3,941,676	14,857,527	51,241,791		193,147,869	3.77
2009	Rights issue (June)	12,810,447	48,286,964	64,052,238		241,434,833	3.77
2010	Private placement (April)	1,418,000	5,344,928	65,470,238		246,779,761	3.77
2010	Employee stock options	529,682	1,996,553	65,999,920		248,776,314	3.77
2011	Private placement (Jan.)	2,500,000	9,423,357	68,499,920		258,199,670	3.77
2011	Employee stock options	423,662	1,596,927	68,923,582		259,796,598	3.77
2013	Private placement (March)	6,000,000	22,616,055	74,923,582		282,412,653	3.77
2015	Rights issue (Jan.)	14,984,716	56,482,529	89,908,298		338,895,183	3.77

## Financial definitions

**Proportion of risk-bearing capital:** Shareholders' equity plus minority interests and deferred tax liabilities as a percentage of the total assets.

**Unrestricted liquidity per share:** Cash and cash equivalents and short-term investments, divided by the number of shares at year-end.

**Shareholders' equity per share:** Recognized consolidated shareholders' equity, divided by the number of shares at year-end.

**Net indebtedness:** Net interest-bearing liabilities, that is, interest-bearing liabilities and provisions less cash and cash equivalents, short-term investments and other interest-bearing long-term holdings of securities.

**Net debt/equity ratio:** Net interest-bearing liabilities divided by shareholders' equity, including minority interests.

**Earnings per share after tax:** Recognized consolidated earnings, divided by the average number of shares.

**Return on shareholders' equity:** Profit/loss for the year as a percentage of average shareholders' equity.

**Return on capital employed:** Profit/loss after net financial items plus financial expenses, as a percentage of average capital employed.

**Interest-coverage ratio:** Operating profit/loss after financial items plus financial expenses, divided by financial expenses.

**Equity/assets ratio:** Shareholders' equity plus minority interests, as a percentage of total assets.

**Net worth per share:** Shareholders' equity and surplus values in short-term investments, divided by the number of shares at year-end.

**Capital employed:** Total assets less non interest-bearing provisions and liabilities.

**Surplus value in short-term investments:** The difference between the market value of short-term investments and the carrying amount. Due to the Group's tax situation, no deduction was made for deferred tax.

# Intellectual property rights

A key aspect of Active Biotech's strategy is to protect its knowledge through strong patents. The patent protection covers inventions of chemical compounds, biotechnological structures, methods and processes related to the company's operation in key markets. Active Biotech has built up its position in the area of patents through strategically defined patent families, primarily in the areas of autoimmunity/inflammation and cancer. Patents and patent applications refer primarily to the commercially important markets of Europe, the US and Japan. An application was approved in the early stage SILC development project in 2016 and two additional applications are being processed by the

European Patent Office. Both of these applications are also for currently unknown compounds that bind to the S100A9 target protein.

Laquinimod and tasquinimod are specifically protected by six patent families and a large number of national patents, see the table below. In 2015, two patent applications for medical treatment of multiple myeloma using tasquinimod were submitted via the European Patent Office. The company also has patent protection for compounds that are closely related to laquinimod and tasquinimod, for compounds in the ANYARA project, for the compound paquinimod and for other projects.

## Patent protection for laquinimod

Type of protection	Area	Status	Year of expiry
Product (W09955678)	Europe	Granted	2019
	US	Granted	2019
	Japan	Granted	2019
	(total 79)	(granted 79)	
Manufacturing method (W003106424)	Europe	Granted	2023
	US	Granted	2025
	Japan	Granted	2023
	(total 52)	(granted 50, application 2)	
Pharmaceutical formulation (W02005074899)	Europe	Granted	2025
	US	Granted	2027
	Japan	Granted	2025
	(total 81)	(granted 80, application 1)	
Alternative manufacturing method (W02012004338)	Europe	Granted	2031
	US	Granted	2031
	Japan	Application	2031
	(total 35)	(granted 28, application 7)	

## Patent protection for tasquinimod

Type of protection	Area	Status	Year of expiry
Product (W00003991)	Europe	Granted	2019
	US	Granted	2019
	Japan	Granted	2019
	(total 79)	(granted 79)	
Treatment method (W00130758)	Europe	Granted	2020
	US	Granted	2020
	Japan	Granted	2020
	(total 28)	(granted 28)	
Manufacturing method (W003106424)	Europe	Granted	2023
	US	Granted	2025
	Japan	Granted	2023
	(total 52)	(granted 50, application 2)	
Alternative manufacturing method (W02012004338)	Europe	Granted	2031
	US	Granted	2031
	Japan	Application	2031
	(total 35)	(granted 28, application 7)	
Treatment method (W02016/ 042112)	Europe	Application	2035
	US	Application	2035
	Japan	Application	2035
Treatment method (priority application)	Application via European Patent Office	Application PCT/EPO 2015/ 075769	2035

## Patent protection for SILC

Type of protection	Area	Status	Year of expiry
Product (W02014184234)	Europe	Granted	2034
	US	Application	2034
	Japan	Application	2034
Product (W02015/177367)	Europe	Application	2035
	US	Application	2035
	Japan	Application	2035
Product (W02016/042172)	Europe	Application	2035
	US	Application	2035
	Japan	Application	2035

# Corporate Governance Report 2015

Active Biotech is a Swedish public limited liability company whose shares are traded on Nasdaq Stockholm (Mid Cap). In accordance with its Articles of Association, Active Biotech is to engage in research, development, production, marketing and sales of medical, chemical and biotechnology products, conduct administrative services for the Group, own and manage properties, and undertake any other operations compatible therewith. This Corporate Governance Report describes Active Biotech's corporate governance, which includes the management and administration of the company's business and internal control of the financial reporting. Corporate Governance in Active Biotech is based on applicable rules (primarily the Swedish Companies Act and accounting rules and regulations), the Articles of Association, Nasdaq Stockholm's Rule Book for Issuers, internal guidelines and policies, and the Swedish Corporate Governance Code.

## Application of and deviations from the Code

Active Biotech applies the Swedish Corporate Governance Code (the Code). Information about the Code can be found at [www.corporategovernanceboard.se](http://www.corporategovernanceboard.se). The company deviated from item 2.4 of the Code in 2015. The Election Committee appointed the Chairman of the Board to be the Chairman of the Election Committee. The motivation for this is the Election Committee's assessment that it is natural that the person who is indirectly the largest owner of Active Biotech should also lead the work of the Election Committee.

## Shareholders

At December 31, 2015, the number of shareholders in Active Biotech amounted to 11,490. For information concerning the company's major shareholders and the ownership structure, see page 41 of this Annual Report.

## Annual General Meeting

The Annual General Meeting (AGM) is Active Biotech's highest decision-making body. In addition to shareholders' statutory rights to participate in the AGM, Active Biotech's Articles of Association stipulate the requirement of advance notification of participation at the Meeting within a prescribed time as stated in the notice of the AGM. The shareholder is to state the number of accompanying assistants, if any, in such notification. At the AGM, each share carries one vote. Each shareholder entitled to vote at the Meeting may vote for the full number of shares held. Each share offers equal entitlement to dividends and any surplus on liquidation of the company. At the AGM, which is held not more than six months after the close of the fiscal year, the annual accounts for the preceding year are adopted, the Board of Directors is elected, auditors are appointed, if applicable, and other statutory matters are addressed. Between AGMs, the Board of Directors is the company's highest decision-making body.

At the AGM on June 11, 2015, it was resolved to grant authorization to the Board, for a period that does not extend past the date of the next Annual General Meeting, on one or several occasions, with or without pre-emptive rights for shareholders, to resolve on the issue of new shares and/or convertibles. It should also be possible to make such an issue resolution stipulating in-kind payment, the right to offset debt or other conditions. The authorization may not be utilized to a greater extent than would enable a total of not more than seven million shares to be issued and/or arise through the conversion of convertibles issued with the support of the authorization.

## Election Committee

At the AGM on June 11, 2015, it was resolved that the company's Chairman, based on ownership at the end of September 2015, convene an Election Committee to prepare proposals for the 2016 AGM. According to the resolution, the Election Committee comprises the Chairman of the Board and representatives of each of the three largest shareholders in the company. The members of the Election Committee receive no remuneration from the company for their work. The Election Committee performs the tasks incumbent on the Election Committee under the Code. The composition of the Election Committee was announced on November 23, 2015. A meeting of the Election Committee was convened on one occasion ahead of the 2016 AGM, which was attended by all its members.

Members	Represents	Board member or not
Mats Arnhög	Chairman of the Board	Chairman
Johnny Sommarlund	MGA Holding AB	Not a member
Tomas Billing	Nordstjernan AB	Not a member
Lennart Johansson	Investor AB	Not a member

## Board of Directors

In accordance with Active Biotech's Articles of Association, the Board comprises between three and nine members with at most nine deputies. The 2015 AGM elected the current Board, which consists of four ordinary members with no deputies. Mats Arnhög was elected Chairman of the Board. The AGM resolved that remuneration of the Board's ordinary members be paid in the amount of SEK 125,000 per year for Board members who are not employed at the company, and remuneration of the Chairman of the Board be paid in the amount of SEK 250,000 per year. For a more detailed presentation of the Board members and President & CEO, see page 48–49 of this Annual Report. Of the Board members elected by the 2015 AGM, all are independent in relation to the company and executive management. Three of the four members are independent in relation to the company's major shareholders.

Mats Arnhög is not independent of the shareholder MGA Holding AB, in which he is Chairman of the Board and owner.

### The work of the Board and formal work plan

The Board works in accordance with an established formal work plan describing the minimum number of Board meetings to be held each year, routines for the preparation of the agenda and minutes of the meetings as well as the distribution of material. One section of the formal work plan regulates the division of duties in the Board and describes the responsibilities of the Board, the Chairman and the President & CEO. The Board principally devotes itself to general and long-term issues as well as to issues of an exceptional nature or of otherwise substantial importance. The Chairman directs the work of the Board and represents the Board both externally and internally. The formal work plan also identifies the Board members who, in accordance with specific decisions, have been appointed as the management's contacts in the event of a crisis. At each scheduled Board meeting, the President & CEO reports on operations. The report comprises information on project development, plans and progress in research activities, financial reporting with forecasts as well as business development. The Board decides on issues in which the Swedish Companies Act and the Articles of Association require the Board's decision as well as on such issues as policy matters, strategy, business decisions (such as research plans), budget, business plans and key agreements. In 2015, seven meetings were held at which minutes were taken. Important issues addressed by the Board included development of research projects, business development projects, partner strategy, financial statements and budget and financing matters. Minutes were recorded by the Board's secretary, a role that was filled by the company's CFO Hans Kolam during the year. The Chairman of the Board ensures that an annual assessment of the Board's work is conducted that provides the Board members with the opportunity to present their views on work procedures, Board material, their own efforts and the efforts of other Board members and the scope of the task.

The Election Committee has been informed of the results of the assessment. On the basis of this information, the Election Committee can assess the expertise and experience that Board members are required to possess. The Election Committee has also been informed of the company's assessment of the quality and efficiency of the work of the auditors, including recommendations regarding auditors and auditors' fees.

The assessment is that the Board's collective expertise is favorably compatible with the company's strategic visions and goals. The Board functions well and all members make a constructive contribution to the strategic discussions and the governance of the company. The dialog conducted between the Board and management was also deemed to be productive.

Board member	Attendance at Board meetings	Independent/dependent	
		Company	Owners
Mats Arnhög	7/7	independent	dependent
Peter Thelin	6/7	independent	independent
Peter Hofvenstam	4/4	independent	independent
Peter Sjöstrand	6/7	independent	independent
Magnhild Sandberg	6/7	independent	independent
Rolf Kiessling	1/4	independent	independent

### Remuneration and Audit Committee

The company does not have separate committees for remuneration and audit matters. Instead, these matters are dealt with by the Board in its entirety. Salaries, remuneration, terms and conditions of employment and so forth, for the Board, President & CEO and executive management are detailed in Note 5.

### Control systems and risk management regarding financial reporting

In accordance with the Companies Act and the Swedish Corporate Governance Code, the Board of Directors is responsible for the company's internal control. Active Biotech's work on internal control is designed to provide reasonable assurance that the company's goals are achieved in terms of an appropriate and efficient operation, reliable financial reporting and compliance with applicable legislation and regulations. Active Biotech's business is primarily operated at one site and is therefore deemed to be of limited complexity.

The internal control environment at Active Biotech follows the established COSO framework that comprises the following five components:

1. *Control environment*
2. *Risk assessment*
3. *Control activities*
4. *Information and communication*
5. *Monitoring*

#### 1. Control environment

The basis of the internal control of the financial reporting is the control environment that comprises the organization, decision-making procedures, authorities and responsibility, as documented and communicated in governance documents such as internal policies, guidelines and manuals. Authorizations and responsibilities are documented, such as the division of duties between the Board and the President & CEO.

The guidelines for Active Biotech's operations are available on the company's intranet, which also includes:

- The Group's business concept, vision, strategies and values
- Organizational structure
- Administrative processes, guidelines and instructions, such as authorities, authorization manual, purchasing and investment policies, health and safety in the workplace and accounting and reporting instructions, etc.

## 2. Risk assessment

Structured risk assessments and risk management enables identification of significant risks that affect the internal control relating to financial reporting and where these risks are found. The aim of risk management is to minimize the number of risk factors within the financial reporting.

## 3. Control activities

The aim of control activities is to prevent, detect and correct errors and non-conformities in the financial reporting. Activities include analytical follow-ups and comparison of earnings trends, account reconciliations and balance specification, approval and reporting of business transactions and partnership agreements, power of attorney instructions, authorization manual, accounting policies and measurement principles.

## 4. Information and communication

Active Biotech has information and communication channels that aim to ensure that information relating to the financial reporting is provided efficiently and accurately. The guidelines for the financial reporting have been established in a policy document. Meetings are held at management group level within the company, and subsequently at the level deemed suitable by the managers, and a number of meetings are held for all employees. The Board regularly receives financial reports on the Group's financial position and earnings trend, including comments, and the Group's financial situation is addressed at every Board meeting. The Board of Active Biotech ensures the quality of financial reporting by ensuring that the company has an appropriate organization combined with procedures and instructions for its work on financial reporting. The aim of the procedures for the external provision of information is to provide the market with relevant, reliable and correct information on Active Biotech's performance and financial position. Active Biotech has an information policy that meets the requirements imposed on listed companies. Financial information is regularly provided in the form of:

- Year-end and interim reports, published as press releases.
- Annual reports.
- Press releases regarding important news and events that may have a significant impact on the valuation of the company and the share price.
- Presentations and telephone conferences for financial analysts, investors and media.

All reports, presentations and press releases are published on the Group's website, [www.activebiotech.com](http://www.activebiotech.com), when they are simultaneously communicated to the market.

## 5. Monitoring

The internal control is monitored at various levels at Active Biotech. The Board discusses all interim reports, year-end reports and annual reports before they are published.

The company's external auditors report, in person, on their observations and opinion of the internal control to the Board.

### Internal audit

Given the Group's uncomplicated legal and operational structure and the established governance and internal control systems, the Board has decided not to have a separate internal audit function.

The Board evaluates and continuously follows up the issue of possibly establishing an internal audit function.

### Auditors

The company has at least one and at most two auditors and at most two deputy auditors. At the AGM on June 11, 2015, KPMG AB was elected as the company's auditor for the period extending until the end of the AGM held in 2016. Authorized Public Accountant David Olow is auditor-in-charge. Information concerning auditors' fees is presented in Note 4 on page 23. The interim report for the January-September period 2015 was the subject of review by the auditors.

### Policies

#### Information policy

With the aim of determining principles for the company's communication, the Board has established an information policy. This summarizes overriding goals and responsibilities for the external publication of Active Biotech's information. The goal when providing information to the stock market is to achieve a correct valuation of the company's share that reflects the company's underlying values, growth and earnings capacity in as stable a manner as possible. An unconditional requirement is that the information to the stock market complies with Nasdaq Stockholm's Rule Book for Issuers and applicable legislation and ordinances. The company's Board, management and personnel with operational responsibility must possess the requisite level of competence, and the company must have an organization in place that ensures the rapid and correct dissemination of stock market information.

#### Environmental policy

Within Active Biotech, environmental and safety work is important and the company has therefore established an environmental policy. Responsibility is decentralized in the



various departments in the Group so that each manager and employee is responsible for meeting goals relating to both the internal and external environment, as well as safety. This applies to all areas from proprietary research to contract manufacturing of candidate drugs and production. In addition, Active Biotech places great importance to ensuring that external partners have their own environmental and safety requirements that conform to the company's values.

#### *Responsible treatment of laboratory animals*

Despite a rapid advance in non-animal based models for medical research, no alternative can yet entirely replace the complex system represented by a living organism. Accordingly, the responsible treatment of laboratory animals in scientific research is ethically justified. Active Biotech endeavors to replace, reduce and refine the use of laboratory animals to the greatest possible degree. When no alternative exists, testing is to be properly planned and take ethical requirements into consideration in the implementation phase. Pain, suffering and stress are to be minimized – and preferably eliminated. All who work with laboratory animals are trained and skilled in the area. Animals are treated with care and the greatest possible degree of consideration is given to their health and well-being in a careful balance between ethical and scientific requirements. Furthermore, animal keeping and management is conducted in a manner that maximizes well-being and prevents the spread of infection. All work involving animals complies with the applicable strict local procedures and national and international legislation. Legislation and other ethical considerations with respect to the care and well-being of laboratory animals are carefully monitored and continuously reviewed to harmonize laboratory animal operations in the company.

### **Auditors' report of the Corporate Governance Statement**

To the annual meeting of the shareholders in Active Biotech AB, Corporate identity number 556223-9227.

It is the Board of Directors who is responsible for the Corporate Governance Statement for the year 2015 on pages 44 - 47 and that it has been prepared in accordance with the Annual Accounts Act.

As a basis for our opinion that the Corporate Governance Statement has been prepared and is consistent with the annual accounts and the consolidated accounts, we have read the Corporate Governance Statement and assessed its statutory content based on our knowledge of the company. This means that our statutory examination of the Corporate Governance Statement is different and substantially less in scope than an audit conducted in accordance with International Standards on Auditing and generally accepted audit standards in Sweden.

In our opinion, the Corporate Governance Statement has been prepared and its statutory content is consistent with the annual accounts and the consolidated accounts.

Malmö 27 April 2016  
KPMG AB

David Olow  
Authorized Public Accountant

# Board of Directors and Auditors



## Mats Arnhög

Board member since 2000.  
Chairman of the Board since 2003.

*Born:* 1951.

*Education:* M.Sc. Stockholm School of Economics.

*Other current assignments:* Chairman of MGA Holding AB, Rederi AB Sea-Link and Psoriasis + Creams Sweden AB. Board member of Ideella Föreningen Prima Gruppen and member of the Advisory Board of the Stockholm School of Economics.

*Holding in the company:* 23,271,555 shares through MGA Holding AB.



## Peter Thelin

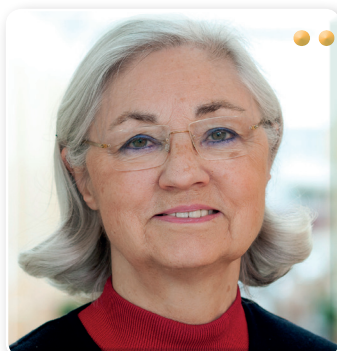
Board member since 2011.

*Born:* 1956.

*Education:* Graduate, Stockholm School of Economics.

*Other current assignments:* Board member of Brummer & Partners AB, ELC Fastigheter AB, East Bay AB, Sjuenda Gård AB, Carve Intressenter AB, Sjuenda Holding AB, Rebellion Oil AB, Psoriasis + Creams Sweden AB and Järna mejeri AB.

*Holding in the company:* 1,392,870 shares (privately and via companies).



## Magnhild Sandberg-Wollheim

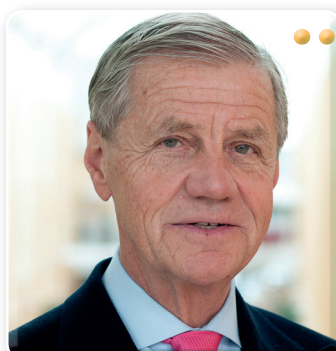
Board member since 2007.

*Born:* 1937.

*Education:* Associate Professor of Neurology and Consultant at the neurological clinic at Skåne University Hospital.

*Other current assignments:* Board member of MS-konsulten AB and Parkinson Research Foundation.

*Holding in the company:* None.



## Peter Sjöstrand

Board member since 2000.

*Born:* 1946.

*Education:* M.Sc. Stockholm School of Economics. Medical Degree, Karolinska Institute in Stockholm.

*Other current assignments:* Chairman of Byggnads AB S:t Erik, the Oscar Hirsch's Memory Foundation and Ringens Varv AB. Board member of SAMF Sweden AB, Peter Sjöstrand AB and assignments in the Acturum Group. Member of the Strategic Council, School of Technology and Health (Royal Institute of Technology) and Vatera Holding Advisory Board.

*Holding in the company:* 24,000 shares.



## Auditors

KPMG AB with David Olow as auditor-in-charge.

*Born:* 1963.

Company auditor at Active Biotech AB since 2009.  
Authorized Public Accountant KPMG.

# Executive management



## Tomas Leanderson

President and CEO. Employed by the company since 1999. Tomas Leanderson has held a number of academic research positions both in Sweden and internationally.

*Born:* 1956.

*Education:* Doctor of Medical Science, Umeå University.

*Other current assignments:* None.

*Holding in the company:* 103,230 shares.



## Hans Kolam

Chief Financial Officer. Employed by the company since 2000. Hans Kolam has more than 35 years of experience in the pharmaceuticals industry, having held various positions at Pharmacia.

*Born:* 1951.

*Education:* M.Sc. Economics, Uppsala University.

*Other current assignments:* None.

*Holding in the company:* 42,381 shares (of which 2,288 shares via related parties).



## Helén Tuveßon

Chief Scientific Officer. Employed by the company since 1998. Helén Tuveßon has worked in the pharmaceutical industry for almost 20 years and held various positions at Pharmacia.

*Born:* 1962.

*Education:* Doctor of Cellular and Molecular Biology, University of Lund.

*Other current assignments:* None.

*Holding in the company:* 7,362 shares.

# Glossary

**ANYARA:** Active Biotech's candidate drug against renal cell cancer. Only out-licensing activities are conducted.

**Autoimmunity:** When the body's immune system reacts against structures in the body itself. Autoimmune diseases arise when the immune system combats the body itself, despite it being otherwise healthy.

**CHMP:** Committee for Medicinal Products for Human Use, a scientific committee within the European Medicines Agency (EMA).

**CRO:** Contract Research Organization, specialized in the implementation of clinical trials.

**EMA:** European Medicines Agency.

**EDSS:** Expanded Disability Status Scale, a rating scale for neurological disability progression.

**Phase 1 studies:** The first studies on humans are carried out on a small group, normally 20–80 healthy volunteers. The purpose of these studies is mainly to show that the compound is safe for humans.

**Phase 2 studies:** Phase 2 studies test the compound on patients suffering from the disease that the potential drug is designed to treat. Tests are normally conducted on 100–300 patients. The primary aim of a Phase 2 study is to show that the compound has the intended medical effect and determine an optimal dosage.

**Phase 3 studies:** In Phase 3, the compound is tested on a large number of patients, often between 1,000 and 3,000 patients. The primary aim of Phase 3 studies is to show that a new drug is at least as good as, or better than, previously approved treatments for the specific disease.

**FDA:** Food and Drug Administration, the US pharmaceuticals authority.

**HR:** Hazard Ratio, a measurement of treatment efficacy. Values below 1 indicate a benefit for patients treated with an active substance.

**IND:** Investigational New Drug; the application, submitted to the pharmaceutical authority, for permission to commence pharmaceutical studies in humans.

**Inflammation:** The body's response to localized damage.

**Ipsen:** Ipsen SA, Active Biotech's former partner for tasquinimod.

**Clinical studies:** Studies of how a pharmaceutical affects humans.

**Laquinimod:** Active Biotech's candidate drug for treatment of neurodegenerative diseases, such as various forms of MS and Huntington's disease.

**Candidate Drug (CD):** A specific compound selected during the preclinical phase. The candidate drug is the compound that will continue on to clinical testing in humans.

**MediGene:** MediGene AG, Active Biotech's licensee for RhuDex®.

**MS:** Multiple sclerosis, a chronic autoimmune neurodegenerative disease.

**Multiple myeloma:** An incurable cancer of blood cells.

**Neurodegenerative:** Degenerative for the nervous system.

**OS:** Overall survival.

**Paquinimod:** Active Biotech's candidate drug in the 57-57 project against systemic sclerosis. Active Biotech will only conduct out-licensing activities in the future.

**Patent:** Exclusive rights to a discovery or invention.

**PBC:** Primary biliary cirrhosis, a chronic liver disease.

**PFS:** Progression Free Survival.

**Placebo:** A substance with no effect, a "sugar pill". Used for comparative purposes, for example, when studying the effect of a new drug.

**PPMS:** Primary progressive MS.

**Preclinical:** The part of drug development that takes place prior to the drug being tested on human beings.

**Proof of Concept:** When a candidate drug has a proven biological effect in humans.

**Quinoline:** The compound class to which laquinimod and tasquinimod belong.

**RRMS:** Relapsing remitting multiple sclerosis.

**SAP:** Statistical Analysis Plan.

**SILC:** S100 Inhibition by Low molecular weight Compounds. Active Biotech's preclinical oncology project, previously known as the ISI project.

**SSc:** Systemic sclerosis; a chronic autoimmune disease.

**SPMS:** Secondary progressive MS.

**Tasquinimod:** Active Biotech's candidate drug developed for multiple myeloma.

**Teva:** Teva Pharmaceutical Industries Ltd, Active Biotech's partner for laquinimod.

## Business concept, objectives and business strategy

### Business concept

Active Biotech's business concept is to utilize specialist knowledge of the immune defense system and cancer to develop pharmaceuticals in areas where medical needs are extensive.

### Goal

Active Biotech's goal is to generate value for shareholders through the successful development of pharmaceutical products.

### Business strategy

The key components of the company's business strategy are to:

- Achieve the greatest possible growth in value in each project and seek collaboration with strong partners for each project at the appropriate stage. Active Biotech has secured development and commercialization partners for one of its projects; Teva for laquinimod, currently in Phase 3 trials for the treatment of multiple sclerosis (MS). Active Biotech plans to selectively choose partners for the remaining projects at the optimal point in time for each project.

- Progress the clinical development of the company's selected compounds together with partners with relevant expertise.

Active Biotech will also:

- Generate revenue through out-licensing and royalties.
- Limit costs through the utilization of partnership agreements and external expertise.
- Protect its expertise through strong patents and an active patent strategy.
- Create financial sustainability through well-established partnerships and strong and active owners.



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