

### 2021 in brief

#### **Our projects**

- Data from the Phase 1a/b clinical study of KL1333 were released in May and confirmed the safety and pharmacokinetic profile of the drug. In addition, in a cohort of eight patients, there were signs of efficacy across well-established relevant clinical endpoints including two patientreported fatigue endpoints and a functional endpoint.
- In September, favorable feedback was received from UK Regulatory Agency (MHRA) on the NV354 preclinical data package.
- In November, the US Food and Drug Administration approved Abliva's Investigational New Drug (IND) application for KL1333, enabling registrational Phase 2/3 study start in the US with first patients due to be recruited in 2022.

#### **Financing**

- A directed issue of SEK 80m in two portions was carried out during the first half-year.
- Abliva resolved on directed issue of convertibles amounting to SEK 26m.

#### Other

• Dr. Ellen K. Donnelly was appointed CEO of Abliva, replacing Erik Kinnman.

#### Events after the end of the year

• An extraordinary general meeting was held on 14 January 2022. The general meeting approved the Board of Directors' resolution from 20 December 2021 on a directed issue of convertibles to Life Science Specialist Hadean Ventures of SEK 26m.

#### **Reading instructions**

The figures in brackets, unless otherwise specified, refer to 2020 operations. Swedish kronor (SEK) are used throughout. SEK million is shortened SEK m.

This Annual Report is published in Swedish and English. In the event of any difference between the English version and the Swedish original, the Swedish version shall prevail.



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### Statement from CEO Ellen Donnelly

2021 was a banner year for Abliva with both KL1333 and NV354 making significant progress. KL1333 was de-risked substantially over the year with efficacy and safety readouts confirming the profile – and potential – of KL1333. NV354 completed preclinical development and received a nod from the UK regulatory agency that it had the package required to start a clinical study. These were important and necessary milestones for both programs and we will move into 2022 with confidence around the path forward for the assets.

#### KL1333 ENTERS 'LATE STAGE' DEVELOPMENT

It is hard to believe, as we continue to lay the groundwork for our global, Phase 2/3 study, that the Phase 1 study just readout in May of 2021. Although the primary objective of this study was to evaluate the safety and tolerability of KL1333, there was one cohort in the study looking for early signs of efficacy in Primary Mitochondrial Disease patients. I remember at the time that we were all a bit cautious about this cohort as this was our first study in patients and we really didn't know what to expect from the drug as we were only dosing for 10 days at a low (50 mg) dose. It was also in the midst of COVID and the UK hospitals were overwhelmed with patients fighting the coronavirus. We were relieved when we recruited that last patient and delighted when we reviewed the data. KL1333 delivered on all fronts with good differences between the placebo and KL1333 groups on all three efficacy measures, a nice exposure-effect relationship, and demonstration of target engagement. We also 'checked the box' with the safety profile in the Phase 1 study and then again with the readout of the drug-drug interaction study (confirming that patients taking KL1333 could still take other commonly prescribed medications) and the chronic toxicology study.

The approval of the IND (Investigational New Drug) at the end of November was an important milestone as it not only confirmed that the KL1333 package was sufficient for the US regulators to allow us to dose patients, but it also provided us with useful regulatory feedback on the Phase 2/3 study design – everything from the patient population to the duration, dosing, endpoints and analysis of the data. Over the coming months we will submit the Phase 2/3

documents to the remaining countries as we work also to finalize the clinical design with all regulators , including in the US, and gain approval for study start across the remaining global footprint. Our CRO (Contract Research Organization) partner, ICON, came on board middle of 2021 and they have been busy ensuring that we have the countries and sites selected, translations ready, database built and all of the other prep work done in anticipation of our first patient entering the study in 2022.

#### **NV354 TAKES ONE STEP CLOSER TO THE CLINIC**

Although KL1333 received the bulk of our attention in 2021, NV354, our brain-penetrable pro-drug of succinate, also met our expectations. After the completion of the preclinical data package in the summer, the team took the program to a meeting with UK pharmaceutical regulators, MHRA, for scientific advice and posed a number of questions. One of the last questions we asked was whether the current package supported entry into humans – and they said yes! The next steps for this program will be the assembly of the clinical trial application (CTA) for submission to the regulatory authorities.

#### **FINANCIAL POSITION**

The company began 2022 with a convertible loan of SEK 26 million from Hadean Ventures. The loan was intended to provide Abliva with the runway necessary to secure the capital to fund the planned (not yet contracted) Phase 2/3 study with KL1333. Given the impact of external factors on the market, the financing has taken longer than expected. The management and board are working with financial advisors to explore and evaluate a broad range of financing alternatives and scenarios to support the company with the goal of securing sufficient financing for the Phase 2/3 study. Given the ongoing discussions with investors and strategic partners, both management and the Board are confident in the financial future of the company and look forward to the start of the KL1333 study later this year.

#### **ESTABLISHING ABLIVA AS A LEADER IN THE FIELD**

With our portfolio of unique, first-in-class molecules to treat



DR. ELLEN DONNELLY CEO

"With our portfolio of unique, firstin-class molecules to treat patients with primary mitochondrial diseases, the first of which may be on the market as early as 2025, we are well positioned to become a leader in mitochondrial disease drug development."

patients with primary mitochondrial diseases, the first of which may be on the market as early as 2025, we are well positioned as a leader in mitochondrial disease drug development. It is critical, however, that we continue to expand our communication and our network beyond Sweden into Europe and the US. We made good strides in this area in 2021 with the establishment of our US subsidiary in Boston, MA, important patient outreach in Europe and the US, and by establishing our global site network for our upcoming study. We also presented our story a great deal to a wide variety of stakeholders in 2021. I look forward to continuing this work in 2022 and remain hopeful that these largely virtual interactions will transition back to face-face opportunities over the next year.

Best wishes,

Ellen

### The Impact of Fatigue for Patients with Mitochondrial Disease

IN 2021, ABLIVA COMPLETED AN INTERVIEW STUDY WITH MITOCHONDRIAL DISEASE PATIENTS WHO ALSO SUFFER FROM CHRONIC FATIGUE

Summary of the video interview Study on the Impact of Fatigue for Patients with Mitochondrial Disease, recorded and moderated by Phil Yeske, Science & Alliance Officer at the US patient organization UMDF (United Mitochondrial Disease Foundation) with Magnus Hansson (Abliva) and Sarah Clifford and Roxy Bahar from Sprout Health Solutions.

Watch the full interview here: https://youtu.be/vg79FPRLmls

### Magnus, first of all, could you tell us a little bit about why this study became so important to you?

"What we have learned from speaking to patients over the last several years, is that fatigue is really important. There are actually a number of existing general fatigue questionnaires for different types of diseases, but there is no specific tool to evaluate fatigue in mitochondrial disease patients - there's no "mito fatigue" scale. We wanted to create a specific short form with a set of questions that capture what is most important from the fatigue in mitochondrial disease patients. We can then use that tool in our upcoming trial to really test if KL1333 is effective or not on mito fatigue."

#### Sarah, how did Sprout become involved in this project?

"We've done work in understanding fatigue in other chronic illnesses, and we've also had a lot of experience in selecting and evaluating fatigue measures. It seemed a really good fit, for us to help Abliva with this."

### Roxy, who participated in the study and what was involved in the study?

"We had people in the United States with primary mitochondrial disease who had moderate to severe fatigue. We ended up with 14 participants, and they were between the ages 20 - 75. They had two interviews with us. Each one, about an hour, were informal conversations. In the first interview, we wanted to know what fatigue is like when you have primary mitochondrial disease and how it shows up in your body. How does it impact your life and what's

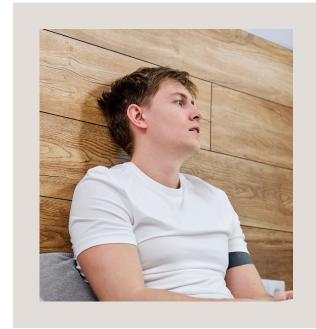
most important to people with primary mitochondrial disease in terms of their experience, what means the most to them? After that, we had a second interview where we asked them to evaluate the questions for the questionnaire. Is this relevant? Does it make sense? Is it easy to answer?"

"...not being able to take care of children or play with them, which was very emotional for the people that told us about this because they felt like they were missing out on their children's lives."

### What did the primary mitochondrial disease patients tell you in these interviews?

"It was really overwhelming in some cases, to talk to people about their experience. There were the things that we expected, like that people feel very tired. They can feel exhausted and out of energy, they have muscle fatigue and specific fatigue in different parts of the body. And there was also mental fatigue and memory issues, difficulty focusing, difficulty concentrating and retaining and taking in information. Also, moving slowly physically and not being able to keep up with people. The impacts were ranging from a level of getting out of bed in the morning, taking a shower, being able to physically wash your hair and use those muscles, to getting dressed and presenting yourself to the world. Most people who don't experience this fatigue wouldn't even think about it.

The patients also told us it has to be very structured throughout the day, needing to plan the day to manage energy, needing to plan the week and strategize, not being able to work or having difficulty keeping up at work, not being able to take care of children or play with them, which was very emotional for the people that told us about this because they felt like they were missing out on their





children's lives. Difficulty doing chores like cleaning your house, and a feeling of shame and embarrassment that they couldn't do these things that our society expects us to do.

"People would say to our participants: "Yes, I'm really tired, too." And that felt very hurtful and minimizing to them. A lot of people felt like they weren't seen for what their experience was."

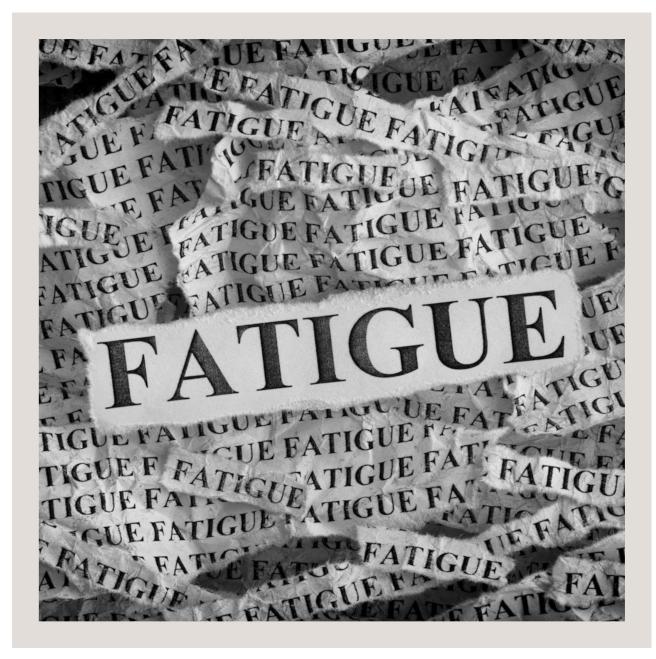
Also, difficulties to focus and stay mentally engaged in relationships with family and friends was evident. Friends or family would say to our participants: "Yes, I'm really tired, too." And that felt very hurtful and minimizing to them. A lot of people felt like they weren't seen for what their experience was. This could affect their mood and give rise to the feeling that they can't even participate in life. "What's the point?" "Who am I if I can't do these things?", "What is my identity?" It was so pervasive and had such huge impacts on our participants' lives in every way."

### What will you do with these data, the results from these interviews?

"We went in with 20 questions. From that, we ended up finding that there were nine questions that we felt covered the range of all those fatigue experiences and impacts, and that all our participants found to be clear, easy to answer, and relevant to their experience. There was also a consensus around these nine questions. Those nine questions then became the fatigue questionnaire that Abliva will be able to use in their clinical trial."

#### To round this up, Magnus, what next?

"This has been a really valuable study and something that the authorities require us to do. If we're going to have an outcome measure, we need to show that we have validated it. Now we have this tool with nine questions that we think really capture mito fatigue really well. The next step is to get that into the efficacy trial, where patients will have taken either the active compound KL1333 or an inactive placebo tablet."



### Strategic focus: primary mitochondrial diseases

Abliva is focused on becoming the leading biotech company in mitochondrial medicine, developing therapeutics for primary mitochondrial diseases, orphan indications of high unmet medical need. In the future, the company will build a fully integrated research, development, and commercial organization, developing innovative therapeutics and taking them directly to the patients.

#### **Building the Premier Mitochondrial Medicine Company**

Abliva's long-term goal is to become the leading global biotech company focused on the therapeutics for mitochondrial diseases. Abliva has the foundation to do this with a clear strategy, a strong portfolio of assets, a research organization and a team that has over two decades of experience in mitochondrial medicine as well as years of experience in drug development.

Over the next five years we will focus on conducting clinical development to bring our drug candidates to the market. We will augment our strong research and development capabilities and build a commercial organization. We will bring new innovative therapeutics to the clinic and fuel our pipeline with new candidates from discovery. We will attract and retain talented colleagues with a passion for drug development. We will build a strong network of experts that will complement, enhance and support our efforts across development that will include patients, physicians, researchers, regulators, payers and technical experts. We will generate future revenues through two paths: sales revenue for the drugs Abliva intends to bring to market, and revenue from out-licensing assets (through milestone payments and royalties).

#### **Addressing Primary Mitochondrial Diseases**

Mitochondria function as the powerhouses of our cells and are crucial for the cells' energy metabolism. Primary mitochondrial diseases are rare orphan diseases where the energy metabolism in the cells is impaired, causing deterioration that leads to multifaceted disorders and great suffering for patients. The symptoms worsen over time and, in many cases, the diseases lead to premature mortality. Mitochondrial medicine has become an area of

increasing focus for the pharmaceutical industry as there are currently no effective treatment options. Through Abliva's research and development, we have an opportunity to improve the quality of life for these patients.

#### Delivering a Portfolio of First-in-Class Therapies

Abliva's in-house R&D capabilities have been instrumental in creating and delivering a portfolio that includes several projects with mechanisms of action suitable for a wide range of mitochondrial diseases.

KL1333 restores the balance of the coenzymes NAD+ and NADH, creating new mitochondria and improved energy levels. KL1333 has completed a number of key Phase 1 studies to prepare the asset for registrational Phase 2/3 study start in 2022. KL1333 is protected by both a composition of matter patent as well as Orphan Drug Designation (ODD) in the U.S. and in Europe. The commercial opportunity is significant with even conservative estimates exceeding USD 1 billion per year in annual sales<sup>3)</sup>.

NV354, an energy replacement therapy, is a pro-drug of succinate. The drug was invented in the Abliva laboratories at Lund University and is supported by a strong group of patents. NV354 is being developed for the mitochondrial disease Leigh Syndrome initially with potential to expand to other indications that have a dysfunctional complex I in the electron transport chain.

Further, Abliva has additional efforts ongoing in discovery that are focused on the regulation and stabilization of the mitochondrion's energy production.

#### **Leveraging Opportunities in Rare Diseases**

Abliva is continually working to take advantage of the opportunities afforded to companies working in the rare disease space. The company requested, and was granted, orphan drug designation (ODD) for KL1333 in both the US and EU. ODD is a regulatory designation that provides sponsors with a number of advantages including more regulatory assistance and scientific advice during

the development process, lower development costs, attractive pricing, and market exclusivity (10 years in the EU and 7 years in the US). The outlook for reaching the market is also better than for traditional medicines<sup>1,2</sup>.

In addition, we have sought advice from pharmaceutical regulators in the US, UK and Europe. This advice has been extremely important to the company, as is clearly demonstrated with the advice from the FDA that led us to move to a single, registrational Phase 2/3 study (versus the traditional sequential Phase 2 followed by Phase 3 design), allowing us to get to market more quickly.

#### **Building a World Class Organization**

The key to the success of any company is the people who work there, and the leadership at Abliva is committed to attracting and retaining a group of bright, innovative scientists, clinicians, and drug development experts. We will continue to support development opportunities for our colleagues and ensure that they have the tools and resources available to deliver on our goals. We will continue to complement our core team with a network of specialists, physicians, advisors and others who will bring their expertise to our programs.

#### **Accessing Capital to Finance the Vision**

Abliva is a public company traded on NASDAQ Stockholm (ABLI, Small cap). The company appreciates the continued commitment of our shareholders and looks to attract new investors as we advance our portfolio and build the company. The investment of Hadean Ventures was the first step to bringing specialist investors into the company and the company aims to continue to attract new specialist and institutional investors across Sweden, Europe and America as the financial needs of the company increase with the KL1333 registrational study, the progression of the portfolio, and the build of a commercial organization.

1) Jayasundra et al. Orphanet J of Rare Dis. Estimating the clinical cost of drug development for orphan versus non-orphan drugs. 2019. 2) EvaluatePharma, Orphan Drug Report 2019. 3) Gorman et al., Prevalence of Nuclear and Mitochondrial DNA Mutations Related to Adult Mitochondrial Disease, 2015.



### **KL1333**

# Innovative therapy heading to registrational Phase 2/3 study

The drug candidate KL1333 is being developed as a treatment for adult patients with multisystemic mitochondrial DNA mutations who suffer from fatigue and myopathy. The team is preparing for a global, registrational Phase 2/3 study to commence in 2022. The development of KL1333 is facilitated by orphan drug designation in both the US and Europe.

Patients suffering from multisystemic mitochondrial disorders such as MELAS-MIDD, CPEO-KSS and MERFF are affected by severe symptoms and have a shortened life expectancy. Although they may have heterogenous conditions, the majority suffer from fatigue and myopathy, the intended endpoints of our upcoming study. KL1333 has the ability to restore the balance of NAD+ and NADH, thereby leading to the formation of new mitochondria, and improved energy levels. KL1333 is intended for chronic oral treatment.

### FIRST PATIENTS DOSED WITH KL1333 IN 2021 HAD IMPROVEMENTS IN FATIGUE AND MYOPATHY

In 2021, Abliva completed several important studies. The Phase 1a/b clinical study, which included both healthy volunteers and patients, confirmed that KL1333 has a good safety profile. In addition, in a cohort of patients in the same study, there were signs of efficacy in mitochondrial fatigue and proximal myopathy.

The company also completed a drug-drug interaction study that confirmed that KL1333 can be co-administered with other commonly prescribed medications. A patient registry study provided additional information on patient populations and the presence of combinations of symptoms. Another patient study, a study designed to validate a mitochondrial disease-specific fatigue scale for use in the upcoming Phase 2/3 study, was full success. The study generated the first primary mitochondrial disease specific

endpoint in the industry - the PROMIS PMD Fatigue Short Form. At the end of November, the FDA approved Abliva's Investigational New Drug (IND) application, enabling the start of the planned Phase 2/3 study in the US.

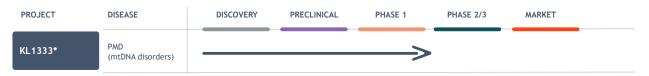
The FALCON study, the planned global, registrational, Phase 2/3 clinical study with KL1333, is going to be a randomized, double-blind and placebo-controlled trial with up to 180 adult patients, subject to final global regulatory interactions. Each patient will be dosed for 12 months, and an interim analysis is planned during 2023. The two intended primary endpoints (analyzed independently) will evaluate the effect of KL1333 on fatigue and proximal myopathy. With a sucessful study, Abliva will apply for market approval of KL1333 as early as 2025.

#### **BLOCKBUSTER POTENTIAL**

The recommendation from the FDA to make a coherent, registrational Phase 2/3 study brings significant benefits to the KL1333 project, and Abliva's intention is to apply for market approval during 2025. The number of patients in the target group for treatment with KL1333 is approximately 40,000<sup>1)</sup> in Europe and the US. At typical orphan drug pricing, this translates into a blockbuster opportunity of over USD 1 billion in sales.

#### **OBJECTIVES FOR 2022**

- Regulatory approval in five countries.
- Initiate the start of the FALCON study.



1 Gorman et al., Prevalence of Nuclear and Mitochondrial DNA Mutations Related to Adult Mitochondrial Disease, 2015



#### ELEONOR ÅSANDER FROSTNER COMMUNICATIONS OFFICER & LAB MANAGER

"Our fantastic team is literally working around the clock to get the FALCON study up and running as soon as possible. Discussions are ongoing with both the national authorities in each country and the site personnel to ensure we have an executable study design that facilitates patient recruitment and retention."



### **NV354**

# First-in-class therapeutic approach heading towards clinical development

The drug candidate NV354 is being developed for the treatment of Leigh syndrome. The project has undergone necessary preclinical pharmacology and safety studies and is being prepared for clinical development.

NV354 is developed for the treatment of Leigh syndrome, a severe pediatric mitochondrial disease that debuts in early infancy with patients usually succumbing to the disease before the age of five. Children with Leigh syndrome usually suffer from developmental delay, psychomotor regression and hypotonia. There are currently no approved medicines.

The mechanism of action of NV354 supports additional primary mitochondrial disease indications as well, such as LHON, a disease affecting the optic nerve, and MELAS in children and adolescents with neurological symptoms. MELAS is a very serious disease with symptoms such as muscle weakness, epilepsy, other severe neurological effects, and shortened life span. LHON is a disease that causes sudden severe permanent visual impairment and can lead to blindness on both eyes. The drug candidate is intended for chronic oral treatment.

#### POSITIVE REGULATORY FEEDBACK RECEIVED

In 2021, Abliva completed the preclinical package of pharmacology and safety studies required to support clinical development. Following positive feedback from the UK Regulatory Agency (MHRA), the Abliva team confirmed that NV354 had the package necessary to move into clinical development. The company will now assemble the regulatory documentation, for the filing of a formal clinical trial application, required to support dosing in healthy volunteers in a Phase 1 study.

#### LARGE POTENTIAL MARKET

25 per 1,000,000 children are estimated to be born with Leigh syndrome. MELAS and LHON could also be treated with NV354. There are approximately 25,000 people with LHON in Europe.<sup>1)</sup>

#### **OBJECTIVES FOR 2022**

- Produce NV354 drug product for Phase 1 studies
- Assemble regulatory documentation to support Phase 1 study start

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ESKIL ELMÉR CHIEF SCIENTIFIC OFFICER

"There are currently no options for children with Leigh syndrome - they are diagnosed when they are babies and they quickly decline, dying in their early childhood. Our candidate NV354 is well on its way to clinical development and has now also been externally validated by the UK Regulatory Agency".



<sup>1</sup> Gorman et al., Prevalence of Nuclear and Mitochond-rial DNA Mutations Related to Adult Mitochondrial Disease. 2015

#### Non-core asset

#### **NEUROSTAT - FOR TREATMENT OF TBI**

Traumatic brain injury (TBI) is caused by external force to the head resulting in immediate damage to nerve cells. The damage continues to worsen for several days after the acute trauma and most individuals remain impacted for the rest of their life.

#### Treatment objective

The aim for NeuroSTAT, targeting the mitochondria, is to counteract the emergence of neurological and functional secondary brain damage after a traumatic injury, and thereby establish a therapy that will lead to increased survival, improved quality of life and preserved neurological function.

#### Project status

NeuroSTAT has shown favorable properties in a Phase 1b/2a clinical study and in advanced experimental TBI models at the University of Pennsylvania (Penn). NeuroSTAT has orphan drug designation in Europe and the US as well as an open IND and Fast Track designation for clinical development in the US.

Abliva is in continued discussions with the TRACK-TBI network regarding a potential collaboration within the scope of the Precision Medicine project<sup>1) 2)</sup> for a Phase 2 study on traumatic brain injury with NeuroSTAT. The study, if authorized by US Department of Defence (DOD), is contingent upon DOD's approval of earlier steps of the project.

With a potential agreement with TRACK-TBI as a partner, the company will review possible options that may enable developing the NeuroSTAT program further.



<sup>1</sup> Precision Medicine grant: TRACK-TBI Precision Medicine is a DOD-funded project run by the leading traumatic brain injury (TBI) clinical trial network TRACK-TBI in the US. The aim of the project is to validate novel imaging and blood -based biomarkers for moderate/severe TBI to enable precision medicine TBI clinical trials with a focus on specific disease pathologies and enriched study populations.

<sup>2</sup> The views expressed regarding the Precision Medicine project are those of the company/authors and may not reflect the official policy or position of the Department of the Army, Department of Defense, or the U.S. Government.

### Organization and expertise



Abliva has operations in both research and development, both in-house and in collaboration with international partners in Europe, Asia and North America. These partnerships include pre-clinical development work and clinical trials at well renowned universities and hospitals throughout the world.

#### **WELL-EDUCATED PERSONNEL**

The average number of employees in the Group during the year was 9 (9), of which 6 (5) are women. The number of employees at year-end was 2 (2) part-time employees and 8 (7) full-time employees. Of a total of 10 (9) employees, 7 (5) were women and a total of 7 (7) were active in the Company's research and development activities.

The company's in-house resources comprise 10 full and part-time employees. All have university or college-level education and six have a Doctor of Medical Science degree whereof two are Associate Professors. Furthermore, two are medical specialists. Four employees are engaged in preclinical work, and three in the company's clinical activities. Further Abliva collaborates with several

external companies and institutions. In 2021, the company invested SEK 88 (26) million in clinical phase research and SEK 8 (9) million in preclinical phase research, including personnel expenses. During the year, the company's employees were based in Sweden except for the Company's CEO based in Boston, MA, US.

#### ACADEMIC AND COMMERCIAL PARTNERSHIPS

Because of its unique research, Abliva has established good relationships with the academic, medical and business communities across the world, enabling successful partnerships.

Abliva cooperates with experts who are very important for the company's way forward. Their specialist competences include regulatory issues, statistics, and CMC (Chemistry, Manufacturing and Controls).

Abliva collaborates with the Korean pharmaceutical company Yungjin Pharm on the clinical development of the KL1333 project for the treatment of primary mitochondrial disorders.

UK-based Isomerase is one of Abliva's key partners, providing chemistry expertise and new novel compounds to the Abliva discovery portfolio The collaboration between the two companies' researchers is also a creative hotbed for identifying new development platforms in the same area, and with its drug development expertise, the Isomerase team brings valuable insights and expertise to Abliva's projects.

Through the NeuroVive Asia Ltd. subsidiary in Hong Kong, Abliva has partnerships with the Chinese pharmaceutical company Sihuan Pharmaceutical, and with Sanofi in South Korea. Abliva also partners with a range of contract research organizations and Contract Manufacturing Organizations, such as ICON Clinical Research Limited, Labcorp Drug Development, Patheon and Symeres.

Abliva also has entered into a partneragreement with Oroboros Instruments in Austria. In addition to these partners, Abliva collaborates with a range of academic institutions all over the world, including CHOP (Children's Hospital of Philadelphia), Newcastle University and University College London (UCL) in the UK.

### The Abliva share

The Abliva share was listed on Nasdaq Stockholm in April 2013. The share is included in the Small Cap segment and the Health Care index. On 30 December 2021 Abliva had 13,196 shareholders.

#### SHARE PRICE DEVELOPMENT AND TURNOVER

Since year-end, 399,299,907 shares were traded with a value of SEK 274,060,922. Ablivas's share price was SEK 0.60 at the end of the year, representing a decrease of 22 percent compared to previous year-end. The highest price paid for the year was SEK 0.98 on March 16 2021 and the lowest price paid was SEK 0.47 on December 21 2021. Market capitalization was SEK 240,998,065 at year-end, compared to SEK 226,700,201 at the previous year-end.

#### **SHARE CAPITAL**

Abliva had 403,006,798 shares on 30 December 2021 and the share capital amounted to SEK 20,150,339.90 with a quotient value

of SEK 0.05. All shares have equal entitlement to dividends and each share has equal voting rights. Each share has one vote at the AGM. The private placement completed in April and May 2021 increased the number of shares to 328,941492 and the share capital to SEK 16,447,074.60 in the first tranche. In the second tranche the number of shares increased to 403,006,798 and the share capital to SEK 20,150,339.90. More information on the issue can be found on Ablivas's website. The table on page 13 shows the development of the number of shares.

#### **OWNERSHIP**

The number of shareholders at the end of the year amounted to 13,196 (12,810), which means an increase of 3 percent during the year.

#### **DIVIDEND**

The Board of Directors proposes that no dividend be paid for 2021.

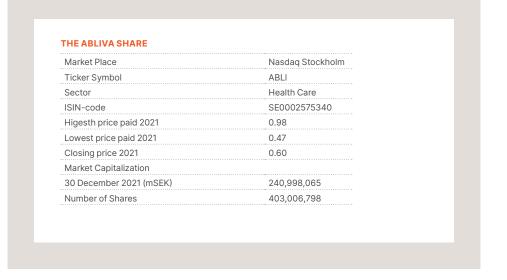
#### **SHAREHOLDER VALUE**

Abliva continuously seeks to develop and improve the financial information provided about the company, with the aim of ensuring a sound basis for an accurate valuation by existing and future shareholders. This includes actively participating at meetings with investors, the media and analysts.

#### SHAREHOLDER INFORMATION ON ABLIVA'S WEBSITE

Abliva's website, www.abliva.com, continuously publishes information on Abliva, progress of the Abliva share, financial reports and contact information.





#### **DEVELOPMENT SHARE CAPITAL**

| Year | Event                  | Total No. of Shares | Total Share Capital |
|------|------------------------|---------------------|---------------------|
| 2000 | Incorporation          | 1,000               | 100,000.00          |
| 2003 | New Issue              | 1,025               | 102,500.00          |
| 2004 | New Issue              | 1,100               | 110,000.00          |
| 2007 | New Issue              | 1,313               | 131,300.00          |
| 2007 | New Issue              | 1,433               | 143,300.00          |
| 2008 | Offset Issue           | 1,493               | 149,300.00          |
| 2008 | New Issue              | 1,576               | 157,600.00          |
| 2008 | Bonus Issue            | 1,576               | 591,000.00          |
| 2008 | Share Split            | 11,820,000          | 591,000.00          |
| 2008 | New Issue              | 13,075,000          | 653,750.00          |
| 2010 | New Issue              | 14,942,857          | 747,142.85          |
| 2012 | New Issue              | 19,159,046          | 957,952.30          |
| 2013 | Private Placement      | 21,659,046          | 1,082,952.30        |
| 2014 | Rights Issue           | 27,788,093          | 1,389,404.65        |
| 2015 | Rights Issue           | 29,088,093          | 1,454,404.65        |
| 2015 | New Issue              | 30,735,152          | 1,536,757.60        |
| 2016 | Non-Cash Consideration | 31,473,685          | 1,573,684.25        |
| 2016 | Rights Issue           | 49,458,645          | 2,472,932.25        |
| 2017 | Warrants               | 49,481,973          | 2,474,098.65        |
| 2017 | Warrants               | 49,485,942          | 2,474,297.10        |
| 2017 | Private Placement      | 50,566,197          | 2,528,309.85        |
| 2017 | Private Placement      | 52,326,197          | 2,616,309.85        |
| 2018 | Rights Issue           | 91,570,841          | 4,578,542.05        |
| 2018 | Warrants               | 91,697,076          | 4,584,853.80        |
| 2019 | Rights Issue           | 163,358,124         | 8,167,906.20        |
| 2019 | Rights Issue           | 165,054,737         | 8,252,736.85        |
| 2019 | Private Placement      | 185,952,591         | 9,297,629.55        |
| 2020 | Rights Issue           | 269,673,466         | 13,483,673.30       |
| 2020 | Private Placement      | 296,340,132         | 14,817,006.60       |
| 2021 | Private Placement      | 328,941,492         | 16,447,074.60       |
| 2021 | Private Placement      | 403,006,798         | 20,150,339.90       |

#### **SHAREHOLDINGS AS OF DECEMBER 31, 2021**

| Shareholding | No. of Owners | No. of Shares | Holding, (%) | Votes, (%) |
|--------------|---------------|---------------|--------------|------------|
| 1-500        | 3,919         | 686,913       | 0.17         | 0.17       |
| 501-1000     | 1,513         | 1,224,900     | 0.30         | 0.30       |
| 1001-5000    | 3,472         | 9,117,643     | 2.26         | 2.26       |
| 5001-10000   | 1,420         | 11,004,668    | 2.73         | 2.73       |
| 10001-15000  | 617           | 7,855,712     | 1.95         | 1.95       |
| 15001-20000  | 465           | 8,471,381     | 2.10         | 2.10       |
| 20001-       | 1,790         | 364,645,581   | 90.48        | 90.48      |

#### LARGEST SHAREHOLDERS AS OF DECEMBER 31, 2021

| EAROEST STIARETTOEDERS AS ST DESEMBER 31, 2021                       | No of shares | Votes and capital |
|--|--------------|-------------------|
| Name   | (pcs.)       | (%)               |
| Hadean Capital I AS*   | 41,277,533   | 9.02              |
| Försäkringsbolaget Avanza Pension **                                 | 24,850,736   | 6.19              |
| Fällström, John  | 22,001,856   | 3.69              |
| Danske Bank International S.A.                                       | 20,025,000   | 2.81              |
| Hventures Capital I AB*  | 18,722,466   | 1.98              |
| Liljenberg, Stefan   | 8,136,162    | 1.65              |
| EuroClear Bank S.A/N.V, W8-IMY (registered holding on behalf of Maas |              |                   |
| Biolab, LLC and Marcus Keep and others with US domicile)***          | 5,727,750    | 1.55              |
| Nordnet Pensionförsäkring AB**                                       | 5,523,634    | 1.4               |
| Berger Gunvald   | 4,907,277    | 1.21              |
| Swedbank försäkring**  | 4,790,275    | 1.05              |
| Other owners (approx. 13,000 shareholders)                           | 247,044,109  | 69.45             |
| In total   | 403,006,798  | 100.00            |

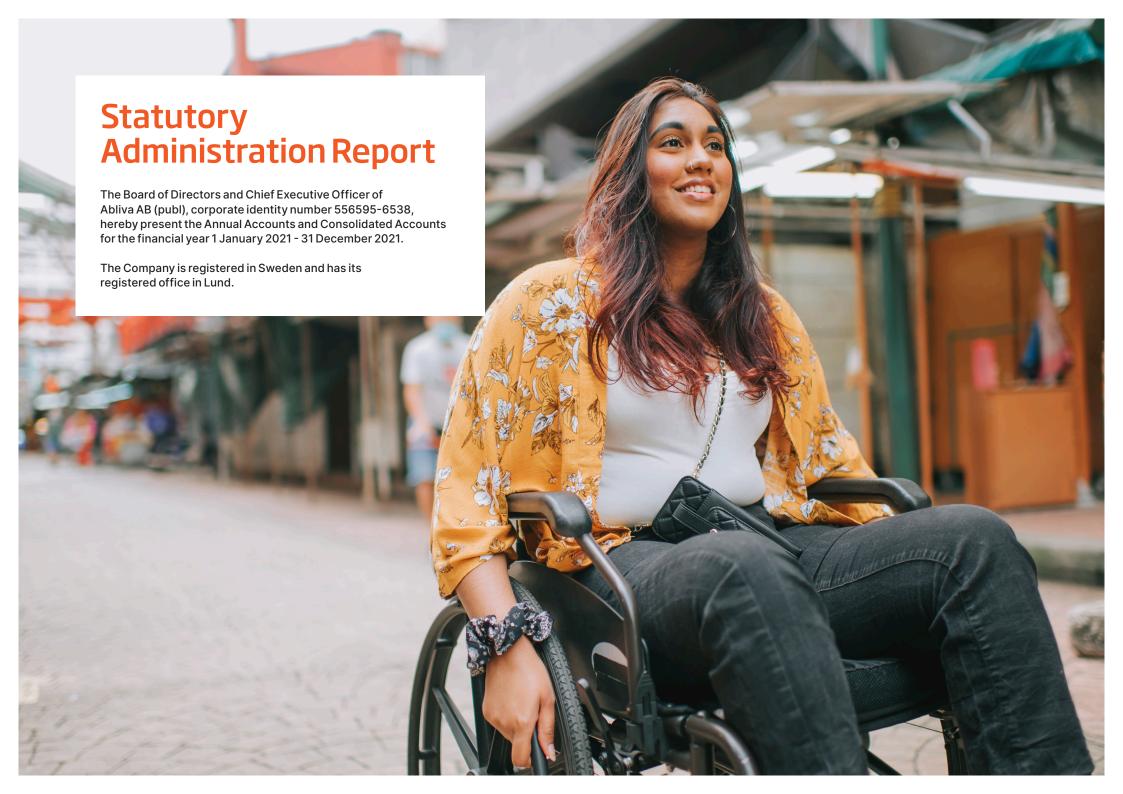
Source: EuroClear Sweden AB



<sup>\*</sup>Fund managed by Hadean Ventures

<sup>\*\*</sup>Capital insurance

<sup>\*\*\*</sup>Maas Biolab, LLC ("Maas") together with other owners residing in the US. Maas owned 3,875,000 shares in Abliva per 30 December 2021 and Maas had at this point 45 shareholders. Maas was owned to 49.41 % by founder Marcus Keep and 16.20 % by CSO Eskil Elmér



### **Operations**

Abliva, based in Lund, Sweden, is a clinical-stage biotech company that conducts research and clinical development to identify new treatments for patients suffering from primary mitochondrial diseases. These congenital, rare and often very severe diseases occur when the cell's energy provider, the mitochondria, do not function properly. The company has a number of programs focused on the development of treatments for primary mitochondrial diseases.

The company has one project entering clinical Phase 2/3 (KL1333) for chronic treatment of primary mitochondrial diseases, and one project in preparation for clinical trials (NV354), for the treatment of primary mitochondrial diseases associated with Complex I deficiency. The R&D portfolio also consists of early projects for primary mitochondrial disease. Abliva is listed on Nasdaq Stockholm, Sweden (ticker: ABLI) since 2013..

Abliva's overall vision and objective is to develop effective therapies for primary mitochondrial diseases to meet the extensive unmet medical need in this area, for which there are currently no effective treatments.

#### **THE GROUP**

The Group's consists of the Parent Company, whose operations include drug development and Group-wide functions. The Group has two wholly owned subsidiaries: Abliva Inc (registered in the USA where the company's CEO is employed) and Abliva Incentive AB (registered in Sweden to manage the Group's option program). There is a third partially-owned subsidiary the Hong Kong-registered company NeuroVive Pharmaceutical Asia Ltd., which holds the Asian license rights for NeuroSTAT and agreements with the Chinese pharmaceutical company Sihuan Pharmaceutical and with Sanofi in South Korea. Abliva AB owns approximately 82.47 percent of the subsidiary.

#### **SIGNIFICANT EVENTS IN 2021**

#### January

The Board of Directors, appointed Dr. Ellen K. Donnelly, Ph.D. as the company's new CEO to lead Abliva's development into a commercial biopharmaceutical company. Dr. Donnelly took office on February 3rd.

The license agreement with Fortify Therapeutics, a wholly-owned subsidiary of BridgeBio, regarding a development of a local treatment for Leber's Hereditary Optic Neuropathy (LHON), was terminated. Fortify's business decision follows an internal review of the entire BridgeBio's portfolio.

#### March

The clinical Phase 1a/b study with KL1333, Abliva's drug candidate for chronic oral treatment of primary mitochondrial diseases, was completed. No serious adverse events (SAEs) were reported.

A directed issue of SEK 80m was carried out, which included Abliva's lead investor Hadean Ventures. The subscription price, SEK 0.75, corresponded approximately to market price. SEK 24.5m was received immediately. SEK 55.5m was recieved after approval at the Extraordinary General Meeting on 29 April, 2021

#### April

The extraordinary General Meeting was held on 29 April 2021. The Board of Director's resolution to issue shares with deviation from the shareholder's preferential rights was approved.

#### Mav

The Annual General Meeting in Abliva was held on 20 May 2021 by postal voting.

Data from the Phase 1a/b clinical study of KL1333 were released and confirmed the safety and pharmacokinetic profile of the drug. In addition, in a cohort of eight patients, there were signs of efficacy across well-established relevant clinical endpoints including two patient-reported fatigue endpoints and a functional endpoint.

#### September

The company announced that NV354 will move to the clinic after having received favorable feedback received from the regulatory authority in the UK, the MHRA, on the preclinical package.

#### November

The US Food and Drug Administration approved Abliva's Investigational New Drug (IND) application for KL1333, enabling the start of a registrational Phase 2/3 studyin the US. First patients are due to be recruited in 2022.

#### December

Abliva resolved on a directed issue of convertibles amounting to SEK 26 million subject to the approval of an extraordinary general meeting, to the Company's largest shareholder Hadean Ventures through its two funds Hadean Capital I AS and HVentures Capital I AB.

#### **REMUNERATION**

The Annual General Meeting (AGM) resolves on the remuneration of the Chairman of the Board and other Board members. The AGM also resolves on remuneration policies for the CEO and other senior executives. For more information about remuneration paid during the year, refer to Note 11 and the Corporate Governance Report on pages 28-29. At the AGM on May 20, 2020 the following guidelines were adopted. Guidelines adopted in 2020 apply until further notice:

These guidelines cover the persons who are members of Abliva AB's Group Management. Group management currently consists of four positions. The guidelines do not cover remuneration resolved by the Annual General Meeting, such as fees to Board members or share-related incentive programs.

#### Annual variable remuneration (STI bonus)

From time to time, senior executives and other key individuals may be offered variable remuneration. Such variable remuneration shall be on market terms and shall be based on the outcome of predetermined financial and operational targets. Variable remuneration shall be based on the fulfilment of Abliva's targets for project results and value growth divided in personal targets for the financial year. The terms and conditions and basis of computation of variable remuneration shall be determined for each financial year. The targets promotes the Company's business strategy, long-term interests and sustainability by linking the remuneration to senior executives to the Company's project- and growth development.

The measurement period for variable remuneration is generally based on performance over a period of approximately 12 months. To which extent the criteria for awarding variable cash remuneration has been satisfied shall be evaluated/determined when the measurement period has ended. At the annual review, the Remuneration Committee, or when applicable, the Board of Directors, may adjust the targets and/or the remuneration with regards to both positive and negative extraordinary events, reorganisations and structurual changes.

The basic principle is that the annual variable portion of pay may be a maximum of 30 percent of basic annual salary to the CEO, maximum 20 percent of the basic annual salary to the management team and maximum 10 percent of the basic annual salary to key personnel. Variable compensation may either be paid as salary or as a lump-sum pension premium. Payment as a lump-sum pension premium is subject to indexation so the total cost for Abliva is neutral.

### Variable remuneration with incentive to acquire Abliva shares (LTI program)

The LTI Bonus is a cash program in which the participants commit to use the cash paid out by the Company to acquire shares in the Company. The shares are acquired by the participants on the stock market. The long-term incentive program shall apply in addition to the annual variable remuneration according to the above.

The decision regarding the annual amount available as LTI Bonus is built into the yearly bonus appraisal process to link yearly achievements to long term goals, to build employee shareholding in Abliva, which creates incentatives to promote the Company's business strategy, long-term interests and sustainability, and to

retain employees. The amount of possible LTI Bonus will depend on the employee's position and the ability to influence the performance of Abliva.

The participants are required to use the full amount of the LTI Bonus, net after income tax to acquire Abliva shares on the stock market. The company will pay the social security costs.

The shares acquired for the LTI Bonus will be locked in for a period of 3 years after the acquisition. An employee who resigns, is terminated or otherwise leaves the Company will be obliged to hold the shares acquired within the LTI Bonus for the full period of 3 years after acquisition notwithstanding the termination of their employment. In the event an employee or former employee breaches the terms of the LTI Bonus program, such as for example by failing to provide information on the status of their shareholding or prematurely disposing of their shareholding they will be subject to contractual sanctions including a penalty equal to the full amount of the LTI Bonus (including income tax, but excluding social security contributions thereon).

The board shall decide on the amount of LTI Bonus. The maximum amount in the LTI Bonus is capped at an amount corresponding to 15 percent of the fixed annual compensation for the current year for the CEO, 10 percent to the management team and 5 percent to other key personnel:

#### General principles for STI and LTI

When determining variable remuneration to management payable in cash, the Board of Directors shall consider introducing restrictions that.

- disqualification from future LTI Bonus in relation to an individual who sells his/her shares during the three year qualification period,
- making payment of a predetermined portion of such remuneration conditional so the performance on which vesting is based is demonstrably sustainable over time, and
- offers the Company the opportunity to reclaim such remuneration paid on the basis of information that subsequently proves manifestly erroneous.

#### **INCENTIVE PROGRAMS/SHARE WARRANTS**

Stock option program 2021/2025

The AGM on May 20, 2021, decided on a four-year incentive stock option program 2021/2025 for the Company's CEO. For further information please see page 29 and Note 12 on page 53.

#### PROSPECTS FOR 2022

KL1333 - disease modifying treatment for primary mitochondrial diseases

- Regulatory approval in five countries
- Initiate the start of the FALCON study

NV354 - alternative energy source in primary mitochondrial disease

- Produce NV354 drug product for Phase 1 studies
- Assemble regulatory documentation to support Phase 1 study start

### PROPOSED ALLOCATION OF THE COMPANY'S UNAPPROPRIATED RETAINED EARNINGS

The following amounts in Swedish kronor (SEK) are at the disposal of the Annual General Meeting:

| Total                    | 40,478,625   |
|--------------------------|--------------|
| Profit/loss for the year | -123,072,362 |
| Accumulated profit/loss  | 93,016,663   |
| Share premium reserv     | 70,534,324   |

The Board of Directors proposes that unappropriated retained earnings of SEK 40,478,625 be carried forward. Accordingly, no dividend is proposed.

### **Financial information**

#### **REVENUE AND RESULTS OF OPERATIONS**

Consolidated sales 2021 amounts to SEK 151,000 (216,000) and are mainly revenues from research compunds sold by the partner Oroboros. During 2021 the Group had no other operating income, other operating income during 2020 related mainly to research grants from Vinnova for the project NV354, SEK 0,000 (1,648,000) relates mainly to research grants from Vinnova for the project NV354. Otherwise, the Company has not generated revenue.

Operating expenses amounted to SEK 123,633,000 (61,934,000). Other external costs 103,696,000 (46,072,000) have increased compared to the previous year due to start up activities in the KL1333 program and a milestone payment to Yungjin Pharmaceutical, Co., Ltd, of USD 2,000,000 related to the IND approval from the US FDA. Costs relating to pre-clinical and clinical phase development projects have affected earnings for the period by SEK -90,690,000 (-29,510,000), excluding personnel costs, of which 85,481,000 (22,817,000), relates to projects in clinical phase.

Personnel expenses 2021 amounts to SEK 16,844,000 (13,035,000) including notice period and severance pay to former CEO of SEK 2,881,000. Other operating expenses amount to SEK 330,000 (0,000) and pertains to exchange-rate losses. The consolidated operating profit/loss was SEK -60,071,000 (-77,074,000). Net financial income/expense was SEK -12,000 (77,000) and refers in 2021 to interest expenses , in 2020 this amount mainly related to result from other securities and receivables related to non current assets. The profit/loss for the period was SEK -123,498,000 (-59,994,000).

#### FINANCIAL POSITION AND GOING CONCERN

Consolidated total assets were SEK 58,918,000 (98,957,000) of which intangible assets were SEK 21,503,000 (22,315,000). The Board of Swedish Accounting Supervision examined the Company's interim report as of September 30, 2020 and the Annual report for 2020 regarding the accounting of capitalized development costs, and referred the case to Finansinspektionen (FI). In October FI announced that they would investigate whether Abliva AB complied with the regulations for accounting in its annual and consolidated accounts for 2020. More specifically, whether Abliva AB had violated

the provisions of Article 4 of the European Parliament and Council Regulation (EC) No 1606/2002 of 19 July 2002 on the application of international accounting standards, and the Annual Accounts Act (1995: 1554) regarding the accounting of development expenses as an intangible asset. As an adaptation to the The Board of Swedish Accounting Supervision's view on the handling of capitalized development costs (IAS 38), the Board has made a correction of Opening balances 1 January 2020 in Equity, in accordance with IAS 8 Accounting Policies, Changes in Accounting Estimates and Errors. As a result of the adjustment, FI dismissed the case. The total adjustment of SEK 51,706,000 refers to accumulated capitalized development costs related to the NeuroSTAT program processed up to and including 31 March 2017.

Cash and cash equivalents at year-end were SEK 22,339,000 (61,643,000). During Q1 2022, the company raised a convertible loan from its largest owner Hadean Ventures of SEK 26 million. The Convertible matures on December 20, 2022, to the extent conversion has not taken place before such date. Should the company embark on the phase 2/3 study (the most costly scenario), the capital need for the next twelve months is estimated at approximately SEK 120-150 million. When publishing the annual report 2021, there is a need for capital for the next 12 months and thus there is significant uncertainty for continued operations. The board has initiated a process to ensure adequate funding to enable execution of the company's strategy with the goal to start the registrational Phase 2/3 study for KL1333.

Equity at year-end was SEK 41,528,000 (88,656,000), and share capital was SEK 20,150,000 (14,817,000). The equity ratio was 70 percent (90) at the end of the period. Equity per share with no non-controlling interest was SEK -0.33 (-0.24). The group has no interest-bearing liabilities during 2021.

#### **CASH FLOW**

Consolidated cash flow for the year was SEK -39,372,000 (3,330,000), with cash flow negatively affected by operating activities of SEK 114,075,000 (67,558,000) and from investments, of SEK 1,089,000 (1,407,000). Cash flow from financing activities was SEK



CATHARINA JOHANSSON DEPUTY CEO AND CFO

"The support from our shareholders has been crucial to enabling all the preparatory activities in our clinical program and means that we are now well equipped for the start of our Phase 2/3 study FALCON"

75,792,000 (72,295,000) and was secured from the directed rights issue done in April and May 2021.

#### **INVESTMENTS**

Total fixed assets amounted to SEK 34,664,000 (35,800,000) as of 31 December 2021. The change, of SEK -1,136,000 (-1,067000) is due to the fact that depreciation has been higher than investments. Investments in tangibles, refers to computors, amounted to SEK 65,000 (0,000) in 2021.

#### PARENT COMPANY

During the year, the parent company had net sales of SEK 151,000 (216,000). In 2021, the parent company had no other operating income, SEK 0,000 (1,648,000). In 2020, other operating income mainly pertained to a research grant from Vinnova. Parent Company's Operating expenses amounts 123,233,000 (61,931,000). Interest expenses includes internally interest of SEK 0 (0). Cash and cash equivalents at year end were SEK 21,696,000 (61,634,000). Most of the Group's operations are conducted within the parent company. Accordingly, no further specific information regarding the parent company is presented.

### Five-year summary

| (SEK 000) | if nothing | else is s | pecified |
|-----------|------------|-----------|----------|
|-----------|------------|-----------|----------|

INICOME CTATEMENT

| INCOME STATEMENT              | 2021     | 2020    | 2019    | 2018    | 2017    |
|-------------------------------|----------|---------|---------|---------|---------|
| Net sales                     | 151      | 216     | 134     | 5       | 27      |
| Other operating income 1)     | -        | 1,648   | 3,500   | 2,461   | 248     |
| Operating expenses            | -123,633 | -61,935 | -80,709 | -75,826 | -71,363 |
| Depreciation and amortization | -2,764   | -2,558  | -2,379  | -4 771  | -1,595  |
| Operating income 1)           | -123,482 | -60,071 | -77,075 | -73,360 | -71,088 |
| Net financial income/expense  | -12      | 77      | 75      | -134    | -515    |
| Profit/loss before tax 1)     | -123,494 | -59,994 | -77,000 | -73,494 | -71,603 |
| Net profit for the year       | -123,498 | -59,994 | -77,000 | -73,494 | -71,603 |
|                               |          |         |         |         |         |

| BALANCE SHEET             | 2021   | 2020   | 2019    | 2018    | 2017    |
|---------------------------|--------|--------|---------|---------|---------|
| Intangible assets         | 21,503 | 22,315 | 74,686  | 73,440  | 74,315  |
| Tangible assets           | 60     | 384    | 786     | 140     | 162     |
| Other current assets      | 1,915  | 1,514  | 1,600   | 2,676   | 3,535   |
| Cash and cash equivalents | 22,339 | 61,643 | 58,319  | 25,951  | 28,992  |
| Assets                    | 58,918 | 98,957 | 148,492 | 115,308 | 120,106 |
| Equity                    | 41,528 | 88,656 | 127,795 | 97,012  | 105,846 |
| Short-term liabilities    | 17,390 | 10,209 | 20,336  | 18,296  | 14,260  |
| Equity and liabilities    | 58,918 | 98,957 | 148,492 | 115,308 | 120,106 |
|                           |        |        |         |         |         |

| CASH FLOW STATEMENT   | 2021     | 2020    | 2019    | 2018    | 2017    |
|---|----------|---------|---------|---------|---------|
| Cash flow from operating activities before changes in working capital | -120,326 | -57,436 | -74,620 | -68,256 | -58,260 |
| Changes in working capital  | 6,251    | -10,122 | 2,208   | 4,626   | 496     |
| Cash flow from investing activities                                   | -1,089   | -1,407  | -2,695  | -4,072  | -15,279 |
| Cash flow from financing activities                                   | 75,792   | 72,295  | 107,471 | 64,656  | 9,145   |
| Cash flow for the period  | -39,372  | 3,330   | 32,364  | -3,046  | -64,258 |
| Change in cash and cash equivalents                                   | -39,304  | 3,324   | 32,368  | -3,041  | -64,259 |
| Cash and cash equivalents at beginning of year                        | 61,643   | 58,319  | 25,951  | 28,992  | 93,251  |
| Cash and cash equivalents at end of year                              | 22,339   | 61,643  | 58,319  | 25,951  | 28,992  |

<sup>1)</sup> Abliva presents certain financial measures in the annual report that are not defined in accordance with IFRS, alternative key figures. For more information, see Definitions at the back of this report.



MAGNUS HANSSON CHIEF MEDICAL OFFICER

"KL1333 has made great strides forward, despite major challenges during the pandemic. Both human and financial resources have been focused on clinical development. During 2021, we completed several crucial preparatory studies with the patient's perspectives in focus. This means that we are well prepared for the next step – the FALCON efficacy study".

<sup>2)</sup> Correction of opening balances related to capitalized costs for product development in Equity has been implemented on comparative figures 2020-2021 in accordance with IAS 8. For further information, please see page 34 Capitalized costs for product development.

### **Risk factors**

Abliva, focused on the development of therapeutics for the treatment of primary mitochondrial diseases, faces the high operational and financial risks inherent in biotech drug development. Operational risks are high throughout all phases of development with possible discontinuation of a candidates' development due to lack of appropriate drug properties, safety, or efficacy. Although the probability of technical and regulatory success increases throughout development, the expenses also rise as large, global clinical studies must be run at the same time drug scale-up and production are done and a sales force is prepared - all of which are done at risk. Operations at Abliva have been conducted at a loss to date, and Abliva currently estimates commercialization of the latest-stage asset, KL1333, could occur in select markets no earlier than 2025. A review of the risks identified by the company and the measures taken to limit risk follows.

### RISKS SPECIFIC TO THE COMPANY BUSINESS AND OPERATIONAL RISKS

Preclinical and clinical development

In order to establish the data necessary to support marketing approval and commercialization of the products (and thus a revenue stream), safety and efficacy must be demonstrated in both preclinical and clinical studies and the data must be deemed sufficient by the regulators to support marketing approval. If Abliva cannot, through clinical studies, adequately demonstrate that a drug is safe and effective, the drug may be delayed or not approved, a result that would have a large impact on the Company's earning potential and revenue stream. During the year, Abliva successfully progressed two compounds in development. First, the Company completed a clinical phase 1a/b study testing KL1333 in primary mitochondrial diseases and actively prepared for the start of a registrational Phase 2/3 study for KL1333 with the intention to dose the first patient in 2022. In addition, the Company completed the preclinical development of NV354 with the aim of starting a Phase 1 clinical trial in 2022.

The progression of programs through development requires a large number of vendors, consultants, personnel and partners to ensure quality and standards across all aspects of the program. In many cases one activity depends on another, and timelines can quickly become altered if one part of the process is delayed. In addition, when the programs enter clinical development, site participation and engagement and patient recruitment become a critical factor in timeline prediction and an unrelated problem at the site can dramatically impact timelines. For this reason, delays often occur in drug development.

Abliva has processes and protocols in place to regularly evaluate the programs and the associated risk in an effort to minimize the impact of these risks.

#### Operational Impacts of COVID-19

COVID-19 continues to have the potential to disrupt many aspects of the companies' work including, for example, internal delays due to personal illness, delays to the clinical studies due to hospitals prioritizing COVID cases, delays due to the re-prioritization of activities at vendors, sites or healthcare authorities, and/or delays in financing or investor attention due to the impact of COVID on the market. There is a risk that the start of the upcoming Phase 2/3 study, which is expected to begin in 2022, will be further delayed due to Covid 19. The company's second drug candidate, NV354, which is being prepared for a phase I study in 2022, also risks being delayed due to the COVID-19 pandemic.

The company's ability to influence this risk is limited. The company follows the development of COVID-19 and the guidelines issued by the authorities and works to limit any potential negative effects.

#### Partners, out-licensing and manufacturing process

Abliva's lead asset, KL1333, has been in-licensed from the Korean pharmaceutical company Yungjin Pharm and this partnership is critical for the further development and commercialization of

KL1333. NV354 is a partnership with a research group at Lund University where collaborative partners are joint owners of the projects and are entitled to a share of future income. The contractual allocation of any future revenue from the projects is based on how much Abliva and each partner has invested in each project.

Abliva has ongoing cooperation with the British company Isomerase Therapeutics Ltd, which is one of Abliva's most important partners. The collaboration includes chemistry support for Abliva's early development projects, intellectual property support and intellectual partnership on strategic issues and business development opportunities. Furthermore, Abliva has collaborations with other vendors, academic groups and contract organizations (contract research organizations (CROs) or contract manufacturing organizations (CMOs)), who provide insights, guidance and operational support across the portfolio.

The company has been seeking a strategic partner for the continued development of NeuroSTAT. It has continued preliminary discussions with the TRACK-TBI network on a potential collaboration for a Phase 2 traumatic brain injury study with NeuroSTAT under the Precision Medicine project funded by the U.S. Department of Defense. The study, if authorized by US Department of Defence (DOD), would commence in 2022, contingent upon DOD's approval of earlier steps of the project. There is a risk that the TRACK-TBI network will not enter into a collaboration with NeuroSTAT and that Abliva will not find another appropriate partner within a reasonable time or that such a partner cannot be identified at all with delayed or non-development of NeuroSTAT as a result.

In addition to the partners described above, the Company will, in the future, depend on additional collaborations and partnerships (for general support of the portfolio, in connection with the out-licensing of drug candidates and/or in marketing and sales of medicines). On top of the opportunities available for traditional licensing, Abliva's management is continuously evaluating a variety of strategic

collaborations with major pharmaceutical companies and/or CRO partners. There is a risk that the Company's current and/or future business partners, suppliers and manufacturers will not fully meet the quality requirements set by the Company or otherwise fully meet its obligations to Abliva or that such agreements may not be concluded on terms favorable to the Company. If existing collaborations work unsatisfactorily or are terminated, the Company may be forced to seek out other partners, which may have a medium high impact on the Company's costs and/or take longer than the Company estimates. Such a scenario may have a high impact on the Company's ability to continue to develop the product candidates according to a fixed timetable, which may result in reduced or missing revenues and higher costs than expected.

Abliva strives to limit this risk through close and strategic partnerships.

#### Recruitment of healthy subjects and patients

Abliva intends to enter into agreements with several different providers of services for clinical trials at clinics and hospitals. An important element of these agreements is the provision of recruitment of healthy subjects and patients to the clinical trials. The extent of recruitment has a relatively large impact on the schedule for the clinical trials. Should such recruitment take longer than planned, this could cause the Company's clinical studies to be delayed and the development of the Company's drug candidates to become more costly than planned. In the event that one or more of these suppliers terminate the collaboration agreements and that these cannot be replaced by agreements with other suppliers, this could also lead to delays in the clinical trials and thus a delay in registration of the Company's drug candidates. Such a delay could in turn lead to additional costs as well as expected revenues being deferred in the future.

Abliva limits this risk through close collaboration with the clinicians and patient associations in the applicable countries. The studies have been designed to be both site- and patient-friendly to encourage active participation by all of the sites.

#### Maintenance of key personnel and qualified personnel

Abliva has built an organization of experienced drug development personnel to ensure the best possible conditions for the development of the Company's programs. However, Abliva is still a small organization and the Company's future growth is largely dependent on the knowledge, experience and commitment of the management and other key personnel. This group consists of four people working within the management group and four additional people supporting the management. The Company may fail to retain these personnel, requiring the recruitment of new qualified personnel in the future, causing a medium to high impact on the timeline and the Company's ability to commercialize any of the drug candidates. If any of the Company's key employees terminate their employment, this could cause delays or interruptions in Abliva's operations and continued development, which could have a high impact on the Company's future sales and earning capacity. In this context, it is especially important that the staff feel that Abliva is a professional employer promising stimulating work and growth opportunities.

To succeed in this, among other things, requirements will be set for professional board work, professional management, the fulfillment of forecasting development and that the Company applies market-based financial incentive systems. Abliva colleagues have a broad network to canvas should the need arise to hire new colleagues and good relationships with recruitment firms experienced in identifying and hiring top talent.

#### Patents and other intellectual property rights

The patent estate is the most valuable asset in any biotech company and the same is true at Abliva. There is a risk that existing and/ or future patent portfolios and other intellectual property rights held by the Company will not provide adequate commercial protection. If Abliva is forced to defend its patent rights against a competitor, this could entail significant costs and have an impact on Abliva's ability to further develop the projects according to plan. Furthermore, there is a risk that Abliva may infringe or allegedly infringe upon third-party patents or other intellectual property rights. Other parties' patents may also limit the possibility for one or more of the Company's future partners to freely use the affected drug or production method. The uncertainty associated with patent protec-

tion means that the outcome of such disputes is difficult to predict. Negative outcomes of intellectual property disputes could result in lost protection, a prohibition on continuing to use the current right or the obligation to pay damages. In addition, the cost of a dispute, even one where the outcome is in favor of Abliva, could be significant.

The above could present difficulties or delays in the commercialization of future medicines and thus also difficulties in generating revenue. The same also applies to other intellectual property rights, such as trademarks. Abliva is also to a certain extent dependent on know-how and corporate secrets, which are not protected by legislation in the same way as intellectual property rights. There is a risk that the Company will not be able to effectively protect its know-how and business secrets, which could be detrimental to Abliva and its continued development of the clinical projects.

To reduce the risk the Company continues to grow the patent portfolio, uses confidentiality agreements and limits the dissemination of confidential information and thus strives for far-reaching protection of sensitive information.

#### There is a risk of side effects and subsequent product liability

Of the two ongoing projects in PMD, only KL1333 has been tested in humans to date. There is a risk that healthy subjects or patients who either participate in clinical studies of Abliva's drug candidates or otherwise come into contact with Abliva's products could suffer from serious side effects. The consequences of such potential side effects may delay or stop the continued development of the product and/or limit or prevent the commercial use of the products. These impacts could lead to increased costs and thus have a medium to high impact on Abliva's earning capacity. There is also a risk that Abliva may be sued by healthy volunteers or patients suffering from side effects, whereby Abliva may be liable for damages. This would have a high impact on the Company's costs and limit possible future earning capacity. With every planned study, (WE NEED TO DISCUSS THIS) there will probably be limitations in the scope of insurance coverage and its amount limits. Therefore, there is a risk that the Company's insurance cover may not fully

cover any future legal requirements, which could have a high negative impact on the Company's costs.

Abliva strives to decrease the risk of side effects through comprehensive, well-designed preclinical and non-clinical experiments, strong rationale for dose selection in the clinical studies and evaluation of clinical strategies (such as split daily dosing) to improve tolerability.

#### INDUSTRY-RELATED RISKS

#### **COMPETITIVE LANDSCAPE**

Research and development of new drugs are highly competitive and are characterized by rapid technological development. The Company's competitors can be both large multinational companies and smaller research companies operating in areas where Abliva operates. Within the Company's main focus area, primary mitochondrial diseases (PMD), there is currently an approved competing drug, Raxone, developed by Santhera Pharmaceuticals. In addition, the Company is aware of a handful of drug development companies with clinical phase projects. If any of these competitors, or future competitors, succeed in developing and launching an effective and safe drug in the areas Abliva develops drugs within, this could have a high negative impact on Abliva's future sales potential and profitability.

Abliva is thus conducting innovative projects with so-called "first in class" drug candidates (which means that the projects will probably be complementary to competitors' strategies). Abliva's strategy is to seek Orphan Drug Designation (ODD) which limits competitors with the same mechanism of action in the same therapeutic area.

#### **FINANCIAL RISKS**

Future financing needs

Abliva has no commercialized products and hence revenue, however the Company continues to spend money to support the development of the portfolio. Drug product development is a capital-intensive activity and Abliva will continue to be dependent on receiving financing for the portfolio. Both the size and timing of the Company's future capital needs depends on a number of factors,

including the success of the programs, the ability of the company to enter into partnerships (research, devlopment or commercial) and the opportunity to identify distributor agreements. Local and global market conditions can impact the ability to raise capital, and the ongoing war in the Ukraine has caused unfavorable market conditions.

There is a risk that any additional capital may not be raised on favorable terms, or that such capital raised will not be sufficient to fund the Company"s development, or that such capital may not be raised at all. This may mean that the development is temporarily halted or that the Company is forced to run the business at a lower rate than desired, which could lead to delays or non-commercialization and thus, to a large extent, adversely affect the Company's future earning capacity. Abliva is thus dependent on the fact that future capital can be raised to the extent required. Possible delays in clinical trials may mean that cash flow is generated later than planned and thus have a medium to high negative impact on Abliva's costs and earning capacity.

Abliva is continuously interacting with investors, potential parters and well-networked industry leaders to identify new opportunities and identify backup plans.

#### **LEGAL AND REGULATORY RISKS**

Authorization and registration

In order to be able to market and sell drugs, permits must be obtained and registered with the relevant authority in each market, such as the Food and Drug Administration ("FDA") in the United States, the European Medicines Agency ("EMA") in Europe and the China Drug Administration ("CDA") in China. In the event that Abliva fails to obtain or maintain the necessary permits and registrations from authorities, the Company may be adversely affected in the form of reduced revenue. Comments on the Company's proposed plans for future studies may also lead to delays and/or increased costs for Abliva. The rules and interpretations that currently apply may also change in the future, which may affect the Company's ability to meet the requirements of different authorities. Permits and registrations may be withdrawn after the Company or its partners have received them, which would have a high negative impact

on the Company's future opportunities for commercialization and its earning capacity.

Abliva has a strategy of seeking regulatory input and guidance early and often in order to ensure incorporation of feedback in a timely manner and keep development programs on track.

#### Tax losses

As of December 31, 2021, the Group had recognized an accumulated loss of SEK 746,391,000. However, the Company has not recognized any value regarding these deficits in the balance sheet. The accumulated deficits may in the future reduce the Company's possible taxable profits and thus reduce the corporate tax that arises in the event of future profits. The tax effect of the accumulated deficits could then possibly be recognized in the balance sheet. The Company's ability to utilize fiscal deficits in the future may be limited or lost due to future changes in Swedish tax legislation or, as per current rules, as a result of changes in ownership. If the loss carryforwards cannot be used to reduce future profits, this would have a high negative impact on the Company's future tax costs

#### **RISKS RELATED TO THE SHARE**

#### SHARE PRICE DEVELOPMENT

Current and potential investors should realize that an investment in Abliva is associated with risk with potential for the share price to both rise and fall. This means that there is a risk that an investor may lose all or part of his invested capital. During the period January 1, 2021 through December 31, 2021, the Company's share price ranged from SEK 0.47 to SEK 0.98. The share price may fluctuate as a result of, amongst other things, communication by the Company pertaining to the advancement or delay in the portfolio, perception of the information contained in the Company's interim reports and the general stock market environment. Limited liquidity in the share can amplify such fluctuations in the share price. The share price may thus be affected by factors that are partially or completely outside the Company's control. An investment in shares in Abliva should therefore be preceded by a thorough analysis of the Company, its competitors and the outside world, general information about the industry, the general economic situation and other relevant information. There is a risk that Abliva shares may not be sold at a price acceptable to the shareholder at any time.

### Future new issues may dilute ownership interests and adversely affect the share price

Abliva is still in the early clinical development phase and has not yet generated any significant revenue. It is difficult to predict in advance when the Company may become profitable. To enable continued development of the Company's pharmaceutical project, Abliva needs additional funding. If additional financing is arranged through equity, further new issues of shares for current shareholders, unless they participate in such potential issues, will dilute their ownership interest in Abliva. Since the timing and terms for any future new issues will depend on Abliva's situation and market conditions at that time, the Company cannot anticipate or estimate the amount, timing or other conditions for such new issues. Depending on what the conditions look like for any further new issues, such issues may have a negative impact on Abliva's share price to a moderate extent.

#### Limited liquidity of the share and equity-related securities

During 2021, an average of approximately 1.6 million shares have been traded per day in Abliva, corresponding to an average daily turnover of approximately SEK 1.3 million. There is a risk that an efficient and liquid market for the Company's shares and equity-related securities will not develop, which may cause difficulties for a shareholder to change his or her holding of shares at the desired time and price.



### **Corporate Governance Report**

Abliva AB (publ) (Abliva or the Company) is a Swedish public limited company with corporate identity number 556595-6538. Abliva's registered office is in the Municipality of Lund and the Company is listed on Nasdaq Stockholm. This Corporate Governance Report has been prepared by Abliva's Board of Directors in compliance with the Annual Accounts Act and the Swedish Code of Corporate Governance (the Code). The Corporate Governance Report is part of the Statutory Administration Report and the Company's Auditors have conducted their statutory review of the Report

#### **ABLIVA GOVERNANCE**

Annual General Meeting

The Annual General Meeting is the chief decision-making body. The Annual General Meeting is planned and held to enable shareholders to exercise their influence over the Company optimally. Resolutions reached at the Annual General Meeting shall adhere to the Swedish Companies Act's regulations on majority requirement

#### Entitlement to participate at the Annual General Meeting

All shareholders listed in the share register maintained by Euroclear Sweden AB on the record date prior to the Annual General Meeting, and who have informed Abliva of their intention to attend by no later than the date indicated in the invitation to the Annual General Meeting, are entitled to participate in the Annual General Meeting and to vote according to the number of shares held

#### Initiatives from shareholders

Shareholders wishing to raise a matter at the Annual General Meeting must submit a written request to the Board of Directors by no later than seven weeks prior to the Annual General Meeting.

#### Nomination Committee

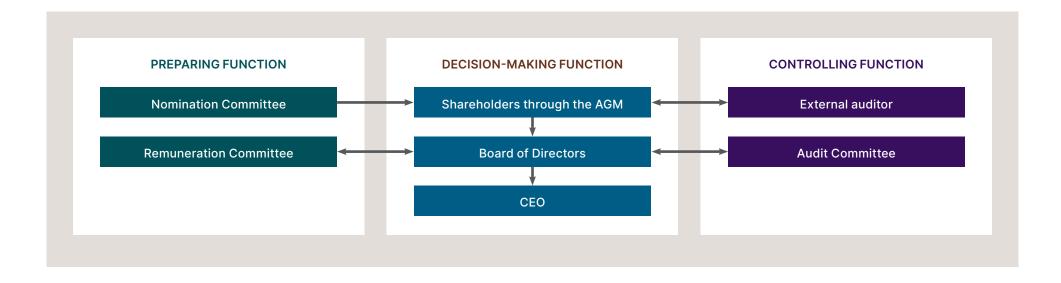
The Company shall have a Nomination Committee comprising one member of each the three largest shareholders in terms of voting rights based on ownership statistics maintained by Euroclear Sweden AB.

#### The Board of Directors

The Board of Directors shall have a minimum of three and a maximum of eight members. Board members are appointed annually by the Annual General Meeting and are elected for a period until the end of the next Annual General Meeting.

#### Chair of the Board

The Annual General Meeting appoints the Chair. The Chair leads the Board's work, monitors the work and assumes responsibility for the Board completing its duties according to applicable legislation, the Articles of Association, the Swedish Code of Corporate Governance and the Board of Director's rules of procedure. The Chair shall monitor the Company's progress through contact with the CEO, consult with the CEO on strategic matters and ensure that strategic considerations are recorded and addressed by the Board of Directors



#### The Board of Directors' duties and responsibilities

The Board of Directors is the highest administrative body at the Annual General Meeting. The Board of Directors' primary duty is to manage overall and long-term issues and matters of major significance to the Company. The Board of Directors assumes overall responsibility for the Company's operations and management and for ensuring that the accounting and fund management are controlled satisfactorily. The Board of Directors is responsible for ensuring that the Company follows applicable legislation, stipulations and the Swedish Code of Corporate Governance and that the Company is subject to satisfactory internal control procedures and formalized routines that safeguard adherence to set principles for financial reporting and internal control.

#### Remuneration Committee

To assist the Board in salaries and remuneration issues, the Board has established a Remuneration Committee which shall consist of at least three Board members. The Remuneration Committee shall assist the Board in matters of salary and remuneration on issues relating to salary and remuneration. The Remuneration Committee's duties include:

- consulting on the Board of Director's decisions on matters relating to remuneration principles, remuneration and other terms of employment of management,
- monitoring and evaluating ongoing and concluded (during the year) programs for variable remuneration for the corporate management, and
- monitoring and evaluating the application of guidelines for remuneration to senior executives that the Annual General Meeting is legally obliged to resolve on, and applicable remuneration structures and remuneration levels in the Company.

#### **Audit Committee**

The members of the Audit Committee are appointed by the Company's Board of Directors at the Board meeting following election and shall consist of a minimum of three Board members. The Audit Committee shall contribute to sound financial reporting that maintains market confidence in the Company by specifically monitoring and controlling the Company's accounting principles, financial administration, risk management and the structure of internal

control, resources, ongoing work and annual reporting. The Audit Committee also reviews the Auditor's non-affiliation to the Company.

#### CEO

The CEO is appointed by the Board of Directors. The CEO's work follows the written instructions adopted annually by the Board of Directors at the Board meeting following election.

The instructions for the CEO regulates customary areas such as the CEO's undertaking in relation to the Company and the Board of Directors, including responsibility for presenting expedient reports to the Board of Directors relevant to the Board's completion of its evaluation of the Company.

The CEO shall ensure that ongoing planning, including business plans and budgets, is completed and presented to the Board of Directors for resolution.

When departure from these plans and special events of a significant nature are feared, the CEO must inform the Board of Directors through the Chair immediately.

### APPLICATION OF AND DEPARTURE FROM THE SWEDISH CODE OF CORPORATE GOVERNANCE

The Code applies to all Swedish companies whose shares are listed on a regulated marketplace in Sweden and shall be applied fully at the first Annual General Meeting held following initial public offering. The Company is not obliged to adhere to all the regulations of the Code, and is free to adopt alternative solutions deemed more suitable to its circumstances, provided that potential departures are reported, the alternative solution described and the reasons explained (Comply or Explain principle) in the Corporate Governance Report

Abliva has applied the Swedish Code of Corporate Governance since 8 June 2012, and this Corporate Governance Report has been prepared in accordance with the Code.

#### ORGANIZATION OF CORPORATE GOVERNANCE

Abliva's internal controls and corporate governance are ased on applicable legislation/regulations and on sector-specific param-

eters considered significant to the Company. The control system encompasses all applicable regulatory frameworks as well as the specific demands Abliva places on its operations.

The internal control and corporate governance tool provides overall control of all critical stages relating to the Company. This provides Abliva's Board of Directors and management with the conditions required to control and govern operations in order to satisfy the stringent demands of the Company, the market, the stock market, the shareholders and the authorities.

The following legislation/regulations as well as the Company's own constitutional documents form the basis of Abliva's corporate governance:

#### **External Regulations**

- The Swedish Companies Act,
- Applicable accounting legislation,
- IFRS,
- The Swedish Code of Corporate Governance,
- Nasdag Stockholm's regulatory framework for issuers.

#### Internal constitutional documents

- The Articles of Association,
- Instructions and rules of procedure for the Board of Directors,
   Committees and CEO.
- Guidelines for remuneration to senior executives,
- Information and communication policy,
- Ethical guidelines,
- Financial administration guidelines.

#### **OWNER STRUCTURE**

Abliva had some 13,196 registered shareholders as of 30 December 2021. According to EuroClear Sweden AB, Hadean Capital I AS was the largest owner with a holding of 41,277,533 shares, corresponding to some 10.24 percent of the shares and votes. Avanza Pension Försäkring AB was the second largest shareholder with 24,850,736 shares, corresponding to some 6.17 percent of the shares and votes. The third largest shareholder according to Euro-Clear register was John Fällström holding 22,001,856 shares, corresponding some 5.46 percent of the shares and votes.



Hadean Ventures, which manages Hadean Capital I AS and Hventures Capital I AB, are the largest individual shareholders in Abliva with a total holding of 14.89 percent. John Fällström is Abliva's second largest individual owner with a total holding of 5.46 percent. Rothesay Ltd is the third largest individual owner with a total holding of 4.97 percent. There were no shareholders with a holding of more than one-fith of the total number of shares and votes in the Company at year-end.

#### SHARE CAPITAL AND VOTING RIGHTS

Abliva's share capital totaled SEK 20,150,339.90 divided between 403,006,798 shares as of 30 December 2021. There is only a single share class. All shares have a quotient value of SEK 0.05 and one vote, and confer equal entitlement to the Company's assets and profits. Abliva's Articles of Association have no limitations regarding the number of votes each shareholder may cast at the Annual General Meeting.

#### **ANNUAL GENERAL MEETING**

The Annual General Meeting is the chief decision-making body in a limited company and the shareholders exercise their decision-making rights at the Annual General Meeting. The Annual General Meeting is planned and held to enable shareholders to exercise their influence over the Company optimally. The invitation to the Annual General Meeting and other information provided is designed to allow shareholders to reach well-founded decisions on the issues addressed at the Annual General Meeting. Resolutions reached at the Annual General Meeting shall adhere to the Swedish Companies Act's regulations on majority requirement. In accordance with the Articles of Association, the invitation to the Annual General Meeting and Extraordinary General Meetings are published in Post- och Inrikes Tidningar and on the Company's website. An announcement that a Meeting has been convened is published in Swedish daily newspaper Svenska Dagbladet.

#### Entitlement to participate at the Annual General Meeting

All shareholders listed in the share register maintained by Euroclear Sweden AB on the record date prior to the Annual General Meeting, and who have informed Abliva of their intention to attend by no later than the date indicated in the invitation to the Annual General Meeting, are entitled to participate in the Annual General Meeting and to vote according to the number of shares held.

#### Initiatives from shareholders

Shareholders wishing to raise a matter at the Annual General Meeting must submit a written request to the Board of Directors by no later than seven weeks prior to the Annual General Meeting. Given the Company's ownership structure and financial circumstances, Abliva does not consider simultaneous interpretation into other languages and translation of all of or part of the documentation relating to the Annual General Meeting as justified. Abliva's website contains information on the Company's previous Annual General Meetings as well as information on shareholders' rights to raise matters at the Annual General Meeting and the cut-off date for Abliva receiving such requests.

#### SHAREHOLDERS' MEETINGS

#### Extraordinary General Meeting

The EGM was held on 29 April 2021, by voting in advance, so called, postal voting, in accordance with Section 22 of the Act (2020:198) on temporary exceptions to facilitate the execution of general meetings in companies and other associations. 12 shareholders attended the Annual General Meeting, in person or through representatives. These shareholders represented 4.0 percent of the shares and votes of Abliva.

The EGM 2021 adopted the following resolutions:

 Resolution to issue shares with diviation from the shareholders' preferential rights.

#### Annual General Meeting 2021

The Annual General Meeting was held on 27 April 2021, by voting in advance so called, postal voting, in accordance with Section 22 of the Act (2020:198) on temporary exceptions to facilitate the execution of general meetings in companies and other associations. 16 shareholders attended the Annual General Meeting, in person or through representatives. These shareholders represented 17.1 percent of the shares and votes of Abliva.

The Annual General Meeting 2021 adopted the following resolutions:

 Adopted the Balance Sheet and Income Statement and Consolidated Balance Sheet and Income Statement.

- Approval of the Board of Directors' Remuneration Report for 2020
- Resolution regarding discharging the Board of Directors and CEO from liability,
- Resolution regarding remuneration to the Board of Directors, Auditors and Committee members,
- Elected the Board of Directors and Auditor.
- Adopted guidelines for the Nomination Committee,
- Adopted a resolution to sanction the Board of Directors to authorize further new issues, warrants and/or convertibles,
- Resolution on amendment of company name

Documentation relating to the Annual General Meeting, such as invitations to meetings, minutes and the basis of decisions, is at Abliva's website, www.abliva.com

#### Annual General Meeting 2022

Abliva's Annual General Meeting 2021 will be held on 20 May 2021, at 1 pm. at Medicon Village, Scheeletorget 1, in Lund, Sweden. Shareholders wishing to attend the Annual General Meeting must notify the Company in advance. Information on how to apply and how to raise a matter at the Annual General Meeting is on the Company's website. Information about the date and place of the Annual General Meeting was uploaded to the company's website 25 October, 2021.

#### Nomination Committee

The Company shall have a Nomination Committee comprising one member of each of the three largest shareholders in terms of voting rights based on ownership statistics maintained by Euroclear Sweden AB. If a shareholder does not exercise its right to appoint a member, entitlement to appoint a member of the Nomination Committee shall transfer to that member who is the second largest shareholder in terms of voting rights. The Chair of the Board convenes the meetings and can be co-opted to the Nomination Committee when required. Neither the CEO nor any other member of management is permitted to be members of the Nomination Committee, nor shall Board members be a majority of the Nomination Committee members. A majority of the Nomination Committee's members shall be non-affiliated to the Company and management, if more than one Board member is included in the Nomination Committee, a maximum of one can be affiliated to the Company's major shareholders. A minimum of one of the Nomination Committee's



members shall be non-affiliated to the Company's largest shareholder or group of shareholders collaborating on the Company's administration. No remuneration is payable to any of the members of the Nomination Committee.

The Nomination Committee initiates the appraisal of the incumbent Board of Directors once it has been completed. The Committee's work shall feature openness and discussion, in order to ensure a well-balanced Board of Directors. The Nomination Committee then nominates members to Abliva's Board of Directors for the coming period of office, who are subsequently proposed to the Annual General Meeting. The Nomination Committee's duty is to propose the Chair of the Annual General Meeting, the Chair of the Board and Board members, the number of Board members, remuneration to Board members and Committee members as well as the election of, and remuneration to, the Auditors. The Nomination Committee also has the duty of proposing guidelines for appointing members of the Nomination Committee and the assignments of the Nomination Committee.

The composition of the Nomination Committee for the Annual General Meeting 2022 was announced at the company's website 25 October, 2021. The Nomination Committee for the Annual General Meeting 2021 consists of the following members, Florian Eckhard (Chair) appointed by Hadean Ventures, Kristina Ingvar, appointed by John Fällström and Andreas Inghammar, appointed by Rothesay Ltd.

#### THE BOARD OF DIRECTORS

#### Composition of the Board of Directors

Abliva's Annual General Meeting on 20 May 2021 re-elected board members David Laskow-Pooley, David Bejker, Roger Franklin, Denise Goode and Jan Törnell. David Laskow-Pooley was re-elected Chair of the Board. None of the Board members are members of the Company's management. The Board members' non-affiliation to the Company, the Company's management and the Company's major shareholders are indicated in the table below.

#### Chair

The Annual General Meeting appoints the Chair. The Chair represents the Board of Directors externally and internally. The Chair leads the Board's work, monitors the work and assumes respon-

sibility for the Board completing its duties according to applicable legislation, the Articles of Association, the Swedish Code of Corporate Governance and the Board of Director's rules of procedure.

The Chair shall monitor the Company's progress through contact with the CEO, consult with the CEO on strategic matters and ensure that strategic considerations are recorded and addressed by the Board of Directors. The Chair shall also ensure that the Board of Directors, through the CEO's agency, receives information on the Company on an ongoing basis in order to enable analysis of the Company's position.

#### The Board of Directors' duties and responsibilities

The Board of Directors is the highest administrative body under the Annual General Meeting. The work of Abliva's Board of Directors is regulated by applicable legislation and recommendations, and by the Board of Directors' rules of procedure, which are adopted annually. The rules of procedure contain stipulations regulating the division of responsibilities between the Board of Directors and the CEO, financial reporting and audit matters. At the Board meeting following election, the Board of Directors adopts other requisite rules of procedure, policies and guidelines that form the basis for the Company's internal regulatory framework.

The Board of Directors' primary duty is to manage overall and long-term issues and matters of major significance to the Company. The Board of Directors assumes overall responsibility for the Company's operations and management and for ensuring that the accounting and fund management are controlled satisfactorily. The Board of Directors is responsible for ensuring that the Company follows applicable legislation, stipulations and the Swedish Code of Corporate Governance and that the Company is subject to satisfactory internal control procedures and formalized routines that safeguard adherence to set principles for financial reporting and internal control, and that the Company's financial reporting is prepared in accordance with statutory requirements, applicable accounting standards and other demands placed on listed companies.

According to the Board of Directors' rules of procedure, the Board of Directors normally meets on seven occasions annually, including the Board meeting following election. The Board of Directors held



#### **BOARD WORK 2021**

January. Appointment of new CEO.
February. Funding. Year-End Report, Audit matters, determining salary and remunerations matters including variable remuneration, the Board of Directors discussion with the company's Auditor without the CEO or other members of Management being present.

March. Resolution on allocation of new shares in directed rigts issue. Resolution on subscription price and allotment of shares in rights issue.

April. Resolution on allocation of new shares in

April. Resolution on allocation of new shares in directed rigts issue. Audit matters, Annual Report, AGM and Corporate Governance Report, evaluation of variable remuneration, prospectus.

May. Review and authorization of Q1 Interim Report. Annual General Meeting. Corporate Governance Policy, Rules of Procedure for the Board of Directors, Rules of Procedure for the Audit and Remuneration Committees and instructions for the CEO. Appointing members of Board Committees. Determining other policies and guidelines.

**June.** Resolution on allotment in stock option program for the Companys CEO.

**July.** Follow up on the company's strategy. **August.** Review and authorization of Q2 Interim

October. Review of Corporate Governance, follow up business objectives and strategies, funding. November. Review and authorization of Q3 Interman Report, financing matters, matters relating to Year-end Report, budget, audit matters, evaluating the Board of Directors' and senior executives'

work in the year. **December.** Resolution on a directed issue of convertibles.

22 meetings during the year. Regular Board meetings covered matters such as reviewing and adopting financial reports, the business plan, budget and funding as well as strategic issues. The Board of Directors also monitors the progress of the Company's current pharmaceutical projects and financial situation continuously. The final ordinary Board meeting of the year included an appraisal of the Board of Directors and the work of the Board. Additional meetings during the year dealt with matters such as decision on new share issues, financing strategy and allocation of shares under the new issues.

The Board members' non-affiliation and attendance are indicated in the table above. For a presentation of Board members, see page 31 of the Annual Report.

#### Evaluation of the Board of Directors' work.

Board members have completed an evaluation document produced specifically to perform a structured evaluation of the Board's work in accordance with the guidelines in the Swedish Code of Corporate Governance. The evaluation has been presented by the Chairman to the Board of Directors at a regular Board meeting.

#### Evaluation of the CEO

The Board of Directors went jointly through the evaluation document produced specifically to perform a structured evaluation in with accordance with the guidelines in the Swedish Code of Corporate Governance regarding evaluating the CEO's work. The evaluation has been presented by the Chairman to the Board of Directors at a regular Board meeting.

#### **REMUNERATION COMMITTEE**

The Board of Directors has established a Remuneration Committee to assist the Board on issues relating to salary and remuneration. The Remuneration Committee's duties include:

- Consulting on the Board of Director's decisions on matters relating to remuneration principles, remuneration and other terms of employment of management,
- monitoring and evaluating ongoing and concluded (during the year) programs for variable remuneration for the corporate management, and

| Board member               | Elected in | Board of Directors (attendence) | Audit committee (attendence) | Remunerations-<br>committee (attendence) | Non<br>affiliated <sup>1</sup> |
|----------------------------|------------|---------------------------------|------------------------------|--|--------------------------------|
| David Laskow-Pooley, Chair | 2016       | 22/22                           |                              | Chair (5/5)                              | Yes                            |
| David Bejker               | 2017       | 22/22                           | Chair (6/6)                  |  | Yes                            |
| Roger Franklin             | 2020       | 19/22                           |                              |  | No                             |
| Denise Goode               | 2018       | 22/22                           | Member (6/6)                 | Member (5/5)                             | Yes                            |
| Jan Törnell                | 2017       | 20/22                           | Member (6/6)                 | Member (5/5)                             | Yes                            |

<sup>&</sup>lt;sup>1</sup> According to the definition in the Swedish Code of Corporate Governance

 monitoring and evaluating the application of guidelines for remuneration to senior executives that the Annual General Meeting is legally obliged to resolve on, and applicable remuneration structures and remuneration levels in the Company.

After consultation within the Remuneration Committee, the Board of Directors takes decisions on remuneration. As a sub-committee of the Board of Directors, the Remuneration Committee has limited decision-making powers. The Committee's Rules of Procedure are determined annually by the Board of Directors at the statutory Board meeting, and indicate the tasks and decision-making powers delegated by the Board to the Committee, and the methods for reporting back to the Board of Directors.

The Remuneration Committee presents ongoing reports on its work to the Board of Directors at regular Board meetings, and presents an annual report on the members' attendance at Committee meetings to the Board of Directors.

Abliva's Remuneration Committee is appointed by the Company's Board of Directors at the Board meeting following election and comprises Denise Goode (Chairman), David Laskow-Pooley and Jan Törnell.

#### **AUDIT COMMITTEE**

The members of the Audit Committee are appointed by the Company's Board of Directors at the Board meeting following election and shall consist of a minimum of three Board members. The Board of Directors appoints the Chair of the Audit Committee, who may not be the Chair of the Board. A majority of the Committee's members shall be non-affiliated to the Company and management. At least one member who is non-affiliated to the Company and .management shall also be non-affiliated to the Company's major shareholders.

The Audit Committee has been established to facilitate the Board of Directors' supervisory responsibility. As a subcommittee of the Board of Directors, the Audit Committee has limited decision-making powers. The Committee's rules of procedure are adopted annually at the Board meeting following election and indicate the decision-making powers the Board of Directors has delegated to the Committee and the manner in which the Committee shall report to the Board of Directors. The Audit Committee reports its work to the Board of Directors on an ongoing basis at regular meetings and also reports its work and members' attendance at Audit Committee meetings to the Board of Directors once annually.

The Audit Committee shall contribute to sound financial reporting that maintains market confidence in the Company by specifi-



cally monitoring and controlling the Company's accounting principles, financial administration, risk management and the structure of internal control, resources, ongoing work and annual reporting. The Audit Committee also reviews the Auditor's non-affiliation to the Company.

The Committee shall consult on matters relating to the choice of Auditor and remuneration to external Auditors, and maintain close contact with the Nomination Committee for its proposals to the Annual General Meeting relating to election of Auditors and determining the Audit fee. The Audit Committee's contact with the Nomination Committee is handled and maintained by the Chair of the Audit Committee.

Abliva's Audit Committee is appointed at the Board meeting following election and comprises David Bejker (Chair), Denise Goode and Jan Törnell for the current period.

#### **CEO AND OTHER SENIOR EXECUTIVES**

The CEO is appointed by the Board of Directors. The CEO's work follows the written instructions adopted annually by the Board of Directors at the Board meeting following election.

The instructions for the CEO regulates customary areas such as the CEO's undertaking in relation to the Company and the Board of Directors, including responsibility for presenting expedient reports to the Board of Directors relevant to the Board's completion of its evaluation of the Company. The CEO shall ensure that ongoing planning, including business plans and budgets, is completed and presented to the Board of Directors for resolution. The CEO shall exercise good leadership in the management of operations to ensure that the Company progresses according to plan and follows the strategies and policies adopted. When departure from these plans and special events of a significant nature are feared, the CEO must inform the Board of Directors through the Chair immediately. The CEO shall ensure that the Company's operations, including its administration, are organized so that they satisfy market requirements, and shall ensure efficient and secure organizational control of operations.

Within the framework of the directives provided by the Board of Directors for the Company's operations, management deals with

consultation regarding, and monitoring of, strategies and budgets, the distribution of resources, the monitoring of operations and preparation for Board meetings.

In the period January 2021 the members of management were CEO Erik Kinnman, Catharina Johansson, Eskil Elmér and Magnus Hansson. In the period February to December 2021 the members of management were CEO Ellen Donnelly, Catharina Johansson, Eskil Elmér and Magnus Hansson. Management meets every two weeks and minutes are taken at all meetings.

### REMUNERATION TO THE BOARD OF DIRECTORS AND SENIOR EXECUTIVES

Remuneration to Board members

The Annual General Meeting 2021 resolved that fees of SEK 400,000 should be paid to the Chair and SEK 250,000 to each of the remaining Board members.

The Annual General Meeting 2021 resolved on remuneration of SEK 100,000 to the Chair of the Audit Committee and SEK 50,000 to each of the remaining members of the Audit Committee. Furthermore, a resolution was made regarding remuneration of SEK 40,000 to the Chair of the Remuneration Committee and SEK 20,000 to each of the remaining members of the Remuneration Committee.

#### Remuneration to senior executives

Following a proposal from the Board of Directors, the Annual General Meeting 2020 reached a resolution regarding guidelines for remuneration to senior executives. The guidelines adopted in 2020 apply until further notice.

The guidelines for remuneration and other terms of employment applying to management mainly imply that the Company shall offer its senior executives remuneration on market terms, that this remuneration shall be determined by a dedicated Remuneration Committee governed by the Board of Directors, and that the criteria for remuneration shall be based on the responsibilities, role, competence and position of the relevant senior executive. Remuneration to senior executives is decided by the Board of Directors, excluding any Board members affiliated to the Company and management. The guidelines shall apply to new agreements, or revisions

to existing agreements reached with senior. executives after the guidelines were determined, and until new or revised guidelines have become effective

Senior executives shall be offered fixed compensation on market terms and based on the managers' responsibilities, role, competencies and position. Fixed compensation shall be reviewed annually.

From time to time, senior executives and other key individuals may be offered variable remuneration. Such variable remuneration shall be on market terms and shall be based on the outcome of predetermined financial and operational targets. Variable remuneration shall be based on the fulfilment of Abliva's targets for project results and value growth divided in personal targets for the financial year. The terms and conditions and basis of computation of variable remuneration shall be determined for each financial year. The targets promotes the Company's business strategy, long-term interests and sustainability by linking the remuneration to senior executives to the Company's project- and growth development.

The measurement period for variable remuneration is generally based on performance over a period of approximately 12 months. To which extent the criteria for awarding variable cash remuneration has been satisfied shall be evaluated/determined when the measurement period has ended. At the annual review, the Remuneration Committee, or when applicable, the Board of Directors, may adjust the targets and/or the remuneration with regards to both positive and negative extraordinary events, reorganisations and structurual changes.

The basic principle is that the annual variable portion of pay may be a maximum of 30 percent of basic annual salary to the CEO, maximum 20 percent of the basic annual salary to the management team and maximum 10 percent of the basic annual salary to key personnel. Variable compensation may either be paid as salary or as a lump-sum pension premium. Payment as a lump-sum pension premium is subject to indexation so the total cost for Abliva is neutral.

In order to incentivize senior executives and other key individuals on a longer term and to encourage investment in Abliva shares, a



cash bonus share savings opportunity has been implemented (the "LTI Bonus"). The LTI Bonus is a cash program in which the participants commit to use the cash paid out by the Company to acquire shares in the Company. The shares are acquired by the participants on the stock market. The LTI applies in addition to the STI Bonus.

The decision regarding the annual amount available as LTI Bonus is built into the yearly bonus appraisal process to link yearly achievements to long term goals, to build employee shareholding in Abliva, which creates incentatives to promote the Company's business strategy, long-term interests and sustainability, and to retain employees. The amount of possible LTI Bonus will depend on the employee's position and the ability to influence the performance of Abliva.

The participants are required to use the full amount of the LTI Bonus, net after income tax to acquire Abliva shares on the stock market. The company will pay the social security costs.

The shares acquired for the LTI Bonus will be locked in for a period of 3 years after the acquisition. An employee who resigns, is terminated or otherwise leaves the Company will be obliged to hold the shares acquired within the LTI Bonus for the full period of 3 years after acquisition notwithstanding the termination of their employment. In the event an employee or former employee breaches the terms of the LTI Bonus program, such as for example by failing to provide information on the status of their shareholding or prematurely disposing of their shareholding they will be subject to contractual sanctions including a penalty equal to the full amount of the LTI Bonus (including income tax, but excluding social security contributions thereon).

The board shall decide on the amount of LTI Bonus. The maximum amount in the LTI Bonus is capped at an amount corresponding to 15 percent of the fixed annual compensation for the current year for the CEO, 10 percent to the management team and 5 percent to other key personnel:

When determining variable remuneration to management payable in cash, the Board of Directors shall consider introducing restrictions that.

- disqualification from future LTI Bonus in relation to an individual who sells his/her shares during the three year qualification period,
- making payment of a predetermined portion of such remuneration conditional so the performance on which vesting is based is demonstrably sustainable over time, and
- offers the Company the opportunity to reclaim such remuneration paid on the basis of information that subsequently proves manifestly erroneous.

Senior executives are entitled to pension solutions on market terms in accordance with collective agreements and/or with Abliva. All pension commitments shall be premium-based. Salary differentials can be utilized to increase pension provisions through lump-sum pension premiums, provided that the total cost to Abliva remains neutral.

From Abliva's side, the maximum notice period shall be six months for the CEO and a maximum of six months for other senior executives. The notice period from the CEO's side shall be a minimum of six months, and from other senior executives' side, shall be a minimum of three months. In addition to this notice period, severance pay subject to a maximum of six months' salary plus benefits may be payable to the CEO.

The Board of Directors may temporarily resolve to derogate from the above Guidelines, in whole or in part, if in a specific case there is special cause motivating the derogation and a derogation is necessary to serve the Company's long-term interests, including its sustainability, or to ensure the Company's financial viability. As set out above, the Remuneration Committee's tasks include preparing the Board of Directors' resolutions in remuneration-related matters. This includes any resolutions to derogate from the Guidelines.

#### SHARE-BASED INCENTIVE PROGRAM

The Annual General Meeting 2021, decided on a four-year incentive stock option program 2021/2025 for the Company's CEO. The incentive stock option program entitles the holder to a new ordinary share in Abliva AB up to a maximum of 4,600,000 ordinary shares. The redemption price amounts to 0.725 öre. The program is vested at 25% per year on June 1, 2022, June 1, 2023, June 1, 2024 and June 1, 2025. Latest redemption date is December 31, 2025.

#### **AUDITORS**

The Auditors shall examine the Company's annual accounts and accounting records, and the Board of Directors' and CEO's administration. The Auditors shall present an Audit Report and a Consolidated Audit Report to the Annual General Meeting at the end of each financial year. The Company's Auditors shall be appointed for a at the Annual General Meeting. The Annual General Meeting 2021 elected Ernst & Young Revisionsbyrå AB as the Company's Auditors until the 2022 Annual General Meeting. Ola Larsmon is Auditor in Charge. In order to ensure that the standards applying to the Board of Directors relating to information and control are satisfied, the Auditors regularly report to the Audit Committee on accounting matters and potential misstatements or suspected improprieties. In addition, the Auditors attend most of the Audit Committee's meetings and Board meetings as required. At least once a year, the Auditors present a report to the Board of Directors without the CEO or other members of the Company's operational management attending.

#### Remuneration to the Auditors

The Annual General Meeting 2021 resolved on remuneration to the Auditors on the basis of approved account and customary debiting practice. Audit assignments are defined as reviewing the annual accounts and accounting records, as well as the Board of Directors' and CEO's administration, any other duties incumbent on the Company's Auditor and consultancy or other assistance arising from observations made in connection with such review or performance of other such duties. During control activities in the year, the Audit Committee concluded that the Auditors are non-affiliated to the Company. Information on Audit fees is in Note 9 on page 50. The Interim Report for the period January-September 2021 has been subject to a summary review by the Auditor.

### PERSONS DISCHARGING MANAGERIAL RESPONSIBILITIES

Persons discharging managerial responsibilities are defined as members of the Board of Directors and management. All these persons has regular access to inside information and the authority to make managerial decisions affecting the future development and business prospects. Such individuals are obliged to notify any changes in their holdings of financial instruments in Abliva in accor-



dance with The Act concerning Reporting Obligations for certain Holdings of Financial Instruments.

Listed companies are required to keep electronic insider list, log-book. The obligation comprises of keeping a logbook of all events where people have access to insider information (eventdriven logbook). This can include persons discharging managerial responsibilities, but also other individuals with access to insider information without being a person discharging managerial responsibilities. Abliva keeps a logbook for each event where the information could affect the share price.

#### INTERNAL CONTROLS OVER FINANCIAL REPORTING

The overall aim of internal controls is to ensure, to a reasonable extent, that the Company's operational strategies and targets are monitored and that the owners' investments are protected. Internal controls should also secure reasonable assurance that external financial reporting is accurate and has been prepared in accordance with generally accepted accounting practice, that applicable legislation and stipulations are followed and that requirements made on listed companies are satisfied. The internal control environment mainly comprises the following five components: control environment, risk assessment, control activities, information and communication and follow-up.

#### Control environment

Abliva's control environment includes its organizational structure, decision-paths, responsibilities and authorizations, which are clearly defined in a number of constitutional documents. The constitutional documents have been adopted by the Board of Directors to ensure an effective control environment.

The Company's control environment consists of collaborative initiatives between the Board of Directors, the Audit Committees, the CEO, the CFO, internally appointed staff and the Company's Auditor. Control is also exercised through the reporting procedures adopted in the Company's finance manual, including financial reporting to the Board of Directors, and a yearly report to the Board of Directors on completed internal control procedures.

The Audit Committee has overall responsibility for ensuring that the internal control regarding financial reporting and reporting to the Board of Directors is effective. The Audit Committee performs quarterly reconciliation with the company's CEO and Auditor. In addition, the documentation produced for Management's evaluation of the company's internal control is reviewed and evaluated annually.

#### Risk assessment

Risks assessment includes identifying risks that may arise if the fundamental standards of financial reporting in the group are not satisfied. A review takes place to ensure that the Company has an infrastructure that enables effective and expedient control, and an assessment of the Company's financial position and significant financial, legal and operational risks. The company identifies and evaluates the risks on a regularly basis, that may arise, in a risk assessment model

Pharmaceuticals development is associated with risks and is a capital-intensive process. The risk factors judged to be of particular significance to Abliva's future progress are the outcome of clinical studies, measures taken by regulatory authorities, competition and pricing, collaboration partners, liability risk, patents, key staff and future capital requirement.

#### Control environment

Control activities limit identified risks and ensure accurate and reliable financial reporting. The Audit Committee and the Board of Directors are responsible for the internal control and monitoring of management. This is achieved through internal and external control activities and by reviewing the Company's constitutional documents governing risk management. The results of internal controls are compiled and a report presented to the Board of Directors and the Audit Committee annually.

#### Information and communication

The Company has information and communication paths intended to promote the accuracy of financial reporting and ensure reporting and feedback from operations to the Board of Directors and management, through means including constitutional documents such as internal policies, guidelines and instructions relating to financial reporting being made available and presented to the relevant staff.

#### Monitoring

Abliva monitors the observance of the Company's constitutional documents and routines relating to internal controls. Management reports to the Audit Committee on internal controls at each meeting. The Board of Directors is regularly updated on the Company's financial position and profit/loss against budget as well as on development projects in relation to the relevant project budgets. The CEO presents a written report at each regular Board meeting, or when the need arises, directly to the Board of Directors on the monitoring and status of the Company's ongoing projects and drug candidates.

#### Special evaluation of the requirement for internal audit

Abliva does not conduct an internal audit. The Board of Directors evaluates the need for this function annually and judges that, given the Company's size with relatively few employees and limited transactions, there is no need to institute a formal internal audit function.

### Compliance with Swedish stock market regulations and accepted stock market practice

Abliva has not been subject to any ruling by Nasdaq Stockholm's disciplinary commission or statements by the Swedish Securities Council relating to breaches of Nasdaq's regulatory framework for issuers or good accounting practice on the stock market in the financial year 2021.

### Abliva's Board



**DAVID LASKOW-POOLEY** 

Chairman

(2017, elected 2016)

Born: 1954

Education: BSc Pharmacy (1st), Pharmaceutical/Chemical engineering specialty and QP., Sunderland School of Pharmacy.

Other ongoing assignments: Director of the Board of Marker Therapeutics Inc. (USA), Pharmafor Ltd (England), and LREsystem Ltd(England).

No. of shares in Abliva: 45,828

Other: Non-affiliated to the Company, the management and to major owners.



#### **DAVID BEJKER**

Director (2017)

Born: 1975

Education: M.Sc. (Econ.), Stockholm School of Economics.

Other ongoing assignments: Director of the Board of LIDDS AB and Amylonix AB, CEO of Affibody Medical AB.

No. of shares in Abliva: 100,000

Other: Non-affiliated to the Company, the management and to major owners.



#### **DENISE GOODE**

Director (2018)

Born: 1958

Education: Institute of Chartered Accountants in England and Wales Chartered Accountant. B.Sc. Zoology from The University of

Manchester (UK).

Other ongoing assignments: Director of the Board and CEO of QED Life Sciences Limited, and VP Business Development at AnaMar AB.

No. of shares in Abliva: -

Other: Non-affiliated to the company, the management, and to major owners.



#### **ROGER FRANKLIN**

Director (2020)

Born: 1979

Education: M.Biochem (1st class), Molecular & Cellular Biochemistry, University of Oxford (UK), PhD, MRC Laboratory of Molecular Biology from University of Cambridge (UK).

Other ongoing assignments: Partner at Hadean Ventures. Director at Gesynta Pharma AB, Crosslanes Holding AB and TargED Biopharmaceuticals B.V. Deputy Director at HVentures AB, HVentures Capital I AB and HVentures Capital II AB. Board observer at Step Pharma SAS, Pipeline Therapeutics Inc, Emergence Therapeutics AG, and Cardior Pharmaceuticals GmbH

No. of shares in Abliva: 59,999,999 (through related company Hadean Ventures)

Other: Non-affiliated to the company and the management, but not to major owners



#### **JAN TÖRNELL**

Director (2017)

Born: 1960

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Education: MD and PhD in Physiology, University of Gothenburg.

Other ongoing assignments: CEO and Director the Board of Innoext AB, Chairman of the Board of LIDDS AB and Glactone Pharma AB, Director of the Board of Diaprost AB, and Deputy Director of the Board of LIDDS Pharma AB.

No. of shares in Abliva: 45,828

Other: Non-affiliated to the Company, the management and to major owners.

#### **SECRETARY**

CATHARINA JOHANSSON

Born: 1967. M.Sc. in Business and Economics. Deputy CEO and Chief Financial Officer of Abliva AB.
Secretary in Abliva's Board since 2016
No. of shares in Abliva: 135.000

#### COMMITTEES

Remuneration committee
Denise Goode (chair), David Laskow-Pooley, Jan Törnell
Audit committee
David Beiker (chair). Denise Goode. Jan Törnell

#### **AUDITOR**

Ernst & Young AB
OLA LARSMON
Authorized Public Accountant

Information regarding individuals' own and related parties' shareholdings pertains to the situation on December 31, 2021

### Abliva's Management



**ELLEN DONNELLY** 

CEO

Born: 1974

Education: Ph.D. in Pharmacology from Yale University.

Previous experience: Almost ten years at Pfizer in leading positions, and CEO of Modus Therapeutics AB (Sweden), Souvien Therapeutics (US), and of the Epigenetics Division of Juvenescence (UK).

Employed since: 2021.

No. of shares in Abliva: 117,500



**ESKIL ELMÉR** 

Chief Scientific Officer

Born: 1970

Education: Associated professor of experimental neurology at Lunds University, Doctors degree .

Previous experience: Researcher, Associate Professor and Adjunct Professor at the Department of Clinical Neurophysiology at Lund University . Specialist physician at the neurophysiological clinic at Skåne University Hospital .

Employed since: 2000

No. of shares in Abliva: 634,383 Privately owned shares (including family) and 16.20 percent of Maas Biolab, LLC.which owns 0.96% of



**MAGNUS HANSSON** 

Chief Medical Officer Born:1976

Education: PhD in Experimental brain research from Lund University, Doctors degree .

Previous experience: Consultant physician and associate professor in medical imaging and physiology at Skåne University Hospital, Sweden .

Employed since: 2008

No. of shares in Abliva: 628,747 shares (including family)



#### **CATHARINA JOHANSSON**

Deputy CEO and CFO

Born:1967

Education: M. Sc. in Business and Economics. Previous experience: More than 15 years of experience from senior financial positions. Interim CFO for medical device company Cellavision, and Accounting Manager for Bong and Alfa Laval Europe.

Employed since: 2013

No. of shares in Abliva: 135,000 shares

Information regarding individuals' own and related parties' shareholdings pertains to the situation on December 31, 2021

## Comprehensive Income

| (SEK 000)  | Note  | 2021     | 2020    |
|--|-------|----------|---------|
| Net sales  | 6     | 151      | 216     |
| Other operating income   | 7     | 0        | 1,648   |
|  |       |          |         |
| Operating expenses   | 9,10  | -103,695 | -46,072 |
| Personnel cost   | 11,12 | -16,844  | -13,305 |
| Depreciation and write-down of tangible and intangible assets                        |       | -2,764   | -2,558  |
| Other operating expenses   | 8     | -330     | -       |
|  |       | -123,633 | -61,935 |
| Operating income   | 5     | -123,482 | -60,071 |
| Profit/loss from financial items   |       |          |         |
| Result from other securities and receivables related to non current assets           |       | -        | 107     |
| Financial costs  | 13    | -12      | -30     |
|  |       | 12       | 77      |
| Profit/loss before tax   |       | -123,494 | -59,994 |
| Income tax   | 14    | -4       | -       |
| Profit/loss for the period   |       | -123,498 | -59,994 |
| Other comprehensive income   |       |          |         |
| Items that may be reclassified to profit or loss                                     |       |          |         |
| Translation differences on foreign subsidiaries                                      |       | 71       | -3      |
| Total other comprehensive income, net after tax                                      |       | 71       | -3      |
| Total comprehensive income for the period  |       | -123,427 | -59,997 |
| Loss for the period attributable to:   |       |          |         |
| Parent company shareholders  |       | -123,492 | -59,989 |
| Non-controlling interests  |       | -6       | -5      |
|  |       | -123,498 | -59,994 |
| Total comprehensive income for the period  |       |          |         |
| Parent company shareholders  |       | -123,420 | -59,992 |
| Non-controlling interests  |       | -7       | -5      |
|  |       | -123,427 | -59,997 |
| Earnings per share before and after dilution (SEK) based on average number of shares | 15    | -0.33    | -0.24   |
|  |       |          |         |

## Financial Position

| (SEK 000)                           | Note | 12/31/2021 | 12/31/2020 |
|-------------------------------------|------|------------|------------|
| ASSETS                              |      |            |            |
| Non-current assets                  |      |            |            |
| Intangible assets                   |      |            |            |
| Development costs*                  | 16   | -          | -          |
| Patents                             | 17   | 20,293     | 20,971     |
| Other intangible assets             | 18   | 1,210      | 1,344      |
|                                     |      | 21,503     | 22,315     |
| Tangible assets                     |      |            |            |
| Equipment                           | 19   | 60         | 41         |
| Right of use assets lease           | 20   | -          | 343        |
|                                     |      | 60         | 384        |
| Financial Assets                    |      |            |            |
| Other non-current receivables       | 22   | 13,101     | 13,101     |
|                                     |      | 13,101     | 13,101     |
| Total non-current assets            |      | 34,664     | 35,800     |
| Current assets                      |      |            |            |
| Other receivables                   |      | 912        | 928        |
| Prepaid expenses and accrued income | 23   | 1,003      | 586        |
| Cash and cash equivalents           | 24   | 22,339     | 61,643     |
|                                     |      | 24,254     | 63,157     |
| TOTAL ASSETS                        |      | 58,918     | 98,957     |

#### \*Capitalized Development Costs

The Board of Swedish Accounting Supervision examined the Company's interim report as of September 30, 2020 and the Annual report for 2020 regarding the accounting of capitalized development costs, and referred the case to Finansinspektionen (FI). In October FI announced that they would investigate whether Abliva AB complied with the regulations for accounting in its annual and consolidated accounts for 2020. More specifically, whether Abliva AB had violated the provisions of Article 4 of the European Parliament and Council Regulation (EC) No 1606/2002 of 19 July 2002 on the application of international accounting standards, and the Annual Accounts Act (1995: 1554) regarding the accounting of development expenses as an intangible asset. As an adaptation to the The Board of Swedish Accounting Supervision's view on the handling of capitalized development costs (IAS 38), the Board has made a correction of Opening balances 1 January 2020 in Equity, in accordance with IAS 8 Accounting Policies, Changes in Accounting Estimates and Errors. As a result of the adjustment, FI dismissed the case. The total adjustment of SEK 51,706,000 refers to accumulated capitalized development costs related to the NeuroSTAT program processed up to and including 31 March 2017.

## Financial Position

| (SEK 000)   | Note | 12/31/2021 | 12/31/2020 |
|---|------|------------|------------|
| EQUITY AND LIABILITIES  |      |            |            |
| Equity attributable to the shareholders of the parent company |      |            |            |
| Share capital Share capital                                   | 25   | 20,150     | 14,817     |
| Additional paid in capital                                    | 26   | 730,560    | 660,025    |
| Translation reserve   | 27   | 688        | 616        |
| Retained earnings*  | 28   | -709,879   | -586,802   |
| Total equity attributable to the shareholders of the parent   |      | 41,519     | 88,656     |
| Non-controlling interests                                     |      | 9          | 0          |
| Total equity  |      | 41,528     | 88,656     |
| Long-term liabilities   |      |            |            |
| Other long-term liabilities                                   |      | -          | 92         |
|   |      | -          | 92         |
| Short-term liabilities  |      |            |            |
| Accounts payable  |      | 9,616      | 4,201      |
| Other liabilities   |      | 277        | 675        |
| Accrued expenses and deferred income                          | 29   | 7,497      | 5,333      |
|   |      | 17,390     | 10,209     |
| Total liabilities   |      | 17,390     | 10,301     |
| TOTAL EQUITY AND LIABILITIES                                  |      | 58,918     | 98,957     |

<sup>\*</sup>Capitalized Development Costs - for further information see page 34.

(SEK 000)

## Changes in Equity

#### Equity attributable to the shareholders of the parent company

|   |               | Additional      | Translation | Retained |          | Non-<br>controlling |              |
|---|---------------|-----------------|-------------|----------|----------|---------------------|--------------|
|   | Share capital | paid-in capital | reserve     | earnings | Total    | interests           | Total equity |
| Opening balance, 1 January 2020                     | 9,298         | 592,980         | 619         | -475,107 | 127,791  | 5                   | 127,795      |
| Retroactive adjustment of capitalized               | -             | -               | -           | -51,706  | -51,706  | -                   | -51,706      |
| development costs**                                 | 0.000         | 500.000         | 242         | F00.040  | 70.004   |                     | 70.000       |
| Restated total equity at the beginining of the year | 9,298         | 592,980         | 619         | -526,813 | 76,084   | 5                   | 76,089       |
| Comprehensive profit/loss for the period            |               |                 |             |          |          |                     |              |
| Profit/loss for the period                          | -             | -               | -           | -59,989  | -59,989  | -5                  | -59,994      |
| Other comprehensive income:                         | -             | -               | -           | -        | -        | -                   | -            |
| Translation differences                             | -             | -               | -3          | -        | -3       | -                   | -3           |
| Other comprehensive profit/loss for the period,     | -             | -               | -3          | -        | -3       | -                   | -3           |
| net after tax                                       |               |                 |             |          |          |                     |              |
| Total comprehensive profit/loss                     | -             | -               | -3          | -59,989  | -59,992  | -5                  | -59,997      |
| Transactions with shareholders:                     | -             | -               | -           | -        | -        | -                   | -            |
| Rights Issue  | 5,519         | 67,045          | -           | -        | 72,564   | -                   | 72,564       |
| Total transactions with shareholders                | 5,519         | 67,045          | -           | -        | 72,564   | -                   | 72,564       |
| Closing balance, 31 December 2020                   | 14,817        | 660,025         | 616         | -586,802 | 88,656   | -                   | 88,656       |
| Opening balance, 1 January 2021                     | 14,817        | 660,025         | 616         | -586,802 | 88,656   | -                   | 88,656       |
| Comprehensive profit/loss for the period            | -             | -               | -           | -        | -        | -                   | -            |
| Profit/loss for the period                          | -             | -               | -           | -123,492 | -123,492 | -6                  | -123,498     |
| Other comprehensive income:                         | -             | -               | -           | -        | -        | -                   | -            |
| Translation differences                             | -             | -               | 72          | -        | 72       | -1                  | 71           |
| Other comprehensive profit/loss for the period,     | -             | -               | 72          | -        | 72       | -1                  | 71           |
| net after tax                                       |               |                 |             |          |          |                     |              |
| Total comprehensive profit/loss                     | -             | -               | 72          | -123,492 | -123,420 | -7                  | -123,427     |
| Transactions with shareholders:                     | -             | -               | -           | -        | -        | -                   | -            |
| Rights Issue*                                       | 5,333         | 70,535          | -           | _        | 75,868   | -                   | 75,868       |
| Share-based payment                                 | -             | -               | -           | 415      | 415      | -                   | 415          |
| Shareholder contribution                            | -             | -               | -           | -        | -        | 16                  | 16           |
| Total transactions with shareholders                | 5,333         | 70,535          | -           | 415      | 76,283   | 16                  | 76,299       |
| Closing balance, 31 December 2021                   | 20,150        | 730,560         | 688         | -709,879 | 41,519   | 9                   | 41,528       |

<sup>\*</sup> Total equity includes funds from the April 6, 2021 and May 4th completed directed share issue with SEK 75,900,000 less expenses SEK 4,100,000.



<sup>\*\*</sup> The adjustment pertains to development costs, for further information, see page 34. \*Capitalized Development Costs

# Consolidated Statement of

# **Cash Flows**

| (SEK 000)  | Note  | 2021     | 2020    |
|--|-------|----------|---------|
|  |       |          |         |
| Cash flow from operating activities  |       |          |         |
| Operating income   |       | -123,482 | -60,071 |
|  |       |          |         |
| Adjustments for non-cash items:  |       |          |         |
| Depreciation   |       | 2,660    | 2,558   |
| Currency differences on intercompany items                                 |       | -7       |         |
| Impaired value patents   |       | 104      |         |
| Share based payments   |       | 415      | -       |
| Result from other securities and receivables related to non current assets |       | -        | 107     |
| Interest paid  |       | -12      | -30     |
| Tax paid   |       | -4       | -       |
| Net cash from operating activities before changes in working capital       |       | -120,326 | -57,436 |
| Changes in working capital   |       |          |         |
| Increase/decrease of other current assets                                  |       | -400     | 86      |
| Increase/decrease of other short-term liabilities                          |       | 6,651    | -10,208 |
|  |       | 6,251    | -10,122 |
| Cash flow from operating activities  |       | -114,075 | -67,558 |
| Investing activities   |       |          |         |
| Acquisition of intangible assets   | 17,18 | -1,024   | -1,407  |
| Acquisition of tangible assets   | 19    | -65      | -       |
| Cash flow from investing activities  |       | -1,089   | -1,407  |
| Financing activities   |       |          |         |
| Shareholder contribution subsidiary  |       | 16       | -       |
| New share issue  | 25    | 75,868   | 72,564  |
| Amortization lease liabilities   |       | -92      | -269    |
| Cash flow from financing activities  |       | 75,792   | 72,295  |
| Cash flow for the period   |       | -39,372  | 3,330   |
| Cash and cash equivalents at the beginning of the period                   |       | 61,643   | 58,319  |
| Effect of exchange rate changes on cash                                    |       | 68       | -6      |
| Cash and cash equivalents at end of period                                 | 24    | 22,339   | 61,643  |



# **Income Statement**

| (SEK 000)  | Note  | 2021     | 2020    |
|--|-------|----------|---------|
|  |       |          |         |
| Net sales  | 5     | 151      | 216     |
| Other operating income   | 7     | -        | 1,648   |
|  |       | 151      | 1,864   |
| Operating expenses   |       |          |         |
| Other external expenses  | 9,10  | -107,521 | -46,411 |
| Personnel cost   | 11,12 | -12,952  | -13,305 |
| Depreciation and write-down of tangible and intangible assets              |       | -2,420   | -2,215  |
| Other operating expenses   | 8     | -330     | -       |
|  |       | -123,223 | -61,931 |
| Operating income   | 5     | -123,072 | -60,067 |
| Profit/loss from financial items   |       |          |         |
| Result from other securities and receivables related to non current assets |       | -        | 107     |
| Interest expenses and other similar loss items                             | 13    | -        | -1      |
|  |       | -        | 106     |
| Profit/loss before tax   |       | -123,072 | -59,961 |
| Income tax   | 14    | -        | -       |
| Profit/loss for the period   |       | -123,072 | -59,961 |

Parent Company

# Statement of Comprehensive Income

| (SEK 000)                                      | Note 2021 | 2020    |
|--|-----------|---------|
| Profit/loss for the period                     | -123,072  | -59,961 |
| Other comprehensive income                     | -         | -       |
| Total comprehensive profit/loss for the period | -123,072  | -59,961 |

# **Balance Sheet**

| (SEK 000)                           | Note | 12/31/2021 | 12/31/2020 |
|-------------------------------------|------|------------|------------|
|                                     |      |            |            |
| ASSETS                              |      |            |            |
| Non-current assets                  |      |            |            |
| Intangible assets                   |      |            |            |
| Development costs*                  | 16   | -          | -          |
| Patents                             | 17   | 20,293     | 20,971     |
| Other intangible assets             | 18   | 1,210      | 1,344      |
|                                     |      | 21,503     | 22,315     |
| Tangible assets                     |      |            |            |
| Equipment                           | 19   | 60         | 41         |
|                                     |      | 60         | 41         |
| Financial assets                    |      |            |            |
| Shares in subsidiaries              | 21   | -          | 23,625     |
| Other non-current receivables       | 22   | 24,557     | 13,101     |
|                                     |      | 37,658     | 36,726     |
| Total non-current assets            |      | 59,221     | 59,082     |
| Current assets                      |      |            |            |
| Short term receivables              |      |            |            |
| Receivables from group companies    |      | -          | -          |
| Other receivables                   |      | 890        | 926        |
| Prepaid expenses and accrued income | 23   | 1,003      | 585        |
|                                     |      | 1,893      | 1,511      |
| Cash and bank balances              | 24   | 21,696     | 61,634     |
| Total current assets                |      | 23,589     | 63,145     |
| TOTAL ASSETS                        |      | 82,810     | 122,226    |

<sup>\*</sup>Capitalized Development Costs - for further information see page 34.

# **Balance Sheet**

| (SEK 000)                            | Note | 12/31/2021 | 12/31/2020 |
|--------------------------------------|------|------------|------------|
|                                      |      |            |            |
| EQUITY AND LIABILITIES               |      |            |            |
| Equity                               |      |            |            |
| Restricted equity                    |      |            |            |
| Share capital                        | 25   | 20,150     | 14,817     |
| Statutory reserve                    |      | 1,856      | 1,856      |
| Development expenditure reserve      |      | 2,613      | 3,821      |
|                                      |      | 24,619     | 20,494     |
| Unrestricted equity                  |      |            |            |
| Share premium reserve                |      | 70,534     | 67,045     |
| Retained earnings *                  |      | 93,017     | 84,725     |
| Profit/loss for the period           |      | -123,072   | -59,961    |
|                                      |      | 40,479     | 91,809     |
| Total equity                         |      | 65,098     | 112,302    |
| Short-term liabilities               |      |            |            |
| Accounts payable                     |      | 9,616      | 4,201      |
| Other liabilities                    |      | 273        | 406        |
| Accrued expenses and deferred income | 29   | 6,570      | 5,317      |
|                                      |      | 17,712     | 9,924      |
| TOTAL EQUITY AND LIABILITIES         | 30   | 82,810     | 122,226    |

<sup>\*</sup>Retained earnings - for further information see page 34, Capitalized Development Costs

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# **Changes in Equity**

|  |         | R         | estricted Equity | Unres    | tricted Equity |                   |
|--|---------|-----------|------------------|----------|----------------|-------------------|
| <del>-</del>   |         |           | Fund             | Share    |                |                   |
|  | Share   | Statutory | Development      | premium  | Retained       | Total             |
| (SEK 000)  | capital | reserve   | costs            | reserve  | earnings       | Equity            |
|  |         |           |                  |          |                |                   |
| Opening balance 1 January 2020                           | 9,298   | 1,856     | 14,106           | 103,067  | 23,079         | 151,406           |
| Retroactive adjustment of capitalized development costs* | -       | -         | -9,755           | -        | -41,951        | -51,706           |
| Restated total equity at the beginning of the year       | 9,298   | 1,856     | 4,351            | 103,067  | -18,873        | 99,700            |
| Comprehensive profit/loss for the period                 | -       |           | -                | -        | -              | -                 |
| Disposition according to AGM                             | -       | -         | -                | -103,067 | 103,067        | -                 |
| Profit/loss for the period                               | -       | -         | -                | -        | -59,961        | -59,961           |
| Total comprehensive profit/loss                          | -       | -         | -                | -103,067 | 43,106         | -59,961           |
|  | -       | -         | -                | -        | -              | -                 |
| Transactions with shareholders                           | -       | -         | -                | -        | -              | -                 |
| New share issue  | 5,519   | -         | -                | 67,045   | -              | 72,564            |
| Total transactions with shareholders                     | 5,519   | -         | -                | 67,045   | -              | 72,564            |
| Development expenditure reserve                          | -       | -         | -530             | -        | 530            | -                 |
| Closing balance, 31 December 2020                        | 14,817  | 1,856     | 3,821            | 67,045   | 24,764         | 112,302           |
| -<br>-   | -       |           | -                | -<br>    |                | <del>-</del><br>- |
| Opening balance 1 January 2021                           | 14,817  | 1,856     | 3,821            | 67,045   | 24,764         | 112,302           |
| Comprehensive profit/loss for the period                 | -       | -         | -                | -        | -              | -                 |
| Disposition according to AGM                             | -       | -         | -                | -67,045  | 67,045         | -                 |
| Profit/loss for the period                               | -       | -         | -                | -        | -123,072       | -123,072          |
| Total comprehensive profit/loss                          | -       | -         | -                | -67,045  | -56,027        | -123,072          |
|  | -       | -         | -                | -        | -              | -                 |
| Transactions with shareholders                           | -       | -         | -                | -        | -              | -                 |
| New share issue  | 5,333   | -         | -                | 70,534   | -              | 75,867            |
| Total transactions with shareholders                     | 5,333   | -         | -                | 70,534   | -              | 75,867            |
| Development expenditure reserve                          | -       | -         | -1,208           | -        | 1,208          | _                 |
| Closing balance, 31 December 2021                        | 20,150  | 1,856     | 2,613            | 70,534   | -30,055        | 65,098            |

<sup>\*</sup> The adjustment pertains to development costs, for further information, see page 34. \*Capitalized Development Costs

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# Statement of Cash Flows

| (SEK 000)  | Note  | 2021     | 2020    |
|--|-------|----------|---------|
| Cash flow from operating activities                                  |       |          |         |
| Operating income   |       | -123,072 | -60,067 |
| Adjustments for non-cash items:                                      |       |          |         |
| Depreciation   |       | 2,316    | 2,215   |
| Impaired value patents   |       | 104      | -       |
| Result from shares in associated company                             |       |          | 107     |
| Interest received  |       | -        | -       |
| Interest paid  |       | -        | -1      |
| Net cash from operating activities before changes in working capital |       | -120,652 | -57,746 |
| Changes in working capital   |       |          |         |
| Increase/decrease of other current assets                            |       | -382     | 86      |
| Increase/decrease of other short-term liabilities                    |       | 7,250    | -10,135 |
|  |       | 6,868    | -10,049 |
| Cash flow from operating activities                                  |       | -113,784 | -67,795 |
| Investing activities   |       |          |         |
| Acquisition of intangible assets                                     | 16,17 | -1,024   | -1,407  |
| Acquisition of tangible assets                                       |       | -65      | -       |
| Change in other financial assets                                     |       | -933     | -       |
| Cash flow from investing activities                                  |       | -2,022   | -1,407  |
| Financing activities   |       |          |         |
| New share issue  | 24    | 75,868   | 72,564  |
| Cash flow from financing activities                                  |       | 75,868   | 72,564  |
| Cash flow for the period   |       | -39,938  | 3,362   |
| Cash and cash equivalents at the beginning of the period             |       | 61,634   | 58,272  |
| Cash and cash equivalents at end of period                           | 24    | 21,696   | 61,634  |



# Note 1 – General Information

Abliva AB (publ), with corporate identity number 556595-6538, is a limited company registered in Sweden, with its registered office in Lund. The address of the head office is Medicon Village, Scheeletorget 1, 223 81 Lund, Sweden. The company and its subsidiary (the "group") develops medicines for the treatment of primary mitochondrial diseases. These congenital, rare

and often very severe diseases occur when the cell's energy provider, the mitochondria, do not function properly. The company is focused on two projects. KL1333, a powerful NAD+ and NADH regulator, entering late stadge development and has been granted orphan drug designation in Europe and the US. NV354, an energy replacement therapy, has just completed preclin-

ical development. The Company changed name from NeuroVive Pharmaceutical AB to Abliva AB on May 27, 2020. "Abliva" or "The Company" refers to Abliva AB (publ).

# Note 2 – Critical accounting policies

# Grounds of preparation of the reports

Group accounting policies have been prepared in accordance with the Annual Accounts Act, RFR's (Rådet för finansiell rapportering, the Swedish Financial Reporting Board) recommendation RFR 1, Supplementary Accounting Rules for Groups and the International Financial Reporting Standards (IFRS) and interpretation statements from the International Financial Reporting Interpretations Committee (IFRIC), as endorsed by the EU.

# Basis of preparation of the financial statements

The group's functional currency is the Swedish krona (SEK), which is also the company's presentation currency. Unless otherwise stated, financial reports are in SEK. Unless otherwise stated, all amounts are rounded to the nearest thousand.

Assets and liabilities are recognized at historical cost, except from some financial assets and liabilities, which are valued at fair value.

The preparation of the financial statements in compliance with IFRS requires the Board of Directors and management to make judgments and estimates in the appropriate application in applying the accounting policies and reported amounts of assets, liabilities, income and expenses. These judgments and estimates are based on historical experience and know-how of the sector in which Abliva is active and that are believed to be reasonable under the circumstances. The results of the judgments and estimates are used to determine the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these judgments and estimates. The judgments and estimates are reviewed on an on-going basis and revisions are recognized in the Income Statement. Judgments made by the Board of Directors and management when applying the accounting principles in accordance with IFRS that could have a significant impact on the financial statements, and judgments that could imply significant adjust-

ments to financial statements for ensuing years are presented in more detail under Note 3.

The group's accounting policies described below have been applied consistently to all periods presented in the Group's financial reports, unless otherwise stated below, unless otherwise stated.

# New and amended standards applied by the Group

No other standards to be applied by the Group for the first time for fiscal years beginning January 1, 2020 have had or are expected to have any impact on the Group's accounting policies or disclosures.

### New standards and interpretations not yet adopted by the Group

No new standards and interpretations that may have an impact on the Group's financial statements will come into effect for the financial year beginning after January 1, 2021.

No other IFRS or IFRIC-interpretations, which not yet has entered into force, is estimated to have any major impact on the Group.

#### Consolidated accounts

Subsidiaries are defined as all companies where the company has a controlling influence. The group is judged to control a company when it is exposed to or becomes entitled to variable returns on its holding in the company and is able to influence such returns as a result of its influence in the company. Subsidiaries are included in the consolidated financial statements from the date the controlling influence is transferred to the group. They are deconsolidated from the date when the controlling influence ceases.

The acquisition method is applied for recognizing the group's business combinations. The purchase price for acquiring a subsidiary consists of the fair value of transferred assets, liabilities that the group takes over from the

previous owner of the acquired company, and those shares issued by the group. The purchase price also includes the fair value of all assets or liabilities that are a result of an agreement on conditional purchase price. Identifiable acquired assets and liabilities taken over in a business combination are initially recognized at fair value on the acquisition date. Acquisition-related costs are expensed when they arise. For each acquisition, the Group decides whether non-controlling interests in the acquired company are reported at fair value or at the holding's proportionate share in the carrying amount of the acquired company's identifiable net assets.

For each acquisition—i.e. acquisition by acquisition—the group decides whether non-controlling interests in the acquired companies should be recognized at fair value or at the holding's proportional share of the carrying amount of the acquired company's identifiable net assets. Acquisition-related costs are expensed immediately.

The group's profit or loss and components of other comprehensive income are attributable to the parent company's equity holders and to non-controlling interests, even if this results in a negative value of noncontrolling interests. The accounting policies of the subsidiary are adjusted as required for consistency with the group's accounting policies. All intragroup transactions, balances and unrealized gains and losses attributable to intra-group transactions are eliminated in the preparation of the consolidated accounts.

# Transactions with non-controlling interests

Changes to parent company holdings in a subsidiary that do not cause a loss of controlling influence are recognized as equity transactions (i.e. transactions with the group's equity holders). Any difference between the amounts by which non-controlling interests are restated and the fair value of the compensation received or paid are recognized directly in equity and allocated to the parent company's equity holders.



For information about which subsidiaries are included in the group and financial information about the most significant non-controlling interests in subsidiaries, see Note 22 of the Parent Company financial statements.

#### **Operating segments**

An operating segment is a part of a Company that conducts business operations from which it can receive revenues or incur expenses, whose operating earnings are regularly reviewed by the Company's chief operating decision-maker, and for which there is independent financial information available. Abliva's reporting of operating segments is consistent with its internal reporting to the chief operating decision-maker. The chief operating decision-maker is that function that judges the profit or loss of operating segments and decides on the allocation of resources. Abliva's judgment is that the CEO is the chief operating decision-maker. Profit or loss for the group as a whole is stated in the regular internal reporting to the CEO. The CEO does not regularly review profit or loss at a lower level to take decisions on the allocation of resources or for judging the profit or loss of different parts of the group. Accordingly, the group is considered to consist of a single operating segment.

#### Non-current assets held for sale

Non-current assets (or disposal groups) are classified as held for sale if their carrying amounts will be mainly recovered through sale and not through continuous usage. To satisfy this criterion it has to be very likely that the sale will occur and the asset (or disposal group) should be available for immediate sale in its current condition. Non-current assets (or disposal groups) classified as held for sale are recognized at the lower of carrying amount and fair value with a deduction for selling expenses. At present, the group does not have any non-current assets held for sale.

# Revenue recognition

The company's revenues comprise the fair value of the consideration received for the sale of goods and services in Abliva's operations. Revenues are recognized without VAT, and with elimination of intra-Group sales. Abliva recognizes a revenue when the customer obtains control of the promised good or service and is able to use and obtain the benefits from the good or service. Future contracts for revenue will be evaluated prior to decisions related to whether revenue is recognized over time, or at a point in time. The following description is an overview of the elements that may be involved in the generation of future revenue.

### Upfront fees.

Upfront fees may be received upon contract inception and are non-refundable. An upfront fee where the company has outstanding performance obligations is normally considered an advance payment. Revenue recognition of an up-front payment can vary depending on contract conditions and may be "at a point in time" or "over time". The method used is dependent on the performance obligations included in the contract and when these are carried out.

**Milestone payments.** Any agreed milestone payments are recognized as revenue when the contractual parties have satisfied the agreed criteria under the existing contracts i.e. over time.

**Royalties.** Any future royalties will be recognized as revenue in accordance with the performance obligations described in the contracts, which may be both over time and at a point in time.

**Revenue from the sale of goods.** Future sales of developed drugs may also comprise the sale of goods. These revenues will be recognized when ownership and control of the asset have been transferred to the buyer i.e. at a specific point in time.

**Dividend and interest income.** Dividend income is recognized when the shareholder's right to receive payment has been determined. Interest income is recognized and allocated over its term by applying the effective interest method. Effective interest is the interest that makes the present value of all future payments made and received during the fixed interest period equal to the carrying amount of the receivable.

#### Leases

When signing leases, a right-of-use asset and a lease liability are recognized in the balance sheet. Cost comprises the discounted remaining lease payments for non-cancellable lease terms. Potential extension periods are included if the Group is reasonably certain that these will be utilized. In discounting, the company's incremental borrowing rate is applied, which is currently 5%.

The lease could be changed during the lease term, upon which remeasurement of the lease liability and the right-of-use asset is carried out.

Lease payments are distributed between amortization of the lease liability and payment of interest. The Group's material leases comprise the rental of office premises.

The company applies exemption rules for leases when the underlying asset is of low value and has a short lease. These leases are recognized as a cost in the period in which use occurs.

#### Foreign currency

Items recognized in the financial statements of the various units of the group are recognized in the currency used in the primary economic environment where each unit mainly conducts operations (functional currency). In the consolidated accounts, all amounts are translated to Swedish kronor (SEK) which is the parent company's functional currency and the group's reporting currency. Transactions in foreign currency are translated in each unit to the functional currency of that unit at the rate of exchange ruling on the transaction date. Monetary items in foreign currency are translated at closing day rates. Nonmonetary items, measured at fair value in a foreign currency, are translated at the rate of exchange ruling on the date when fair value is determined. Non-monetary items measured at historical cost in a foreign currency are not translated.

Exchange rate differences are recognized in profit or loss for the period when they occur. When preparing the consolidated accounts, foreign subsidiaries' assets and liabilities are translated to Swedish kronor at the closing day rate. Revenue and expense items are translated at average rates of exchange for the period, unless the rate of exchange fluctuated significantly in this period, when instead, the rate of exchange ruling on the transaction date is utilized. Potential translation differences arising are recognized in other comprehensive income and transferred to the group's translation reserve. When disposing of a foreign subsidiary, such translation differences are recognized in profit or loss as a part of the capital gain.

# **Borrowing costs**

Borrowing costs Directly attributable to the purchase, construction or production of an asset that requires significant time for completion for intended use or sale are included in the cost of an asset until the time when the asset is completed for its intended usage or sale. Interest income from the temporary investment of borrowed funds for the aforementioned assets are deducted from the borrowing costs that may be included in the cost of the asset. Other borrowing costs are recognized in profit or loss in the period they arise.

# **Government grants**

Government grants are recognized at fair value when it is reasonably certain that the Company will satisfy the conditions associated with the grant and the grant will be received. Government grants are recognized systematically in profit or loss over the same period as the grants are intended to compen-



sate for. Grants that relate to purchases of assets are recognized as a reduction of the fair value of the assets, which means that the grant is recognized in profit or loss during the depreciable asset's useful life in the form of lower depreciation. Grants relating to profit or loss are recognized in other operating income in the Statement of Comprehensive Income.

#### **Employee benefits**

Employee benefits in the form of salaries, bonuses, vacation pay, paid sickness absence, etc. as well as pensions should be recognized as they are accrued. Pensions and other benefits after terminated employment are classified as defined contribution or defined benefit pension plans. The group has defined contribution pension plans only.

**Defined contribution plans.** For defined contribution plans, the Company pays predetermined fees to a separate independent legal entity and has no obligation to pay any further contributions. The group's profits or loss is charged for expenses as benefits accrue, which is normally coincident with the timing of when premiums are paid.

## **Stock Option Program**

Share-based Payment are regulated with equity instruments. The fair value of employee stock options is calculated according to Black-Scholes' valuation model at the time the options are granted. The cost, which is distributed over the vesting period of four years, is reported against equity. No costs for social security contributions are expected to occur, consequently no provisions are made for social security costs, only the cost of the employee stock option is reported.

# **Taxes**

The tax expense is the total of current tax and deferred tax.

Current tax. Current tax is computed on taxable profit or loss for the period. Taxable profit differs from reported profit or loss in the Statement of Comprehensive Income because it has been restated for non-taxable income and non-deductible expenses and for revenue and expenses that are taxable or tax deductible in other periods. The group's current tax liability is computed using the tax rates that are enacted or substantively enacted on the reporting date.

**Deferred tax.** A deferred tax liability is recognized for the taxable temporary differences relating to investments in subsidiaries, apart from those cases the group can control the timing of reversal of the temporary differences and

It is likely that such reversal would not occur within the foreseeable future. The deferred tax receivables that relate to deductible temporary differences regarding such investments should only be recognized to the extent it is likely that amounts can be used against future taxable surpluses, and it is likely that such usage will occur within the sustainable future. The carrying amount of deferred tax receivables is tested at each reporting date and reduced to the extent it is no longer likely that sufficient taxable surpluses will be available to be used wholly or partly against the deferred tax receivable. Deferred tax is computed using the tax rates expected to apply for the period when the asset is recovered or the liability is settled, based on the tax rates (and tax laws) enacted or substantively enacted on the reporting date. Deferred tax assets and tax liabilities are offset when they relate to income taxes charged by the same authority, and when the group intends to settle the tax with a net amount.

**Current and deferred tax for the period.** Current and deferred tax is recognized as an expense or revenue in profit or loss, apart from when tax relates to transactions recognized in other comprehensive income or directly against equity. In such cases, tax should also be recognized in other comprehensive income, or directly against equity. In current and deferred tax arising on recognition of business combinations, the tax effect should be recognized in the acquisition analysis.

### Tangible fixed assets

Tangible fixed assets are recognized at historical cost after deducting for accumulated depreciation and potential impairment. Historical cost consists of the purchase price, expenditure directly related to the asset to bring it to the place and condition for use and estimated expenditure for disassembly and removal of the asset and restoration of the site of its location. Additional expenditure is only included in the asset or recognized as a separate asset if it is likely that future economic benefits that relate to the item will flow to the group and the historical cost for the item can be measured reliably. All other expenses for repairs and maintenance and additional expenditure is recognized in profit or loss in the period when it arises. Depreciation of tangible fixed assets is expensed so that asset value less estimated residual value at the end of the useful life is depreciated on a straight-line basis over its estimated useful life, which is estimated at:

Equipment 3-5 yrs.

Estimated useful lives, residual values and depreciation methods are reconsidered at least at the end of each accounting period, with the effect of

potential changed assessments recognized prospectively. The carrying amount of a tangible fixed asset is de-recognized from the Statement of Financial Position on disposal or sale, or where there are no future economic benefits expected from usage or disposal/sale of the asset. The gain or loss arising on the disposal or sale of the asset consists of the difference between potential net revenues on sale and its carrying amount, recognized in profit or loss in the period when the asset is de-recognized from the Statement of Financial Position.

# Intangible assets

Separately acquired and self-generated intangible assets. Intangible assets with definite useful lives that are acquired separately are recognized at historical cost less deductions for accumulated amortization and potential accumulated impairment. Amortization is on a straight-line basis over the asset's estimated useful life. Estimated useful lives and amortization methods are reconsidered at least at the end of each financial year, with the effect of potential changed ssessments recognized prospectively. Estimated useful lives essentially correspond to the terms of the patents. Term extensions have not been included. Estimated useful lives of intangible assets are estimated at:

Patents 10-30 yrs.
Other intangible assets 5-20 yrs.

Accounting policies for research and development. Development expenses are normally not capitalized until a development project enters market approval.

Expenditure for research designed to obtain new scientific or technological knowledge is recognized as an expense when it arises. Expenditure for development, where research results or other knowledge are applied to achieve new or improved products or processes, is recognized as an asset in the Statement of Financial Position only if the following conditions are satisfied:

- It is technically possible to complete the intangible asset and use or sell it.
- The Company intends to complete the intangible asset and use or sell it,
- The conditions to use or sell the intangible asset are in place,
- The Company demonstrates how the intangible asset will generate likely future economic benefits,



- There are adequate technological, economic and other resources to complete development and to use or sell the intangible asset, and
- The expenditure relating to the intangible asset during its development can be measured reliably

Because the period when the Company's research and development projects are expected to be registered as pharmaceuticals lies a long way in the future, it is highly uncertain when the probable future economic benefits will flow to the Company. All of the above criteria can normally be considered satisfied for Abliva's projects relating to pharmaceuticals when development projects enter market approval.

Other development expenditure that does not satisfy these criteria is expensed when it arises. Development expenditure previously expensed is not recognized as an asset in subsequent periods.

Directly related expenditure that is capitalized mainly consists of expenditure from subcontractors and expenses for employees.

After first-time reporting, capitalized development expenditure is recognized at cost after deducting for accumulated amortization and potential accumulated impairment. Amortization of capitalized expenditure for product development has not yet commenced.

**Disposal and sale.** Disposal and sale. An intangible asset is de-recognized from the Statement of Financial Position on disposal or sale, or when no future economic benefits are expected from the use or disposal/sale of the asset. The gain or loss arising when an intangible asset is de-recognized from the Statement of Financial Position consists of the difference between the amount received on sale and the asset's carrying amount, and is recognized in profit or loss when the asset is de-recognized from the Statement of Financial Position.

# Impairment of tangible fixed assets and intangible assets

The group analyses the carrying amounts of tangible and intangible assets at each reporting date to determine whether there is any indication that the value of these assets has decreased. If so, the asset's recoverable amount is computed to be able to determine the value of potential impairment. When it is not possible to compute the recoverable amount of an individual asset, the group computes the recoverable amount of the cash-generating unit that the asset belongs to. Intangible assets with indefinite useful lives and intangible assets that

are not yet ready for use should be tested for impairment yearly, or when there is an indication of impairment. Accordingly, capitalized expenditure for product development is subject to impairment tests at least yearly. The recoverable amount is the greater of the fair value less selling expenses and value in use. When computing value in use, estimated future cash flow is discounted to present value using a discount rate before tax that reflects the current market estimate of the time value of money and the risks associated with the asset. If the recoverable amount of an asset (or cash generating unit) is set at a lower value than the carrying amount, the carrying amount of the asset (or the cash-generating unit) is impaired to the recoverable amount, Impairment should be immediately expensed in profit or loss. When an impairment loss is subsequently reversed, the carrying amount of the asset (or cash-generating unit) is revalued to the recoverable amount, but the increased carrying amount may not exceed the carrying amount that would have been determined if no impairment had been made on the asset (the cash-generating unit) in previous years. A reversal of an impairment is recognized immediately in profit or loss.

#### Financial instruments

A financial asset or liability is recognized on the balance sheet when the company becomes a party to the contractual provisions of the instrument. A financial asset or part thereof is derecognized when its contractual rights are realized, expire or when the company loses control of the asset. A financial liability or part thereof is derecognized when the contractual obligations are fulfilled or otherwise extinguished.

#### Classification and measurement

Abliva's principles for classifying and measuring financial assets is based on an assessment of both the company's business model for managing its financial assets, and the contractual cash flow characteristics of the financial asset. Financial instruments are measured initially at fair value, including transaction costs, except for derivatives and instruments belonging to the category of financial assets at fair value through profit or loss, which are measured excluding transaction costs. For reported financial years, Abliva has the following categories of financial instruments.

#### Financial assets measured at amortized cost

Here, Abliva recognizes the assets held within a business model whose objective is to hold assets in order to collect contractual cash flows, and that the contractual terms of the financial asset give rise on specified dates to cash flows that are solely payments of principal and interest on the prin-

cipal amount outstanding. Financial assets measured at amortized cost are included in current assets, except for those items with maturities of more than 12 months after the balance-sheet date, which are classified as fixed assets. After the acquisition date, the asset is measured at amortized cost less any provision for loan losses. The Group's loan losses have been negligible to date, which is why no provisions had been made at December 31, 2020.

### Financial assets at fair value through other comprehensive income

Abliva holds shared in companies. Since these shares are not intended to be held for sale, the Group has elected to recognize changes in fair value in other comprehensive income. This decision is irrevocable. Here, Abliva recognizes its holding in the unlisted company, Note 22. The holdings were recognized at cost since this, in the absence of sufficient information, was considered the best estimate of their fair value.

#### Other financial liabilities

In this category there are all liabilities in Abliva. Liabilities in this category are reported at amortized cost.

Amortized cost. Amortized costs means the amount at which the asset or liability was initially reported less amortization, additions or deductions for accumulated accruals according to the effective interest method of the initial difference between the amount received/paid and the amount to be paid/received on maturity, and with deductions for impairment. Effective interest is the interest that results in the initial carrying amount of the financial asset or financial liability after discounting all future expected cash flows over the expected term.

**Offsetting financial assets and liabilities.** Financial assets and liabilities are offset and recognized at a net amount in the Balance Sheet when there is a legal right to offset and when there is an intention to settle the items with a net amount or simultaneously realize the asset and settle the liability.

Cash and cash equivalents. Cash and cash equivalents include cash funds and bank balances and other short-term, liquid investments that can be readily converted to cash and are subject to an insignificant risk of value fluctuations. For classification as cash and cash equivalents, maturities may not exceed three months from the time of acquisition. Cash funds and bank balances are categorized as "financial assets at accrued acquisition," which means measurement at amortized cost. Because bank balances are payable on demand, amortized cost corresponds to nominal amount.



**Other receivables.** Other short-term receivables is reported at amortized cost. However, the expected maturity of these receivables is short, and accordingly, they are recognized at nominal amount without discounting. There is a deduction for debt considered doubtful. Impairment of receivables is recognized in operating expenses.

**Accounts payable.** Accounts payable. Accounts payable are categorized as "other financial liabilities," which means measurement at amortized cost. However, the expected maturity of accounts payable is short, so these liabilities are recognized at nominal amount without discounting.

Liabilities to credit institutions and other loan liabilities. Interest-bearing bank borrowings, overdraft facilities and other loans are categorized as "other financial liabilities" and measured at amortized cost according to the effective interest method. Any differences between the loan amount received (net of transaction expenses) and repayment or amortization of loans is recognized over the loan term in accordance with the group's accounting policy on borrowing costs (see above).

#### **Provisions**

Provisions are recognized when the group has an existing obligation (legal or informal) as a result of an event that has occurred, it is likely that an outflow of resources will be required to satisfy the obligation and the amount can be measured reliably. The amount provisioned is the

best estimate of the amount necessary to satisfied the existing obligation on the reporting date, considering the risks and uncertainties associated with the obligation. When a provision is computed by estimating the payments expected to be required to satisfy the obligation, the carrying amount should correspond to the present value of these payments. When part or all of the amount necessary to settle a provision is expected to be replaced by a third party, this reimbursement should be recognized separately as an asset in the Statement of Financial Position when it is essentially certain that it will be received if the company satisfies the obligation and the amount can be measured reliably. Abliva is not reporting any provisions as of 31 December 2019 or 31 December 2018.

#### Equit

Transaction expenses directly attributable to the issue of new ordinary shares or options are reported in equity as a deduction from the issue proceeds, net of tax.

## Accounting policies for the parent company

The parent company applies the Swedish Annual Accounts Act and the Swedish Financial Reporting Board's recommendation RFR 2, Accounting for Legal Entities. The application of RFR 2 means that as far as possible, the parent company applies all IFRS as endorsed by the EU within the auspices of the Swedish Annual Accounts Act and the Swedish Pension Obligations Vesting Act and considering the relationship between accounting and

taxation. The differences between the parent company's and the group's accounting policies are reviewed below:

Classification and presentation. The parent company's Income Statement and Balance Sheet are presented in accordance with the Swedish Annual Account Act's format. The difference against IAS 1, Presentation of Financial Statements, applied on the presentation of the Consolidated Financial Statements, primarily relates to the recognition of financial revenues and expenses, equity and the incidence of provisions as a separate heading. The parent company also presents a separate Statement of Comprehensive Income, separately from the Income Statement.

**Subsidiaries.** Participations in subsidiaries are recognized at cost after deduction of any impairment in the parent company's financial statements. Acquisition-related expenses for subsidiaries, which are expensed in the consolidated accounts, are part of the cost of participations in subsidiaries.

**Financial instruments.** The parent company does not apply IAS 39, Financial Instruments: Recognition and Measurement. The parent company applies a cost-based method, pursuant to the Swedish Annual Accounts Act.

**Leases.** The Parent Company uses the exception regarding the application of IFRS 16 Leasing Agreement, which means that all leases are recognized as a cost on a straight-line basis over the lease period.

# Note 3 – Critical estimates and judgments

# Important sources of uncertainty and estimates

The most important assumptions regarding the future and other important sources of uncertainty estimates as of the reporting date that involve a significant risk of material restatements to carrying amounts of assets and liabilities in following financial years are reviewed below.

Intangible assets. Patents and other intangible and tangible non-current assets are subject to impairment tests if there is any indication that they are impaired. Impairment tests are based on a review of recoverable amounts, which are estimated based on assets' value in use. Management computes future cash flows in accordance with internal business plans and forecasts. This review also uses estimates of items including the discount rate and future growth rates beyond predetermined budgets and forecasts. The carrying amounts of intangible assets amount to SEK 21,503,000 (22,315,000), of which patents represents SEK 20,293,000 (20,971,000). Changes to the assumptions made by management for impairment tests would have a sig-

nificant impact on the Company's results of operations and financial position. For further information see Note 17.

**Financial assets.** Participation in subsidiaries are subject to impairment tests if there is any indication that they are impaired. Impairment tests are based on a review of recoverable amounts, which are estimated based on assets' value in use. Management computes future cash flows in accordance with internal business plans and forecasts. This review also uses estimates of items neluding the discount rate and future growth rates beyond predetermined budgets and forecasts. The carrying amounts of intangible assets amount to SEK 24,557,000 (23,265,000). Changes to the assumptions made by management for impairment tests would have a significant impact on the Company's results of operations and financial position. For further information see Note 21

Milestone Payment On 1 May 2017, the company in-licensed the KL1333 substance from YungJin Pharm under a collaboration agreement. The license covers all rare conditions associated with mitochondrial dysfunction. Under the agreement, the parties will be responsible for clinical development, regulatory processes, launch, marketing, distribution and sales of KL1333 in their respective markets, which for Abliva means the entire world except for South Korea and Japan. Yungjin Pharm is entitled to payments and sales milestones and incremental, from single to low double-digit, rovalty rates on future net sales. Payments will be made in conjunction with the successful achievement of various clinical milestones (a total of USD 12 million), and of milestones linked to marketing authorization, pricing and reimbursement (a total of USD 42 million). In connection with the approval by the US Drug Administration of Abliva's application for clinical trial (IND) for KL1333, USD 2 million was paid out of these USD 42 million. The agreement is to a certain extent exclusive, which entails that Abliva does not have the possibility of making equivalent agreements with other parties.



# Critical judgments when applying the group's accounting policies

The following section reviews critical judgments, apart from those involving estimates (see above), made by management when applying the group's accounting policies, and that have the most significant effect on carrying amounts in the financial statements.

Capitalization of expenditure for product development. Due to the review carried out by the Board of Swedish Accounting Supervision which led to the matter being handed over to Finansinspektionen regarding the Company's accounting of capitalized development expenses, the Board has made a correction of Opening Balances on January 1, 2020 in Equity, in accordance with IAS 8 Accounting Policies, Changes in Accounting Estimates and Errors. The total adjustment of SEK 51,706,000 refers to accumulated capitalized

development costs for the NeuroSTAT program, which were processed up to and including 31 March 2017.

# Note 4 – Financial risk management and financial instruments

Through its operations, the group is exposed to various types of financial risks such as market, liquidity and financing and credit and counterparty risks. Market risks primarily consist of interest risk and currency risk. The Company's Board of Directors is ultimately responsible for the exposure, management and monitoring of the group's financial risks. The Board of Directors sets the framework that applies to the exposure, management and monitoring of the financial risks and this framework is evaluated and revised yearly. The Board can decide on temporary departures from its predetermined framework. For all financial assets and liabilities, the carrying amount is considered a reasonable estimate of their fair value, unless otherwise specified in the related notes.

### Market risks

Currency risks. Currency risks means the risk that the fair value of future cash flows fluctuate because of changed exchange rates. Exposure to currency risk is primarily sourced from payment flows in foreign currency, termed transaction exposure, and from the translation of balance sheet items in foreign currency, as well as upon the translation of foreign subsidiaries' income statements and balance sheets to the group's reporting currency, which is Swedish kronor, called balance exposure. The group's outflows mainly consist of Swedish kronor, EUR and USD and to some extent DKK and GBP. Currently, the group does not generate any inflows in foreign currency. Accordingly, the group's exposure to currency risk is limited. The group does not hedge its transaction exposure. Foreign entities represent an insignificant share of the group's total assets, and accordingly, translation exposure resulting from the translation of foreign entities is limited. A 5% change in the exchange rate of the EUR, USD and GBP against the Swedish krona could affect profit or loss and equity by SEK 671,000 (217,000).

**Interest risks.** Interest risk means the risk that fair value or future cash flows fluctuates as a result of changed market interest rates. The group has no loans, and accordingly, any exposure to interest risk is limited. A 1% change in the group's interest on bank balances would mean that profit or loss and equity would change by SEK 618,000 (580,000).

The Group's exposure of the euro and USD at the reporting date is illustrated by the table below:

#### The Group exposure of Euro, USD and GBP at the time of reporting

|                    | Eu     | ro     | US   | D    | GB     | P    |
|--------------------|--------|--------|------|------|--------|------|
| (000)              | 2021   | 2020   | 2021 | 2020 | 2021   | 2020 |
|                    |        |        |      |      |        | _    |
| Assets/Liabilities | -7,900 | -3,837 | -313 | 6    | -4,683 | -511 |

#### Liquidity and financing risk

Liquidity risk means the risk that the group encounters difficulties in satisfying commitments related to the group's financial liabilities. Financing risk means the risk that the group is unable to arrange sufficient finance for a reasonable cost. The group is financed through equity and has no financial borrowings. Current liabilities amount to SEK 17,390,000 (10,209,000) and mature within one year. The group's current receivables that become due within one year amount to SEK 1,915,000 (1,514,000). The group has cash and cash equivalents of SEK 22,339,000 (61,643,000). KSEK.

# Categories of financial assets and financial liabilities

|                                     | Gro        | Group     |            | company |  |
|-------------------------------------|------------|-----------|------------|---------|--|
|                                     | 2021       | 2020      | 2021       | 2020    |  |
| Financial Assets by category        |            |           |            |         |  |
| Financial assets recognized at fair | value thro | ugh incom | ne stateme | ent     |  |
| Other long-term securities          | 13,101     | 13,101    | 13,101     | 13,101  |  |
| Financial assets at accrued acquisi | tion       |           |            |         |  |
| Other recivables                    | 912        | 928       | 890        | 926     |  |
| Cash and cash equivalents           | 22,339     | 61,643    | 21,696     | 61,634  |  |
| Total financial assets              | 36,352     | 75,672    | 35,687     | 75,661  |  |

#### Financial liability Financial liabilities at accrued acquisition Other financial liabilities Accounts payable 9.616 4.201 9.616 4.201 Other current liabilities 277 675 1.526 406 Accrued Expenses 3,613 2,713 3,480 2,713 **Total financial liabilities** 13,506 7,589 14,622 7,320



# Credit and counterparty risk

Credit risk means the risk that a counterparty in a transaction generates a loss for the group by being unable to satisfy its contracted obligations. The group's exposure to credit risk mainly relates to other current receivables, which are insignificant amounts, and accordingly any credit risk in other current receivables is limited.

Credit risk also arises when the Company's surplus liquidity is invested in various types of financial instrument. The Board of Directors' predetermined framework stipulates that surplus liquidity may be invested in interestbearing bank accounts or fixed-income securities. The credit risk in investing surplus liquidity should be reduced by investing only with counterparties with very high credit ratings. The group's and parent company's maximum exposure to credit risk is judged to be covered by the carrying amounts of all financial assets. The credit risk is judged to be limited.

# Categories of financial assets and financial liabilities

Carrying amounts of financial assets and financial liabilities divided by measurement category in accordance with IFRS 9 are indicated in the following table. There were no reclassifications between the measurement categories in the period. Interest income on cash and cash equivalents is stated in note 12. Net gains/losses from other financial assets and liabilities are insignificant.

# Maturity analysis regarding contractual payments for financial liabilities Note that the amounts refer to undiscounted values.

| Group 12/31/2021  | Within one<br>year | Between one and five years | After more than five years |
|-------------------|--------------------|----------------------------|----------------------------|
| Lease liabilities | -                  | -                          | -                          |
| Accounts payable  | 9,616              | -                          | -                          |
| Other liabilities | 277                | -                          | -                          |
| Total             | 9,893              | _                          | _                          |

| Group 12/31/2020  | Within one<br>year | Between<br>one and five<br>years | After more than five years |
|-------------------|--------------------|----------------------------------|----------------------------|
| Lease liabilities | 372                | -                                | -                          |
| Accounts payable  | 4,201              | -                                | -                          |
| Other liabilities | 303                | -                                | -                          |
| Total             | 4,876              | -                                | -                          |

## Measurements of financial instruments at fair value

Carrying amounts are considered a close approximation of the fair values of financial assets and financial liabilities due to their maturities and/or fixed interest periods being short, which means discounting based on applicable current market conditions are not considered to have any significant effect.

# Capital

The group's aim for managing its capital is to ensure the group's capacity to continue its operations to generate a reasonable return to shareholders and benefit other stakeholders. The group is funded through equity, which amounts to SEK 41,528,000 (88,656,000). The group's current policy is not to pay any dividend. A proposal on dividend to shareholders will not be possible until the Company achieves long-term profitability.



# Note 5 Intragroup transactions

Purchases within the same group amount to SEK 3,832,000 (0,000) and sales within the same group amount to SEK 0,000 (0,000). There are no existing loans between parent companies and subsidiaries.

# Note 6 Segment information

The financial information reported to the chief operating decision-maker (CEO), as a basis for allocating resources and judging the group's profit or loss, is not divided into different operating segments. Accordingly the group constitutes a single operating segment.

# Revenues from products and services and information on major customers

The group's net sales consist of no larger products or services during 2021 and 2020.

# Revenues and non-current assets divided by geographical region

The group's sales relatea to the parent company in 2021 and 2020.

The group conducts its operations in mainly one geographical region—Sweden (the Company's domicile). Equipment in the parent company in Sweden totals SEK 34,664,000 (35,800,000).

# Note 7 Other operating income

|  | Group |       | Parent compan |       |
|--|-------|-------|---------------|-------|
|  | 2021  | 2020  | 2021          | 2020  |
| Sick pay compensation                      | -     | 45    | -             | 45    |
| Research grants from Vinnova               | -     | 1,500 | -             | 1,500 |
| Exchange rate gains relating to operations | -     | 103   | -             | 103   |
| Total                                      | -     | 1,648 | -             | 1,648 |

# Note 8 Other operating expenses

|   | Group | )    | Parent con | npany |
|---|-------|------|------------|-------|
|   | 2021  | 2020 | 2021       | 2020  |
| Exchange rate losses relating to operations | 330   | 0    | 330        | 0     |
| Total                                       | 330   | 0    | 330        | 0     |

# Note 9 Disclosure on audit fees and reimbursement

|   | Group | )    | Parent com | pany |
|---|-------|------|------------|------|
|   | 2021  | 2020 | 2021       | 2020 |
| Ernst & Young AB                            |       |      |            |      |
| auditing                                    | 550   | -    | 550        | -    |
| audit work in addition to statutory audit   | 78    | -    | 78         | -    |
| tax consulting                              | -     | -    | -          | -    |
| other                                       | -     | -    | -          | -    |
| Mazars AB                                   |       |      |            |      |
| auditing                                    | -     | 455  | -          | 455  |
| audit work in addition to statutory audit   | -     | 95   | -          | 95   |
| tax consulting                              | -     | -    | -          | -    |
| other                                       | -     | -    | -          | -    |
| Kaizen Certified Public Accountants Limited |       |      |            |      |
| auditing                                    | 12    | 13   | -          | -    |
| audit work in addition to statutory audit   | -     | -    | -          | -    |
| tax consulting                              | -     | -    | -          | -    |
| other                                       | -     | -    | -          | -    |
| Total                                       | 640   | 563  | 628        | 550  |

Auditing means fees for the statutory audit, i.e. work necessary to present an Audit Report, and audit advisory services rendered coincident with auditing.

# Note 10 Leasing

All leasing agreements are recognized in the balance sheet, except for short-term leasing and minor value leasing. As of the year-end, the Group leases for office premises in the balance sheet that are reported as Rights of use assets lease amounts to SEK 0,000 (343,000). The leasing fees have been calculated at present value, using the Group's marginal loan rate, which amounted to 5%.

<sup>\*</sup> The premises rent contract runs for a period of 6 months at a time.

| Costs from leasing agreements                    | 12/31/2021 | 12/31/2020 |
|--|------------|------------|
| Depreciation of right of use assets lease        | 343        | 343        |
| Interest expenses for leasing liabilities        | 11         | 29         |
| Costs attributable to low value lease agreements | 82         | 109        |
| Amounts recognized in profit or loss             | 436        | 481        |

The total cash flow for leasing contracts in 2021 amounted to SEK 454,000 (481,000).



# Note 11 Number of employees, salaries, other benefits and social security contributions

|                             |                  | 2021                |                  | 2020                |
|-----------------------------|------------------|---------------------|------------------|---------------------|
| Average number of employees | No. of employees | Of which no. of men | No. of employees | Of which no. of men |
|                             |                  |                     |                  |                     |
| Parent company, Sweden      | 8                | 3                   | 9                | 4                   |
| Subsidiary, US              | 1                | -                   | -                | -                   |
| Total, group                | 9                | 3                   | 9                | 4                   |

|   |            | Group      | Pare       | Parent company |  |
|---|------------|------------|------------|----------------|--|
| Division of senior executives on reporting date | 12/31/2021 | 12/31/2020 | 12/31/2021 | 12/31/2020     |  |
| Board members                                   | 8          | 8          | 5          | 5              |  |
| of which men:                                   | 5          | 6          | 4          | 4              |  |
| Other employees in management, incl. CEO        | 4          | 4          | 3          | 4              |  |
| of which men:                                   | 2          | 3          | 2          | 3              |  |
| Total   | 12         | 12         | 8          | 9              |  |

#### Pensions

The group's and parent company's expense for defined contribution pension plans is SEK 1,400,000 (1,500,000).

## Remuneration to senior executives and employees

## Guidelines for remuneration for senior executives

The AGM 2020 resolved on the following guidelines for remuneration for senior executives:

Salary and other employment terms and potential share-related incentive programs should be on market terms. Senior executives should be offered basic salary on market terms based on responsibilities, roles, competence and position. Senior executives can be offered variable salary. Such variable salary should be on market terms and based on achievement of predetermined financial and operationell targets and constitute a maximum of 30 percent of basic annual salary. In order to incentivize senior executives and other key individuals on a longer term and to encourage investment in Abliva shares, a cash bonus share savings opportunity is implemented (the "LTI Bonus"). The LTI bonus is based on predetermined share related targets. The LTI Bonus is a cash program in which the participants commit to use the cash paid out by the Company to acquire shares in Abliva AB. The employee is required to keep shares purchased for compensation in the LTI bonus for at least three years.

The notice periods of senior executives shall be a minimum of three months, and for the CEO, six months. The Board of Directors' Remuneration Committee evaluates the need for a share-related incentive program yearly, and where necessary, proposes that the Board submits a proposal for resolutions by the AGM for a well-judged share-related incentive program for senior executives and/or other employees. The Annual General Meeting on May 20, 2021, decided on a four-year employee stock option program 2021/2025 for the company's CEO.

Pension benefits and compensation in the form of financial instruments, etc. to the CEO and other senior executives are payable as part of total compensation.



|  |                |              | 2021                     |                 |                |                     | 2020                          |        |
|--|----------------|--------------|--------------------------|-----------------|----------------|---------------------|-------------------------------|--------|
| Salaries and benefits for the year – group and parent company                  |                | Board & CEO  |                          | Other           |                | Board & CEO         |                               | Other  |
| Parent company   |                | 3,930        |                          | 6,753           |                | 4,587               |                               | 6,399  |
| Subsidiary   |                | 3,648        |                          | -               |                |                     |                               | -      |
| Total  |                | 7,578        |                          | 6,753           |                | 4,587               |                               | 6,399  |
| Social security costs and pension costs  |                | Board & CEO  |                          | Other           |                | Board & CEO         |                               | Other  |
| Parent company   | -              |              |                          |                 |                |                     |                               |        |
| Pension cost   |                | 364          |                          | 1,020           |                | 482                 |                               | 969    |
| Other socieal security costs   |                | 1,234        |                          | 2,161           |                | 1,466               |                               | 2,241  |
| Subsidiary   |                |              |                          |                 |                |                     |                               |        |
| Pension cost   |                | -            |                          | -               |                | -                   |                               | _      |
| Other socieal security costs   |                | 176          |                          | -               |                | -                   |                               | _      |
| Total  |                | 1,774        |                          | 3,181           |                | 1,948               |                               | 3,209  |
| Salaries and benefits for the year Group and parent company 2021               | Directors' fee | Basic salary | Variable remuneration    | Pension expense | Other benefits | Share-based payment | Social Security contributions | Total  |
| David Laskow-Pooley, Chair   | 420            | -            | -                        | -               | -              | -                   | 43                            | 463    |
| David Bejker, Board Member   | 350            |              |                          |                 |                |                     | 110                           | 460    |
| Roger Franklin, Board Member, July-December                                    | -              |              |                          |                 |                |                     | -                             | -      |
| Denise Goode, Board Member   | 340            |              |                          |                 |                |                     | 107                           | 447    |
| Jan Törnell, Board Member  | 320            |              |                          |                 |                |                     | 101                           | 421    |
| Total, Board   | 1,430          |              |                          |                 |                |                     | 360                           | 1,790  |
| Erik Kinnman, CEO, January (1 month) including notice period and severance pay | ,              | 2,500        |                          | 364             | _              |                     | 874                           | 3,738  |
| Ellen Donnelly, CEO, February-December (11 months)                             | -              | 2,499        | 734                      | -               | _              | 415                 | 176                           | 3,824  |
| Other senior executives (CSO 40%, CFO 100%, CMO 100%)                          | _              | 2,627        | 839                      | 613             | 8              |                     | 1,238                         | 5,325  |
| Total CEO and other senior executives  | -              | 7,626        | 1,573                    | 977             | 8              | 415                 | 2,288                         | 12,887 |
| Total  | 1,430          | 7,626        | 1,573                    | 977             | 8              |                     | 2,648                         | 14,677 |
|  |                |              | Vaviable                 | Danaian         |                | Chave beend         | Casial Casumitus              |        |
| Salaries and benefits for the year Group and parent company 2020               | Directors' fee | Basic salary | Variable<br>remuneration | Pension expense | Other benefits | Share-based payment | Social Security contributions | Total  |
| David Laskow Pooley, Chair   | 430            | -            |                          | -               | -              | -                   | 44                            | 474    |
| David Bejker, Board member   | 350            |              |                          |                 |                |                     | 110                           | 460    |
| Roger Franklin, Board member July-December                                     | -              | _            |                          |                 | _              |                     | -                             |        |
| Denise Goode, Board member   | 330            |              |                          |                 |                |                     | 104                           | 434    |
| Jan Törnell, Board member  | 320            | _            |                          | _               | _              | _                   | 101                           | 421    |
| Magnus Persson, Board member April-December                                    | 225            | _            |                          | _               | _              |                     | 71                            | 296    |
| Total Board  | 1,655          | _            | _                        | _               | _              | _                   | 429                           | 2,084  |
| Erik Kinnman, CEO  | -              | 2,265        | 661                      | 482             | 6              | _                   | 1,036                         | 4,450  |
| Other senior executives (CSO 40%, CFO 100%, CMO 100%,                          | -              | 2,959        | 534                      | 655             | 13             | -                   | 1,256                         | 5,417  |
| VP Bussines Development 100%)  |                | ,            |                          |                 |                |                     | ,                             | .,     |
| Total CEO and other senior executives  | -              | 5,223        | 1,195                    | 1,137           | 19             | -                   | 2,293                         | 9,867  |
| Total  | 1,655          | 5,223        | 1,195                    | 1,137           | 19             | -                   | 2,721                         | 11,951 |

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All Directors' fees resolved by the AGM on 20 May 2021 were charged to profit or loss for 2021. Board Member Roger Franklin has waived his fee.



#### Other senior executives:

There are three other senior executives during the period of January to December 2021. The amount stated in the basic salary column corresponding to 2.4 (2.9) full-time equivalents for 2021.

Eskil Elmer, CSO, did not receive any other compensation apart from basic salary and variable compensation and other benefits stated in the amount for other senior executives.

Catharina Johansson, CFO, did not receive any other compensation apart from basic salary and variable compensation stated in the amount for other senior executives.

Magnus Hansson, CMO, did not receive any other compensation apart from basic salary, variable compensation and other benefits stated in the amount for other senior executives.

Other benefits include compensation, to Eskil Elmér and Magnus Hansson, within the framework of agreement for mitochondrial energy regulation projects, for 2021. Compensation to related parties, within the framework of the agreement for mitochondrial energy regulation projects, is reported as Other external costs in the income statement.

#### Pensions

There is no contracted retirement age for the CEO or other senior executives. The pension plan is defined-contribution, which means that the company's only commitment is to pay the premium according to the premium plan. Pensionable salary means monthly salary multiplied by 12.2.

#### Severance pay

There is a mutual notice period of six months between the Company and the CEO. In addition to this notice period, severance pay subject to a maximum of six months' salary plus benefits may be payable to the CEO. A mutual notice period of three to six months applies between the Company and other senior executives.

# Note 12 Employee Stock Option Program

The AGM on May 20, 2021, decided on a four-year incentive stock option program 2021/2025 for the Company's CEO. The incentive stock option program entitles the holder to a new ordinary share in Abliva AB up to a maximum of 4,600,000 ordinary shares. The redemption price amounts to 0.725 öre. The program is vested at 25% per year on June 1, 2022, June 1, 2023, June 1, 2024 and June 1, 2025. Latest redemption date is December 31, 2025.

| Valuation Employee Stock Option Program | 6/1/2021      |
|---|---------------|
| Dividend                                |               |
| Expected volatality                     | 0.55          |
| Interest rate                           | -0.02%        |
| Valutaion of the share (SEK)            | 0.725         |
| Valuation model                         | Black-Scholes |

During 2021, costs for the employee stock option program, excluding social security contributions, were charged to operating profit of SEK 415,000. No costs for social security contributions are expected to arise.

# Note 13 Financial costs

|                       | Gro  | Group |      | npany |
|-----------------------|------|-------|------|-------|
|                       | 2021 | 2020  | 2021 | 2020  |
| Interest costs        | -12  | -1    | -    | -1    |
| Exchange rate loss    | -    | -29   | -    | -     |
| Total financial costs | -12  | -30   | -    | -1    |

All interest costs relate to financial liabilities measured at amortized cost.



# Note 14 Tax

| Tax for the year                               | Group | Parent company |      |      |
|--|-------|----------------|------|------|
|  | 2021  | 2020           | 2021 | 2020 |
| Current tax on profit/loss for the year        | -4    | -              | -    | -    |
| Deferred tax relating to temporary differences | -     | -              | -    | -    |
| Total reported tax expense                     | -4    | _              | -    | -    |

Income tax in Sweden is computed at 20.6% (21,4%) on taxable profits for the year. Tax in other jurisdictions is computed at the tax rates applying in each jurisdiction. A reconciliation between reported profit or loss and the year's tax expense follows:

| Tax for the year  | Grou     | ıp      | Parent company |         |  |
|---|----------|---------|----------------|---------|--|
|   | 2021     | 2020    | 2021           | 2020    |  |
| Profit/loss before tax  | -123,494 | -59,994 | -123,072       | -59,961 |  |
| Tax revenue for the year  |          |         |                |         |  |
| Tax computed at Swedish tax rate  | 25,440   | 12,839  | 25,353         | 12,832  |  |
| Tax effect of non-deductible expenses   | -1       | -18     | -1             | -18     |  |
| Tax effect of non-taxable revenues  | -        | -       | -              | -       |  |
| Tax effect operations/impairment shares in subsidary                                    | -        | -       | -              | -       |  |
| Tax effect divest business/shares in subsidary  | -        | -       | -              | -       |  |
| Tax effect of deductible expenses and taxable revenues reported directly against equity | 851      | 3,084   | 851            | 3,084   |  |
| Difference in tax rates between Sweden and foreign subsidiary                           | -        | -33     | -              | -       |  |
| Tax effect of deficits for which no deferred tax receivable is reported                 | -26,294  | -15,872 | -26,203        | -15,898 |  |
| Total   | -4       | -       | -              | -       |  |
| Adjustments recognized in the current year for previous year's current tax              | -        | -       | -              | -       |  |
| Reported tax expense for the year   | -4       | _       | -              | -       |  |

Reported tax expense relate to the US subsidiary, that reports positive result before tax.

The Group's total loss carry forwards as per December 31, 2021 amount to approximately SEK 746,391,000
(618,957,000) whereof SEK 720,526,000 (593,098,000) refers to the Parent Company. The tax loss carry forwards have no fixed maturity. Deferred tax assets attributable to the loss carry forward has been valued at zero as it is currently not possible to assess when tax losses carry forwards can be utilized.

# Note 15 Earnings per share

# Basic and diluted earnings per share.

The following profit or loss and weighted average number of ordinary shares have been used to compute basic and diluted earnings per share

|   | Gro          | up          |
|---|--------------|-------------|
|   | 2021         | 2020        |
| Profit/loss for the year attributable to equity holders of the parent (SEK) | -123,491,709 | -59,988,500 |
| Weighted average number of ordinary shares before dilution                  | 370,168,023  | 250,321,204 |
| Basic earnings per share, SEK   | -0.33        | -0.24       |

# Diluted earnings per share

There were no equity-based remuneration programs that could give rise to dilution effects at the end of the financial year.

# Note 16 Capitalized product development expenditure

|  | Group |         | Parent co | mpany   |
|--|-------|---------|-----------|---------|
|  | 2021  | 2020    | 2021      | 2020    |
| Opening cost   | -     | 51,706  | -         | 51,706  |
| Correction of error pertaining to capitalized development costs* | -     | -51,706 | -         | -51,706 |
| Closing accumulated cost   | -     | -       | -         | -       |
| Closing carrying amount  |       |         |           |         |

\*The Board of Swedish Accounting Supervision examined the Company's interim report as of September 30, 2020 and the Annual report for 2020 regarding the accounting of capitalized development costs, and referred the case to Finansinspektionen (FI). In October FI announced that they would investigate whether Abliva AB complied with the regulations for accounting in its annual and consolidated accounts for 2020. More specifically, whether Abliva AB had violated the provisions of Article 4 of the European Parliament and Council Regulation (EC) No 1606/2002 of 19 July 2002 on the application of international accounting standards, and the Annual Accounts Act (1995: 1554) regarding the accounting of development expenses as an intangible asset. As an adaptation to the The Board of Swedish Accounting Supervision's view on the handling of capitalized development costs (IAS 38), the Board has made a correction of Opening balances 1 January 2020 in Equity, in accordance with IAS 8 Accounting Policies, Changes in Accounting Estimates and Errors. The total adjustment of SEK 51,706,000 refers to accumulated capitalized development costs related to the NeuroSTAT program processed up to and including 31 March 2017.

No product development expenditures have been capitalized in 2021. The products are not considered to meet the requirements for capitalization of product development fees. For further information see Note 3.

The total amount of expenditure for research and development expensed during the year was SEK 90,690,000 (29,510,000).



# Note 17 Patents

|                                  | Gro           | Group   |         | mpany   |
|----------------------------------|---------------|---------|---------|---------|
|                                  | 2021          | 2020    | 2021    | 2020    |
| Opening cost                     | 33,771        | 32,279  | 33,771  | 32,279  |
| Purchases during the year        | 1,562         | 1,492   | 1,562   | 1,492   |
| Impairment patent                | -153          | -       | -153    | -       |
| Closing accumulated cost         | 35,180 33,771 |         | 35,180  | 33,771  |
|                                  | -             | -       | -       | -       |
| Opening amortization             | -12,800       | -10,778 | -12,800 | -10,778 |
| Amortization for the year        | -2,136        | -2,022  | -2,136  | -2,022  |
| Impairment                       | 49            | -       | 49      | -       |
| Closing accumulated amortization | -14,887       | -12,800 | -14,887 | -12,800 |
|                                  | -             | -       | -       | -       |
| Closing carrying amount          | 20,293        | 20,971  | 20,293  | 20,971  |

# Note 18 Other intagible assets

|                                  | Grou   | Group  |        | mpany  |
|----------------------------------|--------|--------|--------|--------|
|                                  | 2021   | 2020   | 2021   | 2020   |
| Opening cost                     | 2,864  | 2,864  | 2,820  | 2,820  |
| Purchases during the year        | -      | -      | -      | -      |
| Closing accumulated cost         | 2,864  | 2,864  | 2,820  | 2,820  |
| Opening amortization             | -1,520 | -1,385 | -1,477 | -1,342 |
| Amortization for the year        | -134   | -135   | -134   | -135   |
| Closing accumulated amortization | -1,654 | -1,520 | -1,611 | -1,477 |
| Closing carrying amount          | 1,210  | 1,344  | 1,210  | 1,344  |

Refers software, acquired in 2011, for compiling documentation for use in a future application for drug registration and part of the Biotica acquisition completed in 2013.

# Note 19 Equipment

|                                  | Grou   | Group  |        | npany  |
|----------------------------------|--------|--------|--------|--------|
|                                  | 2021   | 2020   | 2021   | 2020   |
| Opening cost                     | 1,479  | 1,479  | 1,479  | 1,479  |
| Purchases during the year        | 65     | -      | 65     | -      |
| Closing accumulated cost         | 1,544  | 1,479  | 1,544  | 1,479  |
| Opening depreciation             | -1,438 | -1,380 | -1,438 | -1,380 |
| Depreciation for the year        | -46    | -58    | -46    | -58    |
| Closing accumulated depreciation | -1,484 | -1,438 | -1,484 | -1,438 |
| Closing carrying amount          | 60     | 41     | 60     | 41     |

# Note 20 Right of use assets lease

|                                  | Group  | Group |      | npany |
|----------------------------------|--------|-------|------|-------|
|                                  | 2021   | 2020  | 2021 | 2020  |
|                                  |        |       |      |       |
| Opening cost                     | 1,030  | 1,030 | -    | -     |
| Purchases during the year        | -      | -     | -    | -     |
| Closing accumulated cost         | 1,030  | 1,030 | -    | -     |
|                                  | -      | -     | -    | -     |
| Opening depreciation             | -687   | -343  | -    | -     |
| Depreciation for the year        | -343   | -344  | -    | -     |
| Closing accumulated depreciation | -1,030 | -687  | -    | -     |
|                                  | -      | -     | -    | -     |
| Closing carrying amount          | -      | 343   | -    | -     |

For further information regarding the transition to IFRS 16 Leasing agreements, please see Note 2 Significant accounting principles and Note 10 Leasing agreements.



# Note 21 Participations in subsidiaries

|   | Parent compa |        |
|---|--------------|--------|
|   | 2021         | 2020   |
| Opening cost  | 23,625       | 23,625 |
| Shares Abliva Inc   | 8            | -      |
| Shareholder contribution Abliva Inc                         | 830          | -      |
| Shares Abliva Incentive AB                                  | 25           | -      |
| Shareholder contribution NeuroVive Pharmaceutical Asia Ltd. | 69           | -      |
| Closing cost  | 24,557       | 23,625 |

#### Subsidiaries

|                    | Abliva Inc | Abliva Incentive AB | NeuroVive Pharmaceutical Asia, Inc. |
|--------------------|------------|---------------------|-------------------------------------|
| Domicile           | Delaware   | Lund                | Hong Kong                           |
| Share of equity, % | 100%       | 100%                | 82.47%                              |
| Share of votes, %  | 100%       | 100%                | 82.47%                              |
| Book value         | 838        | 25                  | 23,694                              |

NeuroVive Pharmaceutical AB's subsidiary NeuroVive Pharmaceutical Asia, Ltd. has non-controlling holdings of 17,53%. The share of the votes is identical to the share of ownership. Non-controlling holdings total SEK 9,000 (0,000). The subsidiary, NeuroVive Pharmaceutical Asia Ltd., holds the Asian territorial licensing rights for NeuroSTAT and the agreements with the Chinese pharmaceutical company Sihuan Pharmaceutical and Sanofi Korea. The Hong Kong company is owned by Abliva AB 82.47% and Business Research Ltd. 17.53%.

# Financial information in summary for subsidiaries with non-controlling holdings.

The following information relates to the subsidary NeuroVive Pharmaceutical Asia Ltd, and relates to amounts before intra-group eliminations. The intangible assests was impaired during 2018.

| Summary, Balance Sheet  | 2021               | 2020           |
|---|--------------------|----------------|
| Intangible assets   | -                  | -              |
| Current assets  | 3                  | 3              |
| Cash and bank balances  | 63                 | 9              |
| Total assets  | 66                 | 12             |
|   | -                  | -              |
| Current liabilities   | 17                 | -              |
| Total liabilities   | 17                 | -              |
| Net assets  | 49                 | 12             |
| Summary, earnings and comprehensive income  | 2021               | 2020           |
| Revenue   | -                  | -              |
| Net profit for the year   | -38                | -33            |
| Net profit for the year   |                    |                |
| Comprehensive income for the year  Total comprehensive income attributable to non-controlling holdings  | -38<br>7           | -33<br>6       |
| Comprehensive income for the year   |                    |                |
| Comprehensive income for the year Total comprehensive income attributable to non-controlling holdings   | 7                  | 6              |
| Comprehensive income for the year Total comprehensive income attributable to non-controlling holdings Summary Cash Flow Statement   | 7                  | 6              |
| Comprehensive income for the year  Total comprehensive income attributable to non-controlling holdings  Summary Cash Flow Statement  Cash flow from operating activities  | 7 2021             | 2020           |
| Comprehensive income for the year  Total comprehensive income attributable to non-controlling holdings  Summary Cash Flow Statement  Cash flow from operating activities  Cash flow from operating activities   | 7 2021             | 2020           |
| Comprehensive income for the year Total comprehensive income attributable to non-controlling holdings  Summary Cash Flow Statement  Cash flow from operating activities  Cash flow from operating activities  Interest received   | 7 2021             | 2020           |
| Comprehensive income for the year Total comprehensive income attributable to non-controlling holdings  Summary Cash Flow Statement  Cash flow from operating activities  Cash flow from operating activities  Interest received  Interest paid  | 7 2021             | 2020           |
| Comprehensive income for the year Total comprehensive income attributable to non-controlling holdings  Summary Cash Flow Statement Cash flow from operating activities Cash flow from operating activities Interest received Interest paid Income tax paid  | 7 2021             | 2020           |
| Comprehensive income for the year  Total comprehensive income attributable to non-controlling holdings  Summary Cash Flow Statement  Cash flow from operating activities  Cash flow from operating activities  Interest received  Interest paid  Income tax paid  Internal group transactions   | -38<br>            | - 33<br>33<br> |
| Comprehensive income for the year  Total comprehensive income attributable to non-controlling holdings  Summary Cash Flow Statement  Cash flow from operating activities  Cash flow from operating activities  Interest received  Interest paid  Income tax paid  Internal group transactions  Cash flow from operating activities  | -38<br>            | - 33<br>33<br> |
| Comprehensive income for the year  Total comprehensive income attributable to non-controlling holdings  Summary Cash Flow Statement  Cash flow from operating activities  Cash flow from operating activities  Interest received  Interest paid  Income tax paid  Internal group transactions  Cash flow from operating activities  Cash flow from operating activities   | -3838              | - 33<br>33<br> |
| Comprehensive income for the year  Total comprehensive income attributable to non-controlling holdings  Summary Cash Flow Statement  Cash flow from operating activities  Cash flow from operating activities  Interest received  Interest paid  Income tax paid  Internal group transactions  Cash flow from operating activities  Cash flow from investing activities  Cash flow from financing activities  | 7 2021  -38  90    | -33<br>33<br>  |
| Comprehensive income for the year  Total comprehensive income attributable to non-controlling holdings  Summary Cash Flow Statement  Cash flow from operating activities  Cash flow from operating activities  Interest received  Interest paid  Income tax paid  Internal group transactions  Cash flow from operating activities  Cash flow from investing activities  Cash flow from investing activities  Cash flow from financing activities  Change in cash and cash equivalents            | 7 2021  -38  90 52 | -33<br>33<br>  |
| Comprehensive income for the year  Total comprehensive income attributable to non-controlling holdings  Summary Cash Flow Statement  Cash flow from operating activities  Cash flow from operating activities  Interest received  Interest paid  Income tax paid  Internal group transactions  Cash flow from operating activities  Cash flow from investing activities  Cash flow from financing activities  Change in cash and cash equivalents  Cash and cash equivalents at beginning of year | 7 2021  -38        | -33<br>33<br>  |



# Not 22 Other long-term securities

|                        | Group        |              | Parent company |              |
|------------------------|--------------|--------------|----------------|--------------|
|                        | 31 Dec. 2021 | 31 Dec. 2020 | 31 Dec. 2021   | 31 Dec. 2020 |
| Isomerase Therapeutics | 13,101       | 13,101       | 13,101         | 13,101       |
| Summa                  | 13,101       | 13,101       | 13,101         | 13,101       |

In June 2013, the company entered into a cooperation agreement with Isomerase Therapeutics Ltd. The purpose of the holding is to promote the business of Abliva by creating a lasting connection with Isomerase. Abliva does not have any influence in the company, neither a significant nor a joint influence. The financial effects that arise as a result of ownership are that Abliva receives dividends based on our shareholding and that Abliva replaces Isomerase Therapeutics Ltd. for the work they do in accordance with concluded consulting agreements. In order to strengthen the cooperation between Abliva and Isomerase and to ensure that Abliva's project continues to develop with the highest priority, in January 2016, the Company entered into an acquisition agreement with the shareholders in Isomerase regarding the acquisition of a share of Isomerase. Abliva owns 84,444 shares in Isomerase, which corresponds to approximately 10 per cent of the total number of shares in Isomerase.

Abliva has no board representation or management function in Isomerase, but has the right to take part of the company's earnings and balance sheet twice a year.

# Note 23 Prepaid expenses and accrued income

|                        | Gro          | Group        |              | ompany       |
|------------------------|--------------|--------------|--------------|--------------|
|                        | 31 Dec. 2021 | 31 Dec. 2020 | 31 Dec. 2021 | 31 Dec. 2020 |
| Other prepaid expenses | 1,003        | 586          | 1,003        | 585          |
| Total                  | 1,003        | 586          | 1,003        | 585          |

# Note 24 Cash and cash equivalents/cash and bank balances

|                        | Gro          | Group        |              | ompany       |
|------------------------|--------------|--------------|--------------|--------------|
|                        | 31 Dec. 2021 | 31 Dec. 2020 | 31 Dec. 2021 | 31 Dec. 2020 |
| Cash and bank balances | 22,339       | 61,643       | 21,696       | 61,634       |
| Tota                   | 22,339       | 61,643       | 21,696       | 61,634       |

# Note 25 Share capital

|                                     | Parent company and group |                        |                       |  |
|-------------------------------------|--------------------------|------------------------|-----------------------|--|
|                                     | No. of shares            | Quotient value,<br>SEK | Share capital,<br>SEK |  |
| Opening share capital, 1 Jan. 2020  | 185,952,591              | 0.05                   | 9,297,629             |  |
| New share issue                     | 110,387,541              | 0.05                   | 5,519,378             |  |
| Closing share capital, 31 Dec. 2020 | 296,340,132              | 0.05                   | 14,817,007            |  |
| Opening share capital, 1 Jan. 2021  | 296,340,132              | 0.05                   | 14,817,007            |  |
| New share issue                     | 106,666,666              | 0.05                   | 5,333,333             |  |
| Closing share capital, 31 Dec. 2021 | 403,006,798              | 0.05                   | 20,150,340            |  |

All shares of the same class, are fully paid-up and are entitled to one vote. No shares are reserved to the transfer pursuant to option or other agreements.

A new issue of 328,941,492 shares raising a total of SEK 23,229,110.50 (after issue expenses of SEK 1,221, 909.50) was completed in April 2021. The new issue increased share capital by SEK 1,630,068.00 with the remaining amount of SEK 21,599,042.53 recognized against other paid-up capital/share premium reserve. A rights issue of 74,065,306 shares raising a total of SEK 52,638,546.50 (after issue expenses of SEK 2,910, 433.00) was completed in May 2021. The rights issue increased share capital by SEK 3,703,265.30 with the remaining amount of SEK 48,935,681.17 recognized against other paid-up capital/share premium reserve.

| Allocation Retained Earnings |              |
|------------------------------|--------------|
| Share premium reserv         | 70,534,324   |
| Ackumulated profit/loss      | 93,016,663   |
| Profit/loss for the year     | -123,072,362 |
| Total                        | 40,478,625   |

The Board of Directors proposes that unappropriated retained earnings of SEK 43,091,346 be carried forward. Accordingly, no dividend is proposed.

# Note 26 Other paid-up capital – group

Other paid-up capital consists of the share premium reserve, amounts originally reported in the share premium reserve that were subsequently transferred to accumulated profit or loss, as well as the statutory reserve and shareholders' contributions.

The share issue completed April 2021, and May 2021, increased other paid-up capital by SEK 70,534,324 (67,044,727) after deducting issue expenses of SEK 4,132,343 (14,412,495).



# Note 27 Reserves – group

Reserves means the translation reserve, i.e. currency translation differences on translating foreign operations to SEK, which are recognized in other comprehensive income.

# Note 28 Retained earnings – group

Retained earnings consist of accumulated profit or loss and comprehensive income for the year.

# Note 29 Accrued expenses and deferred income

|  | Group        |              | Parent company |              |
|--|--------------|--------------|----------------|--------------|
|  | 31 Dec. 2021 | 31 Dec. 2020 | 31 Dec. 2021   | 31 Dec. 2020 |
| Accrued salary including social security contributions                 | 1,880        | 2,076        | 1,086          | 2,076        |
| Accrued vacation pay liability including social security contributions | 475          | 1,197        | 475            | 1,197        |
| Accrued Directors' fees incl. social security contributions            | 1,193        | 298          | 1,193          | 298          |
| Accrued pension expenses   | 336          | 338          | 336            | 338          |
| Other accrued expenses   | 3,613        | 1,424        | 3,480          | 1,408        |
| Total  | 7,497        | 5,334        | 6,570          | 5,317        |

# Note 30 Pledged assets and contingent liabilities

The Company has no pledged assets or contingent liabilities.

# Note 31 Transactions with related parties

Transactions between the Parent Company and its subsidiary, which is closely related to the Company, have been eliminated on consolidation and accordingly, disclosures on these transactions are not presented in this note. Disclosures on transactions between the group and other related parties are presented below.

During 2021 compensation based on sales has been paid under the agreement, in relation to mitochondrial energy regulation projects, with the Research Group at Lund University, which includes CSO Eskil Elmér and CMO Magnus Hansson. A part from compensation within the framework of the agreement for mitochondrial energy regulation projects, and remuneration to senior executives, no transactions with related parties have occured during 2021 (2020). Disclosures on remuneration of senior executives and other related parties are presented in note 11.

The company has no outstanding receivables from, or liabilities to, related parties.

# Note 32 Dividend

No dividend was paid in 2021 or 2020. No dividend will be proposed to the AGM on 20 May, 2022.

# Note 33 Adoption of financial statements

These consolidated accounts and annual accounts were adopted by the Board of Directors for issuance on 27 April 2022.

# Note 34 Post-balance sheet events

An extraordinary general meeting was held on 14 January 2022. The general meeting approved the Board of Directors' resolution from 20 December 2021 on a directed issue of convertibles.

The Ukraine war has created unrest and insecurity in the world. The business impact is difficult to predict, but the ongoing war has caused unfavorable market conditions and may affect the ability to raise capital.



# **Board of Directors' declaration**

The Board of Directors and Chief Executive Officer declare that the consolidated accounts have been prepared in accordance with International Financial Reporting Standards (IFRS) as endorsed by the EU and give a true and fair view of the group's financial position and results of operations. The annual accounts have been prepared in accordance with generally accepted accounting principles, and give a true and fair view of the parent company's financial position and results of operations.

The Statutory Administration Report of the group and parent company gives a true and fair view of the progress of the group's and parent company's operations, financial position and results of operations, and states significant risks and uncertainty factors facing the parent company and the companies included in the group.

The Income Statements and Balance Sheets will be submitted to the Annual General Meeting on May 20, 2022 for adoption.

Lund April 27, 2022

# David Laskow-Pooley Chair of the Board

David BejkerDenise GoodeBoard memberBoard member

Roger FranklinJan TörnellBoard memberBoard member

Ellen Donnelly CEO

Our Audit Report was presented on April 28, 2022

Ernst & Young AB

Ola Larsmon Authorized Public Accountant

# Auditor's report

# TO THE GENERAL MEETING OF THE SHAREHOLDERS OF ABLIVA AB (PUBL), CORPORATE IDENTITY NUMBER 556595-6538

# REPORT ON THE ANNUAL ACCOUNTS AND CONSOLIDATED ACCOUNTS OPINIONS

We have audited the annual accounts and consolidated accounts of Abliva AB (publ) except for the corporate governance statement on pages 23-30 for the year 2021. The annual accounts and consolidated accounts of the company are included on pages 14-59 in this document.

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 2021 and its financial performance and cash flow 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 2021 and their financial performance and cash flow for the year then ended in accordance with International Financial Reporting Standards (IFRS), as adopted by the EU, and the Annual Accounts Act. Our opinions do not cover the corporate governance statement on pages 23-30. The statutory administration report is consistent with the other parts of the annual accounts and consolidated accounts.

We therefore recommend that the general meeting of shareholders adopts the income statement and balance sheet for the parent company and the group.

Our opinions in this report on the annual accounts and consolidated accounts are consistent with the content of the additional report that has been submitted to the parent company's audit committee in accordance with the Audit Regulation (537/2014) Article 11.

# **BASIS FOR OPINIONS**

We conducted our audit in accordance with International Standards on Auditing (ISA) and generally accepted auditing stan-

dards in Sweden. Our responsibilities under those standards are further described in the Auditor's Responsibilities section. We are independent of the parent company and the group in accordance with professional ethics for accountants in Sweden and have otherwise fulfilled our ethical responsibilities in accordance with these requirements. This includes that, based on the best of our knowledge and belief, no prohibited services referred to in the Audit Regulation (537/2014) Article 5.1 have been provided to the audited company or, where applicable, its parent company or its controlled companies within the EU.

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

# Significant uncertainties regarding the assumption of going concern

We would like to draw attention to the information provided on pages 33, 34 and 37 of the Annual Report and consolidated financial statements, where it is presented that the company reported a loss of kSEK 123,427 for the year ended 31 December, 2021, that cash flow after investment activities is negative by 115,164 kSEK for 2021 and that cash and cash equivalents amount to kSEK 22,339 as of 31 December 2021. These circumstances, together with other circumstances mentioned in the Financial Position and going concern section of the Annual Report on page 17, indicate that there are significant uncertainties that may lead to significant doubts about the entity's ability to continue its operations. We have not modified our statement because of this.

#### Other information

The audit of the Annual Report for 2020 has been carried out by another auditor who has issued an auditor's report dated 27 April 2021 with unmodified statements in the Annual Report and consolidated financial statements.

#### **KEY AUDIT MATTERS**

Key audit matters of the audit are those matters that, in our professional judgment, were of most significance in our audit of the annual accounts and consolidated accounts of the current period. In addition to the significant uncertainties regarding the assumption of going concern, we have identified additional key audit matters which are described below. These matters were addressed in the context of our audit of, and in forming our opinion thereon, the annual accounts and consolidated accounts as a whole, but we do not provide a separate opinion on these matters. For each matter below, our description of how our audit addressed the matter is provided in that context.

We have fulfilled the responsibilities described in the Auditor's responsibilities for the audit of the financial statements section of our report, including in relation to these matters. Accordingly, our audit included the performance of procedures designed to respond to our assessment of the risks of material misstatement of the financial statements. The results of our audit procedures, including the procedures performed to address the matters below, provide the basis for our audit opinion on the accompanying financial statements.

## **VALUATION OF PATENTS**

## Description

As of 31 December 2021, the carrying amount of patents amounts to 20,293 kSEK, which corresponds to 34.4% of the Group's total assets and 24.5% of the parent company's total assets.

The company annually tests and in case of an indication of a decline in value that carrying amounts do not exceed the estimated recoverable amount. The recoverable amount is determined by a present value calculation of future cash flows. Future cash flows are based on management's forecasts and include a number of assumptions, including earnings development, growth, investment needs and discount rates.

Changes in assumptions have a major impact on the calculation of the recoverable amount and the assumptions applied by the company are therefore of major importance to the assessment of impairment need.

We have therefore assessed that the accounting of patents is a key audit matter in the audit.

A description of the impairment test is found in the assessments, estimates and assumptions section of Note 3 and information on patents is found in Note 17.

How our audit addressed this key audit matter

In our audit, we have evaluated and reviewed management's process for establishing impairment tests, including by evaluating past accuracy in forecasts and assumptions. We have also made comparisons with other companies to evaluate the reasonableness of future cash flows and growth assumptions and with the help of our valuation specialists tested the selected discount rate and assumptions about long-term growth. We have also reviewed the company's model and method for conducting impairment tests.

We have reviewed the disclosures in the annual report.

# **VALUATION OF SHARES IN SUBSIDIARIES**

Description

As of 31 December 2021, the carrying amount of shares in Group companies amounts to kSEK 24,557, which corresponds to 29.7% of the parent company's total assets.

The company annualy tests and in case of an indication of a decline in value that carrying amounts do not exceed the estimated recoverable amount. The recoverable amount is determined by a present value calculation of future cash flows. Future cash flows are based on management's forecasts and include a number of assumptions, including earnings development, growth, investment needs and discount rates.

Changes in assumptions have a major impact on the calculation of the recoverable amount and the assumptions applied by the company are therefore of great importance to the assessment of impairment need.

We have therefore assessed that the accounting of shares in group companies is a key audit matter in the audit.

A description of the impairment test is found in the section assessments, estimates and assumptions in Note 3 and information about shares in group companies is found in Note 21.

How our audit addressed this key audit matter

In our audit, we have evaluated and reviewed the company's process for establishing impairment tests, including by evaluating previous accuracy in forecasts and assumptions. We have also made comparisons with other companies to evaluate the reasonableness of future cash flows and growth assumptions and with the help of our valuation specialists tested the selected discount rate and assumptions about long-term growth. We have also reviewed the company's model and method for conducting impairment tests.

We have reviewed the disclosures in the annual report.

# OTHER INFORMATION THAN THE ANNUAL ACCOUNTS AND CONSOLIDATED ACCOUNTS

This document also contains other information than the annual accounts and consolidated accounts and is found on pages 1-13 and 65-68. The Board of Directors and the Managing Director are responsible for this other information.

Our opinion on the annual accounts and consolidated accounts does not cover this other information and we do not express any form of assurance conclusion regarding this other information.

In connection with our audit of the annual accounts and consolidated accounts, our responsibility is to read the information identified above and consider whether the information is materially inconsistent with the annual accounts and consolidated accounts. In this procedure we also take into account our knowledge otherwise obtained in the audit and assess whether the information otherwise appears to be materially misstated.

If we, based on the work performed concerning this information, conclude that there is a material misstatement of this other information, we are required to report that fact. We have nothing to report in this regard.

# RESPONSIBILITIES OF THE BOARD OF DIRECTORS AND THE MANAGING DIRECTOR

The Board of Directors and the Managing Director are responsible for the preparation of the annual accounts and consolidated accounts and that they give a fair presentation in accordance with the Annual Accounts Act and, concerning the consolidated accounts, in accordance with IFRS as adopted by the EU. The Board of Directors and the Managing Director are also responsible for such internal control as they 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.

In preparing the annual accounts and consolidated accounts, The Board of Directors and the Managing Director are responsible for the assessment of the company's and the group's ability to continue as a going concern. They disclose, as applicable, matters related to going concern and using the going concern basis of accounting. The going concern basis of accounting is however not applied if the Board of Directors and the Managing Director intends to liquidate the company, to cease operations, or has no realistic alternative but to do so.

The Audit Committee shall, without prejudice to the Board of Director's responsibilities and tasks in general, among other things oversee the company's financial reporting process.



# **AUDITOR'S RESPONSIBILITY**

Our objectives are to obtain reasonable assurance about whether the annual accounts and consolidated accounts as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinions. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with ISAs and generally accepted auditing standards in Sweden will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these annual accounts and consolidated accounts.

As part of an audit in accordance with ISAs, we exercise professional judgment and maintain professional skepticism throughout the audit. We also:

- Identify and assess the risks of material misstatement of the annual accounts and consolidated accounts, whether due to fraud or error, design and perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and appropriate to provide a basis for our opinions. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.
- Obtain an understanding of the company's internal control relevant to our audit 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.
- Evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by the Board of Directors and the Managing Director.
- Conclude on the appropriateness of the Board of Directors' and the Managing Director's use of the going concern basis of accounting in preparing the annual accounts and consolidated accounts. We also draw a conclusion, based on the audit evidence obtained, as to whether any material uncertainty exists related to events or conditions that may

cast significant doubt on the company's and the group's ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in our auditor's report to the related disclosures in the annual accounts and consolidated accounts or, if such disclosures are inadequate, to modify our opinion about the annual accounts and consolidated accounts. Our conclusions are based on the audit evidence obtained up to the date of our auditor's report. However, future events or conditions may cause a company and a group to cease to continue as a going concern.

- Evaluate the overall presentation, structure and content of the annual accounts and consolidated accounts, including the disclosures, and whether the annual accounts and consolidated accounts represent the underlying transactions and events in a manner that achieves fair presentation.
- Obtain sufficient and appropriate audit evidence regarding
  the financial information of the entities or business activities
  within the group to express an opinion on the consolidated
  accounts. We are responsible for the direction, supervision and
  performance of the group audit. We remain solely responsible
  for our opinions.

We must inform the Board of Directors of, among other matters, the planned scope and timing of the audit. We must also inform of significant audit findings during our audit, including any significant deficiencies in internal control that we identified.

We must also provide the Board of Directors with a statement that we have complied with relevant ethical requirements regarding independence, and to communicate with them all relationships and other matters that may reasonably be thought to bear on our independence, and where applicable, actions taken to eliminate threats or related safeguards applied.

From the matters communicated with the Board of Directors, we determine those matters that were of most significance in the audit of the annual accounts and consolidated accounts, including the most important assessed risks for material misstatement, and are therefore the key audit matters. We describe these matters in the auditor's report unless law or regulation precludes disclosure about the matter.

# REPORT ON OTHER LEGAL AND REGULATORY REQUIREMENTS

Report on the audit of the administration and the proposed appropriations of the company's profit or loss.

# **OPINIONS**

In addition to our audit of the annual accounts and consolidated accounts, we have also audited the administration of the Board of Directors and the Managing Director of Abliva AB (publ) for the year 2021 and the proposed appropriations of the company's profit or loss.

We recommend to the general meeting of shareholders that the profit be appropriated (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.

# **BASIS FOR OPINIONS**

We conducted the audit in accordance with generally accepted auditing standards in Sweden. Our responsibilities under those standards are further described in the Auditor's Responsibilities section. We are independent of the parent company and the group in accordance with professional ethics for accountants in Sweden and have otherwise fulfilled our ethical responsibilities in accordance with these requirements.

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

# 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. At the proposal of a dividend, this includes an assessment of whether the dividend is justifiable considering the requirements which the company's and the group's type of operations, size and risks place on the size of the parent company's and the group's equity, consolidation requirements, liquidity and position in general.

The Board of Directors is responsible for the company's organization and the administration of the company's affairs. This includes



among other things continuous assessment of the company's and the group's financial situation and ensuring that the company's organization is designed so that the accounting, management of assets and the company's financial affairs otherwise are controlled in a reassuring manner. The Managing Director shall manage the ongoing administration according to the Board of Directors' guidelines and instructions and among other matters take measures that are necessary to fulfill the company's accounting in accordance with law and handle the management of assets in a reassuring manner.

# **AUDITOR'S RESPONSIBILITY**

Our objective concerning the audit of the administration, and thereby our opinion about discharge from liability, is to obtain audit evidence to assess with a reasonable degree of assurance whether any member of the Board of Directors or the Managing Director in any material respect:

- has undertaken any action or been guilty of any omission which can give rise to liability to the company, or
- in any other way has acted in contravention of the Companies
   Act, the Annual Accounts Act or the Articles of Association.

Our objective concerning the audit of the proposed appropriations of the company's profit or loss, and thereby our opinion about this, is to assess with reasonable degree of assurance whether the proposal is in accordance with the Companies Act.

Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with generally accepted auditing standards in Sweden will always detect actions or omissions that can give rise to liability to the company, or that the proposed appropriations of the company's profit or loss are not in accordance with the Companies Act.

As part of an audit in accordance with generally accepted auditing standards in Sweden, we exercise professional judgment and maintain professional skepticism throughout the audit. The examination of the administration and the proposed appropriations of the company's profit or loss is based primarily on the audit of the accounts. Additional audit procedures performed are based on our professional judgment with starting point in risk and materiality.

This means that we focus the examination on such actions, areas and relationships that are material for the operations and where deviations and violations would have particular importance for the company's situation. We examine and test decisions undertaken, support for decisions, actions taken and other circumstances that are relevant to our opinion concerning discharge from liability. As a 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.

# THE AUDITOR'S EXAMINATION OF THE ESEF REPORT

# Opinion

In addition to our audit of the annual accounts and consolidated accounts, we have also examined that the Board of Directors and the Managing Director have prepared the annual accounts and consolidated accounts in a format that enables uniform electronic reporting (the Esef report) pursuant to Chapter 16, Section 4(a) of the Swedish Securities Market Act (2007:528) for Abliva AB for the financial year 2021.

Our examination and our opinion relate only to the statutory requirements.

In our opinion, the ESEF report #[checksum] has been prepared in a format that, in all material respects, enables uniform electronic reporting.

# Basis for opinion

We have performed the examination in accordance with FAR's recommendation RevR 18 Examination of the ESEF report. Our responsibility under this recommendation is described in more detail in the Auditors' responsibility section. We are independent of Abliva AB in accordance with professional ethics for accountants in Sweden and have otherwise fulfilled our ethical responsibilities in accordance with these requirements.

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

# Responsibilities of the Board of Directors and the

# Managing Director

The Board of Directors and the Managing Director are responsible for the preparation of the Esef report in accordance with Chapter 16, Section 4(a) of the Swedish Securities Market Act (2007:528), and for such internal control that the Board of Directors and the Managing Director determine is necessary to prepare the Esef report without material misstatements, whether due to fraud or error.

# Auditor's responsibility

Our responsibility is to obtain reasonable assurance whether the Esef report is in all material respects prepared in a format that meets the requirements of Chapter 16, Section 4(a) of the Swedish Securities Market Act (2007:528), based on the procedures performed.

RevR 18 requires us to plan and execute procedures to achieve reasonable assurance that the Esef report is prepared in a format that meets these requirements.

Reasonable assurance is a high level of assurance, but it is not a guarantee that an engagement carried out according to RevR 18 and generally accepted auditing standards in Sweden will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of the Esef report.

The audit firm applies ISQC 1 Quality Control for Firms that Perform Audits and Reviews of Financial Statements, and other Assurance and Related Services Engagements and accordingly maintains a comprehensive system of quality control, including documented policies and procedures regarding compliance with professional ethical requirements, professional standards and legal and regulatory requirements.

The examination involves obtaining evidence, through various procedures, that the Esef report has been prepared in a format that enables uniform electronic reporting of the annual and consolidated accounts. The procedures selected depend on the auditor's

judgment, including the assessment of the risks of material misstatement in the report, whether due to fraud or error. In carrying out this risk assessment, and in order to design audit procedures that are appropriate in the circumstances, the auditor considers those elements of internal control that are relevant to the preparation of the Esef report by the Board of Directors and the Managing Director, but not for the purpose of expressing an opinion on the effectiveness of those internal controls. The examination also includes an evaluation of the appropriateness and reasonableness of assumptions made by the Board of Directors and the Managing Director.

The procedures mainly include a technical validation of the Esef report, i.e. if the file containing the Esef report meets the technical specification set out in the Commission's Delegated Regulation (EU) 2019/815 and a reconciliation of the Esef report with the audited annual accounts and consolidated accounts.

Furthermore, the procedures also include an assessment of whether the Esef report has been marked with iXBRL which enables a fair and complete machine-readable version of the consolidated statement of financial performance, financial position, changes in equity and cash flow.

# THE AUDITOR'S EXAMINATION OF THE CORPORATE GOVERNANCE STATEMENT

The Board of Directors is responsible for that the corporate governance statement on pages 23-30 has been prepared in accordance with the Annual Accounts Act.

Our examination of the corporate governance statement is conducted in accordance with FAR's standard RevR 16 The auditor's examination of the corporate governance statement. This means that our 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 auditing standards in Sweden. We believe that the examination has provided us with sufficient basis for our opinions.

A corporate governance statement has been prepared. Disclosures in accordance with chapter 6 section 6 the second paragraph points 2-6 of the Annual Accounts Act and chapter 7 section 31 the second paragraph the same law are consistent with the other parts of the annual accounts and consolidated accounts and are in accordance with the Annual Accounts Act.

Ernst & Young AB, Box 7850, 103 99 Stockholm was appointed auditor of Abliva AB by the general meeting of the shareholders on 20 May 2021 and has been the company's auditor since 20 May 2021.

Malmö on 28 April 2022 Ernst & Young AB

# Ola Larsmon

Authorized Public Accountant



# Definitions alternative performance measures

Alternative Performance Measures (APM) are key figures not defined in financial reports prepared according to IFRS. Of the below key figures, only the key figure Earnings per share before and after dilution is mandatory and defined according to IFRS. Of the other key figures, net sales, earnings per share before and after dilution, cash flow from operating activities and cash flow for the period are defined according to IFRS.

| The following key figures are used:                                       | Definition   | Reason for use  |
|---|--|---|
| Net revenues  | Revenue from goods and services sold that are part of the company's normal operations  |   |
| Other operating income  | Income from secondary activities in ordinary activities such as grants received  |   |
| Operating income  | Net sales and other revenues minus expenses for other external costs, personnel costs, depreciation and impairment and other expenses    | Measures the result in the operations   |
| Profit/loss before tax  | Operating income after profit/loss from finacial items and allocations   | Measures the result in the business after profit/loss from financial items and allocations  |
| Earnings per share before dilution(SEK) based on average number of shares | Profit/loss for the period divided by average number of shares before dilution at the end of the period                                  |   |
| Earnings per share after dilution(SEK) based on average number of shares  | Profit/loss for the period divided by average number of shares after dilution at the end of the period                                   |   |
| Cash flow from operating activities                                       | Cash flow from operating activities, including cash flow from working capital, ie changes in current liabilities and current receivables | Measures total cash flow generated in the business  |
| Cash flow for the period  | The company's total cash flow from operating activities, investment activities and financing activities                                  | Measures total cash flow generated in the business including investment activities and financing activities                                   |
| Average number of shares before and after dilution                        | Average number of shares before and after dilution   | Measures the average number of shares during the period before and after dilution. As the Group's earnings are negative, there is no dilution |
| Equity Ratio %  | Equity as a percentage of total assets   | Shows how much of the company's assets are financed with equity and shows the company's ability to pay  |
| Liquidity Ratio (%)   | Current assets divided by current liabilities  | Shows on the company's short-term ability to pay  |



# **Glossary**

**Active compound.** A pharmaceutical active ingredient in a pharmaceutical product.

**Candidate drug.** A particular compound which is selected during the preclinical phase. The candidate drug is subsequently tested in humans in clinical studies.

**Clinical study.** The examination of healthy or unhealthy humans to study the safety and efficacy of a pharmaceutical or treatment method. Clinical trials are divided into different phases, termed Phase 1, Phase 2, Phase 3. Phase 2 is usually divided into an early phase (Phase 2a) and a later phase (Phase 2b). See also "phase (1,2 and 3)".

**Drug-drug interaction study.** A clinical study to investigate the drug-drug interactions when co-administering a (candidate) drug with other drugs. Drug-drug interactions can lead to changed systemic exposure, resulting in variations in drug response of the co-administered drugs.

 $\textbf{Fatigue.} \ \ \textbf{Extreme tiredness.} \ \ \textbf{Often includes muscle fatigue with exercise intolerance.}$ 

**FDA.** The United States Federal Food and Drug Administration. **Hypotonia.** An abnormally low level of tension in the resting muscle. Tension in dormant muscles, muscle tone, is important for posture. **Indication.** A disease condition requiring treatment, such as traumatic brain injury or fatty liver, NASH.

In vivo/in vitro. In vivo are scientific studies in animal models. In vitro are scientific studies carried out outside of the living body, for example in cells in test tubes.

**KSS.** Mitochondrial disease, Kearns-Sayre's syndrome. The disease debuts before the age of 20 and is characterized by eye related symptoms with pigment retention in the retina and paralysis of the outer eye muscles, as well as the effects on the cardiac retinal system and the cerebellum with disorders in the coordination of muscle movements (ataxia).

**Leigh syndrome.** Leigh syndrome is a serious condition with characteristic changes to the brain that usually affects small children. This disease is caused by faults in energy-producing mitochondria and is also known as subacute (fast onset) necrotizing (tissue destroying) encephalomyopathy (a disease of the brain and muscles).

**LHON.** Mitochondrial disease, Leber Hereditary Optic Neuropathy. Affects the retina and the optic nerve, but in rare cases symptoms can be found in other parts of the central nervous system. There is no cure, but treatments are focused primarily on compensating for the visual impairment.

**Liver fibrosis/cirrhosis.** Liver fibrosis is the formation of fibrous tissue (scar tissue) in the liver as a result of, for example, infection. May lead to liver cirrhosis

**MELAS.** MELAS is an acronym of mitochondrial encephalomyopathy (brain and muscle disease) with lactic acidosis (increased lactic acid levels in the blood) and strokelike episodes.

MHRA. The UK Medicines and Healthcare products Regulatory Agency.
MIDD. Maternally Inherited Diabetes and Deafness

Mitochondria. That part of each cell that provides effective energy production in the form of conversion of oxygen and nutrients in the body into chemical energy.

**Mitochondrial medicine.** Field of research and development of pharmaceuticals that protect the mitochondria.

**Mitochondrial myopathy.** Primary mitochondrial disease which affects the muscles.

**NAD+/NADH.** A coenzyme involved in metabolism. NAD+ and NADH have central roles in cell- and mitochondrial metabolism and energy production.

NAFLD. Non-Alcoholic Fatty Liver Disease.

**NASH.** Non-alcoholic steatohepatitis, inflammatory fatty liver disease. **ODD.** Orphan Drug Designation. Facilitates development and commercialization, and may, upon receiving marketing authorization, provide orphan drug status with seven or ten years of market exclusivity (in the US and Europe, respectively).

**PEO/CPEO.** Mitochondrial disease. Progressive External Ophthalmople-gia/Chronic Progressive External Ophthalmoplegia.

**Pharmacokinetics.** Describes how the body affects a specific drug after administration.

**Phase (1,2 and 3).** The various stages of trials on the efficacy of a pharmaceutical in humans. See also "clinical trial." Phase 1 examines the safety on healthy human subjects, Phase 2 examines efficacy in patients with the relevant disease and Phase 3 is a large-scale trial that verifies previously achieved results. In the development of new pharmaceuticals, different doses are trialed and safety is evaluated in patients with relevant disease, Phase 2 is often divided between Phase 2a and Phase 2b.

**Preclinical.** That stage of drug development that occurs before a candidate drug is trialed on humans.

**Primary mitochondrial diseases.** Metabolic diseases that affect the ability of cells to convert energy. An estimated 12 in every 100,000 people affected. Often present in early childhood and lead to severe symptoms, such as mental retardation, heart failure and rhythm disturbances, dementia, movement disorders, severe diabetes, stroke-like episodes, deafness, blindness, limited mobility of the eyes, vomiting and seizures. **Psychomotor regression.** When the development of the ability to perform will-driven movements is initially normal but deteriorates during

**TBI.** Traumatic Brain Injury. An injury to the brain where some nerve cells are subjected to immediate damage. The injury then continues to exacerbate several days after the incident, which significantly impacts the final extent of damage.

infancy or early childhood.



# **Milestones**

## 1993-1994

 Eskil Elmér and his colleagues discover that ciclosporin A is a powerful neuroprotectant.

## 1995

Patent application filed and original discovery published.

# 1997

 Marcus Keep and Eskil Elmér founded Maas Biolab, LLC in the US.

# 1999

 The US Patent and Trademark Office granted the patent underlying NeuroVive's first project portfolio.

# 2000

 NeuroVive was founded under the name of NeuroPharma i Sverige AB.

#### 2004

 NeuroVive in-licensed formulation patent for NeuroSTAT from German company CicloMul-sion AG.

#### 2008

IPO on Aktietorget.

## 2010

 Results from the NeuroSTAT trial demonstrate bioequivalence and a superior safety profile to comparative preparation Sandimmune® Injection.

#### 2012

- Agreement with Fresenius Kabi enabling expansion to full-scale production of NeuroSTAT and CicloMulsion.
- Collaboration agreement with Sihuan Pharmaceutical for the development and commer-cialization of CicloMulsion and NeuroSTAT for the Chinese market.

#### 2013

- · Acquisition of new potent cyclophilin inhibitors from Biotica Ltd.
- Listing on Nasdag Stockholm.
- First patient enrolled in Phase 2 CHIC trial at the Copenhagen University Hospital intended to evaluate NeuroSTAT's pharmacokinetics and safety in traumatic brain injury.
- Collaboration agreement with Isomerase Therapeutics for product development and com-mercialization of the molecules acquired from Biotica Ltd.

# 2014

 NeuroVive establishes a subsidiary in Taiwan (NeuroVive Pharmaceutical Asia, Inc.) to ma-nage operating activities on-site in the Asian region.

#### 2015

- Start-up of the Phase 2 CiPRICS trial with CicloMulsion as a pre-treatment for acute kidney injury in patients undergoing open heart surgery.
- The Phase 3 CIRCUS (CicloMulsion for the indication of myocardial infarction) trial did not reach its primary endpoint.

# 2016

- Results from the exploratory Phase 2 clinical CiPRICS trial (for the indication of acute kidney injury) did not show the expected effect. As a consequence, the development of CicloMuls-ion was discontinued.
- The licensing agreement with Arbutus Biopharma (formerly OnCore Biopharma Inc.) was terminated and all rights to the NV556 substance were returned to NeuroVive.

#### 2017

 NeuroVive phased out its Asian subsidiary in Taiwan in January, 2017, and reallocated rese-arch resources and activities in the Taiwan-based subsidiary to the parent company, Neuro-Vive Pharmaceutical AB. NeuroVive and its partner Foundation Asia

- Pacific Ltd. reacquired the Hong Kong-based the subsidiary, NeuroVive Pharmaceutical Asia Ltd.
- NeuroVive in-licensed the KL1333 project for genetic mitochondrial disorders from Yungjin Pharm, and obtained global rights for the development and commercialization of KL1333, with the exception of South Korea and Japan.
- NeuroVive decided to continue the clinical development of its NeuroSTAT TBI project following positive results both in its own preclinical studies, and in clinical trials of TBI at the University of Pennsylvania, US, and Copenhagen University Hospital in Denmark.
- NeuroVive and Yungjin Pharm began clinical development of the KL1333 project for genetic mitochondrial disorders.

## 2018

- NeuroVive's KL1333 received FDA Orphan Drug designation for treatment of mitochondrial diseases.
- The Company announced a partnership with TRACK-TBI, a network of US-based world-leading TBI clinicians and researchers.
- NeuroVive and Yungjin reported positive KL1333 Phase 1 clinical study results paving the way for further clinical development.
- BridgeBio entered into an exclusive licensing agreement for a subset of succinate prodrug chemistry under NeuroVive's NVP015 program. BridgeBio launched a subsidiary company, Fortify Therapeutics, to further develop this chemistry for local treatment of Leber's Hereditary Optic Neuropathy (LHON).
- Successful completion of biomarker analyses of samples from clinical study in severe traumatic brain injury patients (the CHIC study) using the company's investigational compound NeuroSTAT. The results provided an early signal of efficacy derived from time-based changes in biomarker levels that correlate with NeuroSTAT drug administration.



### 2019

- The first healthy volunteer in the company's KL1333 Phase
   1a/b study was screened and will be enrolled into the study.

   First subject first visit in NeuroVive's KL1333 Phase 1a/b study
   was completed on 18 March 2019. The main aim of this second
   clinical KL1333 study is to further examine the safety profile
   of KL1333 and how the drug is metabolized following multiple
   doses in healthy volunteers and genetic mitochondrial disease
   patients. In addition, possible efficacy endpoints will be
   explored.
- The US Food and Drug Administration, FDA, approved NeuroVive's IND (Investigational New Drug) application, enabling clinical studies in the US with the company's drug candidate NeuroSTAT in development for treatment of moderate to severe traumatic brain injury, TBI.
- The company's candidate drug NeuroSTAT, in development for treatment of moderate to severe traumatic brain injury, TBI, received Fast Track designation from the US Food and Drug Administration, FDA, facilitating its clinical development and path forwards to market.

## 2020

- NeuroVive announced that the new share issue with preferential rights for existing shareholders, approved by the Extra General Meeting on March 17, 2020, has been completed. In the Rights Issue, 26.2 percent of the Rights Issue, were subscribed for with the use of subscription rights. In addition, 0.3 percent of the Rights Issue, were subscribed for without the use of subscription rights and 63.5 percent of the Rights Issue, were subscribed for by share issue guarantors. In total, the Rights Issue was subscribed to 90.0 percent, which implies that NeuroVive raises approximately SEK 67m before deduction for issue costs.
- NeuroVive Pharmaceutical AB changes its name to Abliva AB.
- Abliva completeded the directed issue of SEK 20m before issue costs to Hadean Ventures. The Board decided to allocate a total of 26,666,666 shares to Hadean Ventures with the prescription price SEK 0.75, of which Hadean Capital I AS has subscribed for, and been allotted, 18,345,570 shares and

- HVentures Capital I AB has subscribed for, and been allotted, 8,321,096 shares. The dilution from the Directed Issue amounts to approximately 9 percent.
- Abliva arranges virtual Capital Markets Day on 23 June.
- Abliva announced that the company's Board of Directors has
  decided to accelerate the KL1333 clinical program, with the
  intention to start a registrational Phase 2/3 clinical study, during
  H2 2021. The decision follows the recent positive feedback
  received from the US Food and Drug Administration ("FDA").
- Abliva announced that the first primary mitochondrial disease patient in the company's ongoing KL1333 Phase 1a/b study has been dosed. In this third part of the study, the pharmaceutical properties of KL1333 will, for the first time, be evaluated in patients.
- Abliva announced it has received positive feedback from the UK Medicines and Healthcare products Regulatory Agency (MHRA) on the accelerated clinical development plan of KL1333 in primary mitochondrial disease (PMD). The feedback positions Abliva for a clinical trial approval also in the UK, of its pivotal clinical Phase 2/3 study.

## 2021

#### January

- The Board of Directors, in agreement with Dr. Erik Kinnman, the then CEO, appointed Dr. Ellen K. Donnelly as the company's new CEO to lead Abliva's development into a commercial biotech company. Dr. Donnelly succeeded Dr. Erik Kinnman, February 3rd.
- The license agreement with Fortify Therapeutics, a whollyowned subsidiary of BridgeBio, regarding a development of a local treatment for Leber's Hereditary Optic Neuropathy (LHON), was terminated. Fortify's business decision follows an internal review of the entire BridgeBio's portfolio.

# March

 The clinical Phase 1a/b study with KL1333, Abliva's drug candidate for chronic oral treatment of primary mitochondrial diseases, was completed. No serious adverse events (SAEs) had been reported.  A directed issue of SEK 80m was carried out, including to company lead investor Hadean Ventures. The subscription price, SEK 0.75, corresponded approximately to market price. SEK 24.5m was received immediately. 55.5 was recieved after approval at the Extraordinary General Meeting on 29 April, 2021

#### April

 Extraordinary General Meeting was held on 29 April 2021. The Board of Director's resolution to issue shares with deviation from the shareholder's preferential rights was approved.

#### May

- Data from the Phase 1a/b clinical study of KL1333 was released and confirmed the safety and pharmacokinetic profile of the drug. In addition, in a cohort of eight patients (six dosed with KL1333, two with placebo), there were signs of efficacy across well-established relevant clinical endpoints including two patient-reported fatigue endpoints and a functional endpoint.
- Annual General Meeting was held on 20 May 2021.

#### October

 The company announced that NV354 will move to the clinic after having received favorable feedback received from the regulatory authority in the UK, the MHRA, on the preclinical package.

# November

 The US Food and Drug Administration has approved Abliva's Investigational New Drug (IND) application for KL1333, enabling the start of a registrational Phase 2/3 study with first patients due to be recruited in 2022.

#### December

 Abliva resolved on a directed issue of convertibles amounting to SEK 26 million subject to the approval of an extraordinary general meeting, to the Company's largest shareholder Hadean Ventures through its two funds Hadean Capital I AS and HVentures Capital I AB.



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