# ABLIVA

# Interim Report

January – June 2022

The second quarter was a successful quarter for the team as we announced a major financing of SEK 200 million.

Ellen Donnelly, CEO

Delivering mitochondrial health

# Second quarter summary

SEK 200 million financing secured.
KL1333 study due to start this year. NV354 is being prepared for clinical studies.

## Important events second quarter (Apr - Jun 2022)

- On June 1, Abliva's Board of Directors announced funding of approximately SEK 200 million that is expected to provide the company with the capital required to pursue the Phase 2/3 study with KL1333 to a key interim analysis, as well as prepare NV354 for clinical phase.
- Annual General Meeting was held on May 20, 2022. All proposals were approved, including the re-election of the Board of Directors.

## Financial information

**April-June 2022***
- Net revenues: SEK 0,000 (18,000)
- Other operating income: SEK 0,000 (0,000)
- Loss before tax: SEK 20,535,000 (30,314,000)
- Loss per share before dilution: SEK 0.04 (0.08)
- Diluted loss per share: SEK 0.04 (0.08)

**January-June 2022***
- Net revenues: SEK 0,000 (18,000)
- Other operating income: SEK 0,000 (0,000)
- Loss before tax: SEK 42,564,000 (51,770,000)
- Loss per share before dilution: SEK 0.09 (0.13)
- Diluted loss per share: SEK 0.09 (0.13)

* APM Alternative performance measures, see definition on page 20.

# Financing Secured, Study Start in Focus

**The second quarter was a successful quarter for the team as we announced a major financing of SEK 200 million, comprised of a directed share issue (SEK 150 million) and a rights issue (SEK 50 million). The quarter also brought an approval from the UK authorities for our Phase 2/3 study. Finally, we continued to increase our visibility within the patient, physician and researcher communities with presentations at the annual UMDF Mitochondrial Medicine Symposium and Bioblast 2022, and publication of a review in Bioenergetics Communications.**

### Financing Secured

The SEK 200 million financing round completed at the end of June continues to receive attention, most recently highlighted in BioWorld in the Top 10 European Company Secondary Offerings and PIPES in 2Q22. With this raise, we have funded the study to an important interim analysis for KL1333, increased our runway, and attracted a syndicate of high-quality investors. We were also pleased that Hadean Ventures reconfirmed their interest in the company through both participation in the share issue and conversion of their convertible loan.

### KL1333 Progressing to Phase 2/3 Start

The team is now focused on the initiation of "FALCON", our registrational, Phase 2/3 clinical trial evaluating KL1333 for the treatment of adults suffering from primary mitochondrial disease. The IND was approved by the FDA late last year and in May we received approval from the UK regulatory authorities as well. The team will continue to work with regulators in the US and Europe to finalize the protocol and get the final country approvals required for the inclusion of our first patient in the study, targeted for late 2022. Given the 8–12-week screening period in the study (required to ensure that all enrolled patients have adequate levels of myopathy and fatigue), we expect the first patient to be dosed in early 2023.

### Spreading the Word to Patients, Physicians and Researchers

The primary mitochondrial disease community is small but active, and we look forward to opportunities to engage with, and learn from, the patients, physicians, and researchers. We had a chance to speak with all of these stakeholders in June when we attended the annual UMDF Mitochondrial Medicine Symposium in Phoenix, Arizona. The meeting brought together the community to exchange ideas and agree upon areas of focus for the next year. Magnus Hansson, CMO of Abliva, gave a presentation during the meeting that focused on the upcoming Phase 2/3 study.

Also in June, Eleonor Åsander Frostner represented Abliva at the Bioblast 2022 meeting in Innsbruck, Austria, where she presented the company to researchers in the area. Eleonor's presentation was accompanied by a review article, written by Abliva, highlighting the current compounds in development for primary mitochondrial diseases, which was published in Bioenergetics Communications (https://www.bioenergetics-communications.org/index.php/bec/article/view/aasander_frostner_2022).

I hope you all have had a relaxing summer spent making memories with family and friends, and I look forward to keeping you updated on our activities at Abliva as we move towards study start.

**Ellen Donnelly**
CEO

*"With this raise, we have funded the study to an important interim analysis for KL1333, increased our runway, and attracted a syndicate of high-quality investors"*

**Primary mitochondrial diseases** are metabolic diseases that affect the cells' ability to convert energy. The diseases can manifest very differently depending on the organs impacted and the number of dysfunctional mitochondria in that organ. Historically viewed as clinical syndromes, our knowledge about the various mutations underlying mitochondrial diseases has increased, improving our ability to identify and treat these patients. It is estimated that 125 persons per million have a primary mitochondrial disease.

Primary mitochondrial diseases often present in early childhood and can lead to severe symptoms, such as stunted growth, muscle weakness, pronounced fatigue, heart failure and rhythm disturbances, diabetes, movement disorders, stroke-like episodes, deafness, blindness, limited mobility of the eyes and epileptic seizures.


*Orphan drug designation in the US and Europe

PMD stands for Primary Mitochondrial Diseases, often referred to as 'mito disease'.
mtDNA disorders are disorders caused by mutation(s) in mitochondrial DNA (as opposed to nuclear DNA).

# 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. The company intends to 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 discovery of 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 decades of experience in drug development.

Over the next five years we will focus on the delivery of our portfolio 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. 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 PMDs.

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[1].

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[2,3].

In addition, we have sought scientific 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.

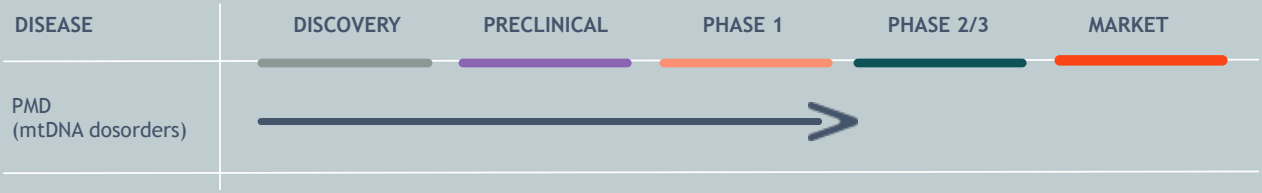
### Accessing Capital to Finance the Vision

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 in 2020 was the first step to bringing specialist investors into the company; 2022 brought investment from life science specialist IP Group plc and Norweigan institutional investor Oslo Pensionsförsäkringar. The company aims to continue to attract new specialist and institutional investors across Sweden, Europe and America.

1) Gorman e tal.,Prevalence of Nuclear and Mitochondrial DNA Mutations Related to Adult Mitochondrial Disease, 2015
2) Jayasundra et al. Orphanet J of Rare Dis. Estimating the clinical cost of drug development for orphan versus non-orphan drugs. 2019.3) EvaluatePharma, Orphan Drug Report 2019.

# KL1333 Innovative therapy heading to registrational Phase 2/3 study

## Financing enables start of the registrational Phase 2/3 study in 2022
## Positive safety results and signs of efficacy from Phase 1a/b study
## Orphan drug designation in both the United States and Europe




**Events in the second quarter**

- The company received approval also from the UK regulatory agencies to start the Phase 2/3 study
- Financing is intended to fund the commencement of the Phase 2/3 study and its progression to the outcome of a key interim analysis of 40 patients which will inform as to the size of the remainder of the study.

- **Objectives for 2022**
- Regulatory approvals in select countries.
- Initiate the start of the FALCON study.

### DISEASE AREA

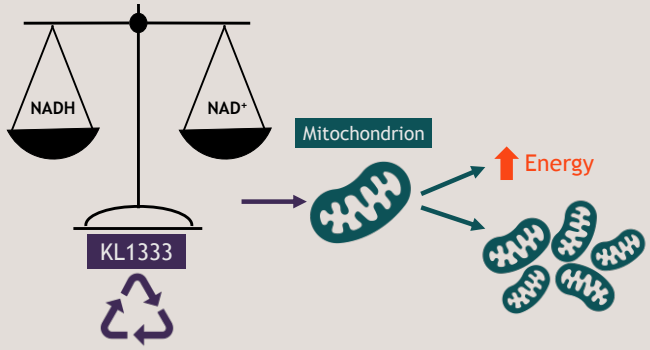
KL1333 is being developed as a treatment for a subset of adult primary mitochondrial disease patients suffering from multiple debilitating symptoms, including mitochondrial fatigue and myopathy. Diagnoses can include MELAS-MIDD and KSS-CPEO spectrum disorders as well as MERRF syndrome.

The drug candidate is intended for long-term oral treatment.

### PATH TO MARKET

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 2026. The number of patients in the target group for treatment with KL1333 is approximately 40,000[1)] in Europe and the US. At typical orphan drug pricing, this translates into a blockbuster opportunity.

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




KL1333 has the ability to restore the ratio of $NAD^+$ and NADH, and thus leads to the formation of new mitochondria and improved energy levels.

# NV354 First-in-class therapeutic heading towards clinical development

## Positive feedback from UK MHRA scientific advice meeting
## Preparation of the program for clinical studies


**Events in the second quarter**
- During the quarter, the company has continued to assemble the regulatory documentation to support clinical entrance.

**Objectives for 2022**
- Produce NV354 clinical trial material for clinical Phase 1 study.
- Complete regulatory documentation to support clinical entrance.

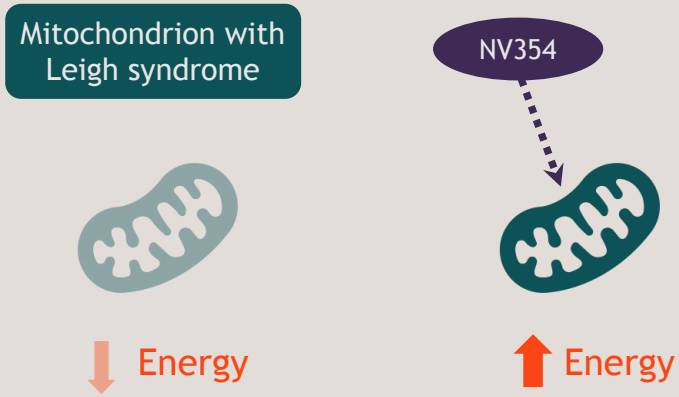
**PRIMARY INDICATION**
NV354 is being developed for the treatment of Leigh syndrome, a severe primary mitochondrial disease that usually debuts at one to two years of age. The disease is fatal and children usually die before age 5.

Symptoms include developmental delay, psychomotor regression and hypotonia. There are currently no approved medicines. The drug candidate is intended for long-term oral treatment.

**EXPANSION OPPORTUNITY**
The unique mechanism of action and high brain uptake may be utilized to develop NV354 for the treatment of MELAS in children and adolescents with neurological symptoms, and for the treatment of LHON. MELAS is a serious disease with symptoms such as muscle weakness, diabetes, fatigue, 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.

**PATH TO 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.[1)]

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




In Leigh syndrome, the first step in energy formation does not work. NV354 restores the energy needed in the diseased mitochondria.

# Non-core asset: NeuroSTAT – For treatment of Traumatic Brain Injury

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.

**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/IIa 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 IND approval and Fast Track designation for clinical development in the US.

Abliva continues in preliminary discussions with the TRACK- TBI network regarding a potential collaboration within the scope of the Precision Medicine project[1) 2)] for a Phase 2 study on traumatic brain injury with NeuroSTAT. The study, if authorized by US Department of Defense (DOD), would commence in 2022, 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.

1 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.

2 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.

## Consolidated Statement of

# Comprehensive Income

### Revenues

The consolidated turnover during the second quarter of 2022 was SEK 0,000 (18,000). Other operating revenues for the second quarter were SEK 0,000 (0,000). During the first six months of 2022 the consolidated turnover was KSEK 0,000 (18,000). Other operating revenues for the first six months amounted SEK 0,000 (0,000).

### Results of operations

The operating loss for the second quarter was SEK 18,275,000 (30,311,000) and for the first six months the operating loss amounted SEK -39,825,000 (51,762,000). The net loss before tax for the second quarter amounted to SEK 20,535,000 (30,314,000). For the first six months the loss before tax was -42,564,000 (-51,770,000).

The operating loss was affected by other external expenses, which for the first six months were SEK 30,236,000 (39,694,000). Expenses related to development projects, as a part of external expenses, have affected the result with SEK 26,092,000 (33,030,000) whereof SEK 25,832,000 (28,736,000) relates to project in clinical phase. Personnel expenses during the first six months amounts to SEK 7,935,000 (10,499,000), personal costs are less than during 2021 due to included notice period and severance pay to former CEO. Other operating expenses amount to, SEK 439,000 (270,000) and pertain to exchange-rate losses.

### Profit/loss from financial items

Financial expenses for the six months amounted to SEK 2,739,000 (8,000) and refer to 10% interest and set-up costs related to the convertible loan from Hadean Ventures, which in connection with the directed share issue in June was converted into shares.

| (SEK 000) | Note | 1 Apr, 2022<br>30 Jun, 2022 | 1 Apr, 2021<br>30 Jun, 2021 | 1 Jan, 2022<br>30 Jun, 2022 | 1 Jan, 2021<br>30 Jun, 2021 | 1 Jan, 2021<br>31 Dec, 2021 |
|---|---|---|---|---|---|---|
| Net sales | | - | 18 | - | 18 | 151 |
| Other operating income | | - | - | - | - | - |
| | | **-** | **18** | **-** | **18** | **151** |
| **Operating expenses** | | | | | | |
| Other external expenses | | -12,886 | -24,154 | -30,236 | -39,694 | -103,695 |
| Personnel cost | | -4,487 | -5,453 | -7,935 | -10,499 | -16,844 |
| Depreciation and write-down of tangible and intangible assets | | -607 | -659 | -1,215 | -1,317 | -2,764 |
| Other operating expenses | | -294 | -63 | -439 | -270 | -330 |
| | | **-18,275** | **-30,329** | **-39,825** | **-51,780** | **-123,633** |
| **Operating income** | | **-18,275** | **-30,311** | **-39,825** | **-51,762** | **-123,482** |
| **Profit/loss from financial items** | | | | | | |
| Financial costs | | -2,261 | -3 | -2,739 | -8 | -12 |
| | | **-2,261** | **-3** | **-2,739** | **-8** | **-12** |
| **Profit/loss before tax** | | **-20,535** | **-30,314** | **-42,564** | **-51,770** | **-123,494** |
| Income tax | 2 | - | - | - | - | -4 |
| **Profit/loss for the period** | | **-20,535** | **-30,314** | **-42,564** | **-51,770** | **-123,498** |
| **Other comprehensive income** | | | | | | |
| *Items that may be reclassified to profit or loss* | | | | | | |
| Translation differences on foreign subsidiaries | | 154 | -4 | 177 | -3 | 71 |
| **Total comprehensive income for the period** | | **-20,381** | **-30,318** | **-42,387** | **-51,772** | **-123,427** |
| **Loss for the period attributable to:** | | | | | | |
| Parent company shareholders | | -20,535 | -30,314 | -42,563 | -51,769 | -123,492 |
| Non-controlling interests | | -1 | -1 | -1 | -1 | -6 |
| | | **-20,536** | **-30,314** | **-42,564** | **-51,770** | **-123,498** |
| **Total comprehensive income for the period** | | | | | | |
| Parent company shareholders | | -20,382 | -30,317 | -42,387 | -51,771 | -123,420 |
| Non-controlling interests | | - | -1 | - | -1 | -7 |
| | | **-20,382** | **-30,318** | **-42,387** | **-51,772** | **-123,427** |
| Earnings per share before and after dilution(SEK) based on average number of shares | | -0.04 | -0.08 | -0.09 | -0.13 | -0.33 |
| Average number of shares before and after dilution | | 459,311,736 | 395,895,687 | 459,311,736 | 395,895,687 | 370,168,023 |

Consolidated Statement of

# Financial Position

### Financial position

The equity/assets ratio was 90 (86) percent as of 30 June 2022, and equity was SEK 163,766,000 (112,798,000). The equity includes funds from the in June completed directed share issue, which provided the company with SEK 137,362,000 after deduction of issue costs of SEK 13,038,000. In addition Equity includes the conversion of the convertible loan from Haean Ventures amounting to 26,961,000 SEK. Cash and cash equivalents amounted to SEK 135,139,000 (94,146,000) as of 30 June 2022, an increase of SEK 112,820,000 from the beginning of the year. Total assets as of 30 June 2022 were SEK 182,606,000 (131,344,000).

| (SEK 000) | Note | 30 Jun, 2022 | 30 Jun, 2021 | 31 Dec, 2021 |
|---|---|---|---|---|
| **ASSETS** | | | | |
| **Non-current assets** | | | | |
| **Intangible assets** | 1 | | | |
| Patents | | 19,689 | 20,268 | 20,293 |
| Other Intangible assets | | 1,143 | 1,277 | 1,210 |
| | | **20,832** | **21,545** | **21,503** |
| **Tangible assets** | | | | |
| Equipment | | 42 | 82 | 60 |
| Rigth of use asset leases | | 1,030 | 172 | - |
| | | **1,072** | **254** | **60** |
| **Financial assets** | | | | |
| Other long-term securities | | 13,101 | 13,101 | 13,101 |
| | | **13,101** | **13,101** | **13,101** |
| **Total non-current assets** | | **35,005** | **34,900** | **34,664** |
| **Current assets** | | | | |
| Other receivables | | 9,815 | 1,325 | 912 |
| Prepaid expenses and accrued income | | 2,627 | 963 | 1,003 |
| Cash and cash equivalents | | 135,159 | 94,146 | 22,339 |
| | | **147,602** | **96,434** | **24,254** |
| **TOTAL ASSETS** | | **182,606** | **131,334** | **58,918** |

Consolidated Statement of

# Financial Position

### Financial instruments

Abliva holds unlisted securities. These assets should be measured at fair value and are classified as "financial assets measured at fair value through other comprehensive income."

The holding corresponds to 10% in one of Abliva's R&D partner companies, which conducts development activities. A prudent assessment is that book value corresponds to the market value.

Other financial assets and liabilities are valued at amortized cost. The carrying amount of these assets and liabilities is estimated to correspond to fair value.

| (SEK 000) | Note | 30 Jun, 2022 | 30 Jun, 2021 | 31 Dec, 2021 |
|---|---|---|---|---|
| **EQUITY AND LIABILITIES** | | | | |
| **Equity attributable to the shareholders of the parent company** | | | | |
| Share capital | | 45,488 | 20,150 | 20,150 |
| Additional paid in capital | | 869,495 | 730,592 | 730,560 |
| Translation reserve | | 864 | 617 | 688 |
| Retained earnings* | | -752,090 | -638,574 | -709,879 |
| **Total equity attributable to the shareholders of the parent** | | **163,757** | **112,785** | **41,519** |
| Non-controlling interests | | 9 | 13 | 9 |
| **Total equity** | | **163,766** | **112,798** | **41,528** |
| **Long-term liabilities** | | | | |
| Other longtrem liabilities | | 704 | - | - |
| | | **704** | **-** | **-** |
| **Short-term liabilities** | | | | |
| Accounts payable | | 11,990 | 8,856 | 9,616 |
| Other liabilities | | 1,877 | 415 | 277 |
| Accrued expenses and deferred income | | 4,270 | 9,265 | 7,497 |
| | | **18,136** | **18,536** | **17,390** |
| **Total liabilities** | | **18,840** | **18,536** | **17,390** |
| **TOTAL EQUITY AND LIABILITIES** | | **182,606** | **131,334** | **58,918** |

Consolidated Statement of

# Changes in Equity

| | Equity attributable to the shareholders of the parent company | | | | | | |
|---|---|---|---|---|---|---|---|
| (SEK 000) | Share-capital | Additional paid in capital | Translation reserve | Retained earnings | Total | Non-controlling interests | Total equity |
| **Opening balance, 1 January 2021** | **14,817** | **660,025** | **616** | **-586,802** | **88,656** | **0** | **88,656** |
| **Comprehensive profit/loss for the period** | - | - | - | - | - | - | - |
| Profit/loss for the period | - | - | - | -51,769 | -51,769 | -1 | -51,770 |
| Other comprehensive income | - | - | - | - | - | - | - |
| Translation differences | - | - | 1 | -4 | -3 | - | -3 |
| **Other comprehensive profit/loss for the period, net after tax** | **-** | **-** | **1** | **-4** | **-3** | **-** | **-3** |
| **Total comprehensive profit/loss** | **-** | **-** | **1** | **-51,773** | **-51,771** | **-1** | **-51,772** |
| **Transactions with shareholders** | **-** | **-** | **-** | **-** | **-** | **-** | **-** |
| Rights issue | 5,333 | 70,567 | - | - | 75,900 | - | 75,900 |
| **Total transactions with shareholders** | **5,333** | **70,567** | **-** | **-** | **75,900** | **14** | **75,914** |
| **Closing balance, 30 June 2021** | **20,150** | **730,592** | **617** | **-638,574** | **112,785** | **13** | **112,798** |
| | | | | | | | |
| **Opening balance, 1 January 2021** | **14,817** | **660,025** | **616** | **-586,802** | **88,656** | **0** | **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, net after tax** | **-** | **-** | **72** | **-** | **72** | **-1** | **71** |
| **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** |
| | | | | | | | |
| **Opening balance, 1 January 2022** | **20,150** | **730,560** | **688** | **-709,879** | **41,519** | **9** | **41,528** |
| **Comprehensive profit/loss for the period** | | | | | | | |
| Profit/loss for the period | - | - | - | -42,563 | -42,563 | -1 | -42,564 |
| Other comprehensive income | | | | | | | |
| Translation differences | - | - | 176 | - | 176 | 1 | 177 |
| **Other comprehensive profit/loss for the period, net after tax** | **-** | **-** | **176** | **-** | **176** | **1** | **177** |
| **Total comprehensive profit/loss** | **-** | **-** | **176** | **-42,563** | **-42,387** | **-** | **-42,387** |
| **Transactions with shareholders** | | | | | | | |
| Rights Issue* | 25,338 | 138,935 | - | - | 164,273 | - | 164,273 |
| Share-based payment | - | - | - | 351 | 351 | - | 351 |
| **Total transactions with shareholders** | **25,338** | **138,935** | **-** | **351** | **164,624** | **-** | **164,624** |
| **Closing balance, 30 June 2022** | **45,488** | **869,495** | **864** | **-752,090** | **163,757** | **9** | **163,765** |

*Total equity includes funds from the June 9th completed directed share issue with net SEK 137,362,000 less expenses SEK 13,038,000 and the conversion of the convertible loan to Hadean amounting to SEK 26,961,000.

Consolidated Statement of

# Cash Flows

### Cash flow and investments

Operating cash flow for the second quarter was SEK -25,785,000 ( -29,448,000). For the first six months the operating cash flow amounted SEK -48,503,000 (-42,990,000). The cash flow effect related to investments in intangibles equals SEK -336,000 (-269,000) for the first six months. The cash flow effect related to investments in financing activities equals SEK 161,585,000 (75,900,000) and refers to the directed share issue that affected cash flow positively by SEK 137,362,000 and the conversion of the convertible loan that affected cash flow positively by SEK 24,223,000. Cash flow for the second quarter equals SEK 111,226,000 (46,166,000). Cashflow for the first six months equals SEK 112,745,000 (32,499,000).

| (SEK 000) | 1 Apr, 2022<br>30 Jun, 2022 | 1 Apr, 2021<br>30 Jun, 2021 | 1 Jan, 2022<br>30 Jun, 2022 | 1 Jan, 2021<br>30 Jun, 2021 | 1 Jan, 2021<br>31 Dec, 2021 |
|---|---|---|---|---|---|
| **Cash flow from operating activities** | | | | | |
| Operating income | -18,275 | -30,311 | -39,825 | -51,762 | -123,482 |
| | | | | | |
| **Adjustments for non-cash items:** | | | | | |
| Depreciation | 607 | 659 | 1,215 | 1,317 | 2,660 |
| Currency differences on intercompany items | 156 | -7 | 170 | -7 | -7 |
| Impaired Value | - | - | - | - | 104 |
| Share-based payments | -240 | - | 351 | - | 415 |
| Interest paid | - | -3 | - | -8 | -12 |
| Paid taxes | - | - | - | - | -4 |
| **Net cash from operating activities before changes in working capital** | **-17,751** | **-29,663** | **-38,088** | **-50,460** | **-120,326** |
| | | | | | |
| **Changes in working capital** | | | | | |
| Increase/decrease of other current assets | -9,043 | -156 | -10,525 | -773 | -400 |
| Increase/decrease of other short-term liabilities | 1,009 | 371 | 111 | 8,243 | 6,651 |
| **Changes in working capital** | **-8,034** | **215** | **-10,414** | **7,471** | **6,251** |
| | | | | | |
| **Cash flow from operating activities** | **-25,785** | **-29,448** | **-48,503** | **-42,990** | **-114,075** |
| | | | | | |
| **Investing activities** | | | | | |
| Acquisition of intangible assets | -349 | -235 | -336 | -269 | -1,024 |
| Acquisition of tangible assets | - | -65 | - | -65 | -65 |
| **Cash flow from investing activities** | **-349** | **-300** | **-336** | **-334** | **-1,089** |
| | | | | | |
| **Financing activities** | | | | | |
| Shareholder contribution subsidiary | - | 14 | - | 14 | 16 |
| New share issue | 137,361 | 75,900 | 137,361 | 75,900 | 75,868 |
| Amoritization lease | - | - | - | -92 | -92 |
| Long-term liabilities | - | - | 24,223 | - | - |
| **Cash flow from financing activities** | **137,361** | **75,914** | **161,584** | **75,822** | **75,792** |
| | | | | | |
| Cash flow for the period | 111,226 | 46,166 | 112,745 | 32,499 | -39,372 |
| Cash and cash equivalents at the beginning of the period | 23,880 | 47,976 | 22,339 | 61,643 | 61,643 |
| Effect of exchange rate changes on cash | 53 | 4 | 75 | 5 | 68 |
| **Cash and cash equivalents at end of period** | **135,159** | **94,146** | **135,159** | **94,146** | **22,339** |

Parent Company

# Income Statement

**Parental company**

Company earnings after tax for the second quarter amount to SEK -20,824,000 (-29,082,000). Earnings after tax for the first six months amount to SEK 42,259,000 (-50,538,000). Most of the Group's operations are conducted within the parent company. Accordingly, no further specific information regarding the parent company is presented.

| (SEK 000) | Note | 1 Apr, 2022 30 Jun, 2022 | 1 Apr, 2021 30 Jun, 2021 | 1 Jan, 2022 30 Jun, 2022 | 1 Jan, 2021 30 Jun, 2021 | 1 Jan, 2021 31 Dec, 2021 |
|---|---|---|---|---|---|---|
| Net sales | | - | 18 | - | 18 | 151 |
| Other operating income | | - | - | - | - | - |
| | | **-** | **18** | **-** | **18** | **151** |
| **Operating expenses** | | | | | | |
| Other external expenses | | -14,656 | -24,185 | -32,874 | -39,815 | -107,521 |
| Personnel cost | | -3,006 | -4,279 | -4,992 | -9,326 | -12,952 |
| Depreciation and write-down of tangible and intangible assets | | -607 | -573 | -1,215 | -1,145 | -2,420 |
| Other operating expenses | | -294 | -63 | -439 | -270 | -330 |
| | | **-18,564** | **-29,100** | **-39,521** | **-50,556** | **-123,223** |
| **Operating income** | | **-18,564** | **-29,082** | **-39,520** | **-50,538** | **-123,072** |
| **Profit/loss from financial items** | | | | | | |
| Interest expenses and other similar loss items | | -2,260 | - | -2,738 | - | - |
| | | **-2,260** | **-** | **-2,738** | **-** | **-** |
| **Profit/loss before tax** | | **-20,824** | **-29,082** | **-42,259** | **-50,538** | **-123,072** |
| Income tax | 2 | - | - | - | - | - |
| **Profit/loss for the period** | | **-20,824** | **-29,082** | **-42,259** | **-50,538** | **-123,072** |

Parent Company

# Statement of Comprehensive Income

| (SEK 000) | Note | 1 Apr, 2022 30 Jun, 2022 | 1 Apr, 2021 30 Jun, 2021 | 1 Jan, 2022 30 Jun, 2022 | 1 Jan, 2021 30 Jun, 2021 | 1 Jan, 2021 31 Dec, 2021 |
|---|---|---|---|---|---|---|
| Profit/loss for the period | | -20,824 | -29,082 | -42,259 | -50,538 | -123,072 |
| Other comprehensive income | | - | - | - | - | - |
| **Total comprehensive profit/loss for the period** | | **-20,824** | **-29,082** | **-42,259** | **-50,538** | **-123,072** |

Parent Company

# Balance Sheet

| (SEK 000) | Note | 30 Jun, 2022 | 30 Jun, 2021 | 31 Dec, 2021 |
|---|---|---|---|---|
| **ASSETS** | | | | |
| **Non-current assets** | | | | |
| *Intangible assets* | 1 | | | |
| Patents | | 19,689 | 20,268 | 20,293 |
| Other intangible assets | | 1,143 | 1,277 | 1,210 |
| | | **20,832** | **21,544** | **21,503** |
| *Tangible assets* | | | | |
| Equipment | | 42 | 82 | 60 |
| | | **42** | **82** | **60** |
| *Financial assets* | | | | |
| Other long-term placement | | 13,100 | 13,101 | 24,557 |
| Shares in subsidiaries | 3 | 24,558 | 24,558 | 13,101 |
| | | **37,658** | **37,659** | **37,658** |
| **Total non-current assets** | | **58,532** | **59,285** | **59,221** |
| **Current assets** | | | | |
| *Short term receivables* | | | | |
| Receivables from group companies | | - | 498 | - |
| Other receivables | | 9,791 | 1,305 | 890 |
| Prepaid expenses and accrued income | | 2,627 | 962 | 1,003 |
| | | **12,418** | **2,765** | **1,893** |
| Cash and bank balances | | 134,789 | 93,884 | 21,696 |
| **Total current assets** | | **147,207** | **96,650** | **23,589** |
| **TOTAL ASSETS** | | **205,739** | **155,935** | **82,810** |

Parent Company

# Balance Sheet

| (SEK 000) | Note | 30 Jun, 2022 | 30 Jun, 2021 | 31 Dec, 2021 |
|---|---|---|---|---|
| **EQUITY AND LIABILITIES** | | | | |
| **Equity** | | | | |
| *Restricted equity* | | | | |
| Share capital | | 45,488 | 20,150 | 20,150 |
| Statutory reserve | | 1,856 | 1,856 | 1,856 |
| Development expenditure reserve | | 2,008 | 3,118 | 2,613 |
| | | **49,352** | **25,124** | **24,619** |
| **Unrestricted equity** | | | | |
| Share premium reserve | | 209,520 | 85,905 | 70,534 |
| Retained earnings | | -29,451 | 77,173 | 93,017 |
| Profit/loss for the period | | -42,259 | -50,538 | -123,072 |
| | | **137,810** | **112,540** | **40,479** |
| **Total equity** | | **187,162** | **137,665** | **65,098** |
| | | | | - |
| **Short-term liabilities** | | | | |
| Accounts payable | | 11,951 | 8,848 | 9,616 |
| Liabilities subsidiary | | 1,813 | - | 1,253 |
| Other liabilities | | 1,551 | 233 | 273 |
| Accrued expenses and deferred income | | 3,262 | 9,190 | 6,570 |
| | | **18,577** | **18,271** | **17,712** |
| **TOTAL EQUITY AND LIABILITIES** | | **205,739** | **155,935** | **82,810** |

# Notes

## Note 1 — Intangible assets

| (SEK 000) | Patents | Other | Total |
|---|---|---|---|
| **ACCUMULATED COST** | | | |
| **Opening balance 1 Jan. 2022** | **35,180** | **2,864** | **38,044** |
| Additions | 525 | - | 525 |
| **Closing balance 31 June 2022** | **35,705** | **2,864** | **38,569** |
| | | | |
| **ACCUMULATED DEPRECIATION** | | | |
| **Opening balance 1 Jan. 2021** | **-14,887** | **-1,654** | **-16,541** |
| Depreciation for the period | -1,129 | -67 | -1,196 |
| **Closing balance 30 June 2022** | **-16,016** | **-1,721** | **-17,737** |
| **Residual value 30 June 2022** | **19,689** | **1,143** | **20,832** |

| (SEK 000) | Patents | Other | Total |
|---|---|---|---|
| **ACCUMULATED COST** | | | |
| **Opening balance 1 Jan. 2021** | **33,771** | **2,864** | **36,635** |
| Additions | 1,562 | - | 1,562 |
| Impaired value | -153 | - | -153 |
| **Closing balance 31 Dec. 2021** | **35,180** | **2,864** | **38,044** |
| | | | |
| **ACCUMULATED DEPRECIATION** | | | |
| **Opening balance 1 Jan. 2021** | **-12,800** | **-1,519** | **-14,319** |
| Depreciation for the period | -2,136 | -135 | -2,271 |
| Impaired value | 49 | - | 49 |
| **Closing balance 31 Dec. 2021** | **-14,887** | **-1,654** | **-16,541** |
| **Residual value 31 Dec. 2021** | **20,293** | **1,210** | **21,503** |

## Note 2 – Tax

The group's total loss carry-forward amount to SEK 775,529,000 as of 30 June 2022 (643,842,000). The parent company's total loss carry-forwards amounts to SEK 749,710,000 as of 30 June 2022 (670,953,000). Because the company is loss making, management cannot judge when deductible loss carry-forwards will be utilized.

## Note 3 – Shares and participations in group companies

These shares are the holding of 82.47% in the subsidiary NeuroVive Pharmaceutical Asia Ltd., domiciled in Hong Kong, the holly owned american subsidiary Abliva Inc., Boston and the Swedish subsidiary Abliva Incentive AB, holding option program for the CEO.

# Other disclosures

### Transactions with related parties

Transactions between the company and its subsidiarie, which are related parties to the company, have been eliminated on consolidation, and accordingly, no disclosures are made regarding these transactions.

| (SEK 000) | 1 Jan.2022-30 Jun. 2022 | 1 Jan.2021-31 Dec. 2021 |
|---|---|---|
| Eskil Elmér, CSO | - | 5 |
| Magnus Hansson, CMO | - | 3 |
| **Total** | **-** | **8** |

No compensation based on sales has been paid during the period 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. Apart from remuneration to senior executives no transactions with related parties have occured.

### Segment information

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

### Human resources

The average number of employees of the group for the period January to June 2022 was 8 (10), of which 6 (6) are women.

### Important events during the second quarter (Apr-Jun 2022)

For further information, see page 2.

### Important events after the reporting period

For further information, see page 2.

### Incentive programs/share warrants

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.

### Audit review

This Interim Report has not been subject to review by the company's auditors.

### Upcoming financial statements

| | |
|---|---|
| Q3 Report January-September 2022 | November 22, 2022 |
| Year-End Report 2022 | February 24, 2023 |

The interim reports and the Annual Year Report are available at: www.abliva.com.

# Risks and uncertainty factors

A research company such as Abliva AB (publ) is subject to high operational and financial risks because the projects the company conducts are in different developmental phases, where a number of parameters influence the likelihood of commercial success. Briefly, operations are associated with risks relating to factors including drug development, competition, technological progress, patents, regulatory requirements, capital requirements, currencies and interest rates.

**Financing**
The Board continuously monitors and evaluates the company's funding need and financial position. The company announced a financing of SEK 200 million in June 2022. However, the company acknowledges the need of further financing in the future.

**Impact of Covid-19 on the Company's clinical trials**
COVID-19 may, among other things, lead to delays in the Company's clinical studies, but it is currently difficult to assess all the potential effects that Covid-19 may have on the Company. Due to Covid-19, there is a risk of further delays because healthcare authorities and healthcare providers re-prioritize available resources, care locations and healthcare professionals to better meet the influx of Covid-19 patients. There is a risk that the start of the upcoming Phase 2/3-study, which is expected to begin in late 2022, with dosing in the first patient in early 2023, will be further delayed due to Covid-19. The company's second drug candidate NV354, which is being prepared for clinical development, also risks being delayed due to the Covid-19 pandemic.

**Macroeconomic and geopolitical factors**
The Russian invasion of Ukraine has worsened the political security situation in the rest of the world and created significant uncertainty in the financial markets, which may affect the company. The company has no direct business in, nor does it conduct any preclinical or clinical studies in Ukraine or Russia, but sees a risk that the company eventually will suffer from increased raw material and energy prices, which are likely to translate into both increased prices for goods and services as well a change in strategy by investors and potential partners.

**Disputes**
Abliva is not involved in any disputes.

For more detail of risks and uncertainty factors, refer to the Statutory Administration Report in the 2021 Annual Report and the prospectus published on June 8, 2022.

# Principles of preparation of the Interim Report

Abliva prepares its consolidated accounts in accordance with International Financial Reporting Standards (IFRS) issued by the International Accounting Standards Board (IASB) and interpretation statements from the IFRS Interpretations Committee, as endorsed by the EU for application within the EU. This Interim Report has been prepared in accordance with IAS 34 Interim Financial Reporting.

IFRS 2 Share-based Payment applies to incentive programs that 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.

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

The group and parent company have applied the accounting principles described in the Annual Report for 2021 on pages 43-58.

# 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 |

# The declaration of the Board of Directors and the CEO

This Interim Report gives a true and fair view of the parent company and group's operations, financial position and results of operations, and states the significant risks and uncertainty factors facing the parent company and group companies.

Lund, Sweden, August 19, 2022

**David Laskow-Pooley**
Chairman of the Board

**David Bejker**
Board member

**Roger Franklin**
Board member

**Denise Goode**
Board member

**Jan Törnell**
Board member

**Ellen Donnelly**
Chief Executive Officer


David Laskow-Pooley


David Bejker


Roger Franklin


Denise Goode


Jan Törnell


Ellen Donnelly

For more information concerning this report, please contact CEO Ellen Donnelly. Telephone: +46 (0)46-275 62 20.

The information was submitted for publication, through the agency of the contact person set out above, at 9:00 p.m. CEST on August 19, 2022.

This Interim 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.

# 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 in healthy volunteers 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.
**Fatigue.** Extreme tiredness. Often includes muscle fatigue with exercise intolerance.
**FDA.** The United States Federal Food and Drug Administration.
**Hypotonia.** An abnormally low level of tension, important for posture, in the resting muscle.
**Indication.** A disease condition requiring treatment, such as traumatic brain injury or fatty liver, NASH.
**Interim analysis.** The analysis of data in a clinical trial comparing intervention groups before the formal completion of the trial, typically before patient recruitment is complete. Can be used for various purposes, such as assessing the statistical strength of the study to meet the predetermined endpoints.
**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.
**MERRF.** (Myoclonic epilepsy with ragged-red fibers). Primary mitochondrial disease with symptoms such as epilepsy, involuntary muscle twitching and difficulty coordinating muscle movements, but the disease can affect many functions. When examined under a microscope, muscle tissue has characteristic changes.
**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 Ophthalmoplegia/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 infancy or early childhood.
**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.

# About Abliva

Abliva discovers and develops medicines for the treatment of primary mitochondrial diseases. These rare and often very severe diseases occur when the cell's energy provider, the mitochondria, do not function properly. The company has prioritized two projects. KL1333, a powerful regulator of the essential co-enzymes $NAD^+$ and NADH, is entering late-stage development. NV354, an energy replacement therapy, has completed preclinical development. Abliva is based in Lund, Sweden.

**What is primary mitochondrial disease?**
Primary mitochondrial diseases are metabolic diseases that affect the cells' ability to convert energy. The diseases can manifest very differently depending on the organs impacted and the number of dysfunctional mitochondria in that organ. Historically viewed as clinical syndromes, our knowledge about the various mutations underlying mitochondrial diseases has increased, improving our ability to identify and treat these patients. It is estimated that 125 persons per million have a primary mitochondrial disease.

Abliva's discovery projects focus on gaining a deeper understanding of the mechanisms underlying primary mitochondrial diseases in order to enable us to design new molecules and develop the next-generation compounds for primary mitochondrial diseases.

**Stock exchange**
Abliva is listed on Nasdaq Stockholm, Sweden (ticker: ABLI).

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