


ABLIVA

Year-End Report
January - December 2020



We are taking the next steps towards our objective of making Abliva a global player in the field of mitochondrial medicine.

Ellen Donnelly, CEO

Delivering mitochondrial health

2020 summary

KL1333 on its way to registrational Phase 2/3 study.
Ellen Donnelly appointed new CEO of Abliva.

Important events during 2020

KL1333

- Positive feedback from the US Food and Drug Administration ("FDA") and the UK MHRA, on the clinical development plan.
- Decision to conduct a cohesive registrational Phase 2/3 study starting in the second half of 2021.
- The first patients in the Phase 1a/b clinical study were dosed.
- The first healthy volunteers in the drug-drug interaction study (DDI study) were dosed.

NV354

- Preclinical pharmacology and safety studies entered the final phase.

Strategy and communications

- Change of company name to Abliva (formerly NeuroVive Pharmaceutical).
- Virtual Capital Markets Day in June.
- Mitochondria Day in September.

Financials

- Directed issue of SEK 20 million to Nordic life science investor Hadean Ventures in June. Dr Roger Franklin, partner at Hadean Ventures was elected as Director of Abliva's Board.
- A preferential rights issue in May raised approximately SEK 67 million before deduction of issue costs.

Other

- Magnus Persson left the Board of Directors to focus on his role as founding partner in Eir Ventures.

Important events after the reporting period

- Ellen Donnelly was appointed new CEO February 3, 2021.
- The license agreement with Fortify Therapeutics, regarding a development of a local treatment for Leber's Hereditary Optic Neuropathy (LHON), was terminated.
- KL1333 phase 1b - seven out of eight patients have been dosed.
- New date for the Annual General Meeting – 20 May 2021.

Financial information

October-December 2020*

- Net revenues: KSEK 112 (49)
- Other operating income: KSEK 1,602 (1,000)
- Loss before tax: KSEK 13,067 (27,112)
- Loss per share: SEK 0.04 (0.15)
- Diluted loss per share: SEK 0.04 (0.15)

January-December 2020

- Net revenues: KSEK 216 (134)
- Other operating income: KSEK 1,648 (3,500)
- Loss before tax: KSEK 59,994 (77,000)
- Loss per share: SEK 0.24 (0.45)
- Diluted loss per share: SEK 0.24 (0.45)

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

CEO statement

Let me begin this CEO statement by saying that I am delighted to join Abliva at such a pivotal time in the company's development. Even though I have been with the company for only a short time, I am impressed with what the Abliva team has built and achieved over the past few years. As a team, we are now about to take the next steps towards our objective of making Abliva a global player in the field of mitochondrial medicine, developing medicines for patients suffering from mitochondrial diseases.



Ellen Donnelly
CEO Abliva

KL1333 is first on our agenda

The first priority of our team is the KL1333 program. The time since FDA's positive feedback, recommending Abliva to run a single efficacy study instead of sequential Phase 2 and Phase 3 studies, has been very intense. This means that this study is now registrational and, if positive, will allow us to get this important medicine to patients much faster. The study program has been redesigned to meet with FDA requirements and the team has already initiated some complementary studies. Ongoing studies, such as the Phase 1a/b study and the DDI study, will be finalized during 2021, and it is our goal to launch the Phase 2/3 study in the second half of this year.

In other good news, the FDA also supports the main aspects of our proposed qualitative study, which is designed to generate evidence regarding primary mitochondrial disease patients' experiences with fatigue. The study will also validate the use of a patient-reported outcome assessment as primary endpoint

in the upcoming KL1333 Phase 2/3 study. This positive news strengthens this project further. For more detailed information on the KL1333 project, see page 5.

Expanding our reach to patients, physicians and parents

At the moment, the KL1333 drug candidate is our most important stepping stone towards our goal of bringing approved therapies to patients. To fully realize this project's potential we will look to expand our horizons internationally, working to enlist physicians and thought leaders to help us review our upcoming data readouts and confirm our Phase 2/3 study design in order to ensure the highest likelihood of success. We are looking forward to learning more about the patient needs in this area through our patient-reported outcomes validation study and patient registry study (both of which are ongoing) and by increasing our interactions with mitochondrial disease patient groups.

Expanding our geographic reach and financial resources

To become a global player, Abliva also needs to expand its geographical footprint. For instance, I think it will be natural for us to establish a presence in the U.S. since part of the KL1333 registrational Phase 2/3 study will take place there. And, in preparation for the potential launch of KL1333 to the market, it is necessary to build a commercial organization in the U.S. and other strategic locations to establish and ensure a global reach.

Another benefit of establishing a U.S. presence is that it brings us closer to the U.S. capital market. In 2021 we will need to strengthen the company's financial resources quite substantially to support the global Phase 2/3 study, and the American capital market offers many opportunities for biotech companies with great prospects. Our ambition therefore is to establish an Abliva presence in the U.S. within a fairly short period of time. I am confident that the Abliva investment case will resonate with

global investors given the large unmet need in primary mitochondrial diseases, our fast to market approach with KL1333, and the large commercial opportunity that exists.

Building on our strengths

Abliva is a Swedish company, and we will continue to build on our strong scientific and international position, which is at the core of Abliva's operations. KL1333 is the project that has progressed the furthest, but our other focus project NV354 also shows great potential and will move towards IND later this year. In addition to these two projects, we have a number of projects in discovery phase which are very promising.

Ellen Donnelly
CEO

Strategic focus: primary mitochondrial diseases

Abliva's objective is to improve life for patients suffering from primary mitochondrial diseases, meaning diseases caused by an inherited genetic defect in mitochondrial function. These diseases often cause great suffering for both patients and family members. The symptoms worsen over time and, in many cases, the diseases lead to a far too early death. Today, a very limited number of treatment options are available, which means there are major unmet medical needs.

Focus on KL1333 and NV354

Strategically, Abliva's focus on mitochondrial diseases means that the company is concentrating financial and personnel resources on the KL1333 and NV354 drug candidates. KL1333 is in clinical trials and NV354 is being prepared for clinical trials. The aim is to take these projects all the way to market authorization, either on our own or together with a partner.

Significant advantages with orphan drug designation

KL1333 has obtained orphan drug designation and NV354 also has the potential to receive orphan drug designation. An orphan drug designation generally offers several positive benefits, including:

- regulatory assistance and scientific advice from pharmaceutical regulators
- efficient development
- lower development costs
- greater chance of regulatory approval compared with drug candidates that lack orphan drug designation
- attractive pricing compared with drug candidates that lack orphan drug designation¹⁾²⁾

On several occasions, Abliva has received advice from pharmaceutical regulators in the US, UK and Europe. In 2020, a recommendation from the U.S. Food and Drug Administration (FDA) concerning drug candidate KL1333, led to the decision to plan for a single registrational Phase 2/3 study instead of separate Phase 2 and 3 efficacy studies.

Abliva collaborates continuously with world-class advisors in the field of orphan drugs, who assist the company in its dialogue with regulators. Abliva has also established partnerships and a continuous dialogue with some of the world's leading clinical centers for the treatment of primary mitochondrial diseases.

Discovery-phase projects

Abliva works with a number of new molecules in the project portfolio for primary mitochondrial diseases. The projects focus on the regulation and stabilization of the mitochondrion's energy production.

Market

The main customers of Abliva's future products include in addition to patients, specialist healthcare and institutions that pay for medicines. Primary prescribers of Abliva's future drugs include highly specialized physicians at national and regional centers of expertise for genetic metabolic disorders. In other words, the future customers are a relatively concentrated group of specialists, decision makers and patients.

Future revenue

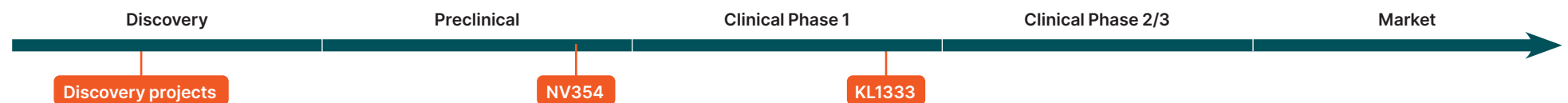
Abliva works under two main scenarios for establishing future revenue: sales revenue for the drugs the company intends to bring all the way to market, and revenue from out-licensing, milestone payments and royalties from out-licensed drug candidates.

Primary mitochondrial disorders are metabolic diseases that affect the ability of cells to convert energy. The diseases can manifest very differently depending on the organs in which the genetic defects are located and have historically been viewed as clinical syndromes, and more recently as disease spectra caused by genetic defects affecting mitochondrial function. 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.

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.



KL1333

Blockbuster candidate heading to registrational Phase 2/3 study

Ongoing Phase 1a/b study: dosing in patients initiated
 Registrational Phase 2/3 study planned to start H2 2021
 Orphan drug designation in both the United States and Europe

Events in the fourth quarter. The first primary mitochondrial disease patient in Abliva's KL1333 Phase 1a/b study was dosed. In this third part of the study, the pharmaceutical properties of KL1333 are for the first time being evaluated in patients. Clinical dosing study in healthy volunteers was initiated, as a part of the Phase 1 study. DDI study (Drug-Drug Interaction study) was initiated.

Events after the end of the period. Seven out of eight patients have been dosed in the company's Phase 1a/b study. The dosing is expected to be completed during the first quarter of 2021. FDA has informed that they support the main aspects of Abliva's proposed qualitative interview study in patients suffering from fatigue.

Objectives for 2021

- Conclude the drug-drug interaction study and report results (H1 2021)
- Conclude the Phase 1a/b study and report results (H1 2021)
- Preparatory activities for the Phase 2/3 study:
 - conduct a patient registry study
 - conduct a validation study of endpoints
 - initiate long-term toxicological studies
- Initiate registrational Phase 2/3 study (H2 2021)

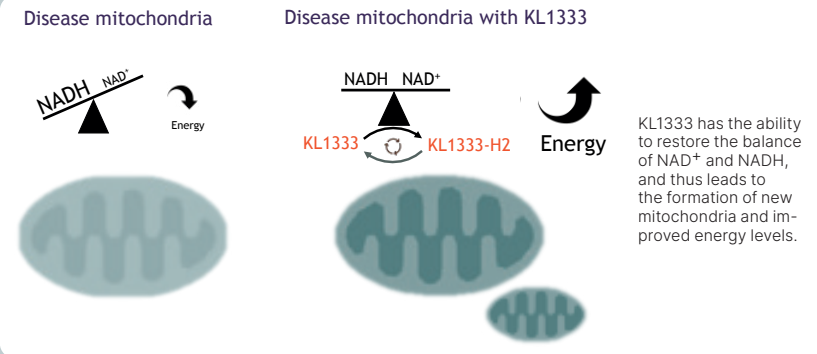
DISEASE AREA

KL1333 is being developed for the treatment of adult patients within the spectra of MELAS-MIDD and CPEO-KSS.

These diseases cause a wide range of severe symptoms, fatigue in particular.

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

MODE OF ACTION



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 2024. The number of patients in the target group for treatment with KL1333 is approximately 40,000¹⁾ 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

CLINICAL DEVELOPMENT PLAN

Indication	Discovery	Preclinical	Clinical Phase 1	Clinical Phase 2/3	Market
MELAS-MIDD and CPEO-KSS			Phase 1a (healthy volunteers) ✓ Dose-dependent exposure ✓ Phase 1b with patients started ✓ DDI study started ✓ Fatigue interview study Patient registry study Clinical dosing study	Registrational study in the US and Europe. Start 2021.	With or without partner

NV354

First-in-class therapeutic approach heading towards clinical development

Finalizing safety studies
Preparing for healthy volunteer studies

Events in the fourth quarter

Abliva has focused on the final parts of the preclinical program, in particular pharmacology and safety studies. In parallel, the company has also started preparations for the clinical program.

Objectives for 2021

- Complete preclinical pharmacology and safety studies (H1 2021)
- Produce NV354 clinical trial material for clinical studies (H2 2021)
- Complete regulatory documentation to support clinical entrance (H2 2021)

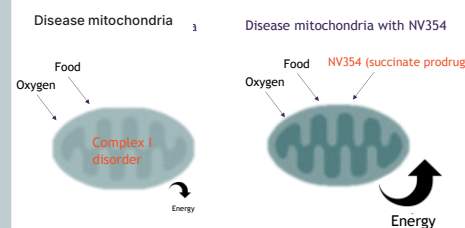
PRIMARY INDICATION

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. Patients usually die within two to three years. 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

In a second step, NV354 may also be developed for the treatment of MELAS and LHON. MELAS is a very serious disease with symptoms such as muscle weakness, epilepsy and 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 long-term oral treatment.

MODE OF ACTION



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

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.¹⁾

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

CLINICAL DEVELOPMENT PLAN

Indication	Discovery	Preclinical	Clinical Phase 1	Clinical Phase 2/3	Market
Leigh syndrome		Ongoing pharmacology and safety studies	Complete regulatory documentation to support clinical entrance (H2 2021)		With or without partner

Non-core asset

The company has been seeking a strategic partner for the continued development of NeuroSTAT. It has initiated 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^{1) 2)} funded by the U.S. Department of Defense.

■ 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.

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 Defence (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 fourth quarter of 2020 was KSEK 112 (49). Other operating revenues for the fourth quarter were KSEK 1,602 (1,000) and pertains mainly of Vinnova grants for the NV354 project. During the full year of 2020 the consolidated turnover was 216 (134) KSEK. Other operating revenues for the full year amounted 1,648 (3,500) KSEK mainly related to Vinnova grant.

Results of operations

The operating loss for the fourth quarter was KSEK 13,169 (27,223) and for the full year the operating loss amounted KSEK -60,071 (-77,075). The net loss before tax for the fourth quarter amounted to KSEK 13,067 (-27,112). For the full year the loss before tax was -59,994 (-77,000).

The operating loss was affected by other external expenses, which for the full year was KSEK 46,072 (63,133). Expenses related to development projects, as a part of external expenses, have affected the result with KSEK 29,510 (45,093) whereof KSEK 22,817 (19,233) relates to project in clinical phase. Personnel expenses during the full year amounts to KSEK 13,035 (14,872). Other operating expenses amount to, KSEK 0 (325) and pertains to exchange-rate losses.

(SEK 000)	Note	1 Oct, 2020 31 Dec, 2020	1 Oct, 2019 31 Dec, 2019	1 Jan, 2020 31 Dec, 2020	1 Jan, 2019 31 Dec, 2019
Net sales		112	49	216	134
Other operating income		1,602	1,000	1,648	3,500
		1,714	1,049	1,864	3,634
Operating expenses					
Other external expenses		-11,440	-23,461	-46,072	-63,133
Personnel cost		-2,799	-4,168	-13,305	-14,872
Depreciation and write-down of tangible and intangible assets		-644	-622	-2,558	-2,379
Other operating expenses		-	-20	-	-325
		-14,883	-28,271	-61,935	-80,709
Operating income		-13,169	-27,223	-60,071	-77,075
Profit/loss from financial items					
Result from other securities and receivables related to non current assets		107	121	107	121
Financial income		-	-	-	-
Financial costs		-5	-10	-30	-46
		102	111	77	75
Profit/loss before tax		-13,067	-27,112	-59,994	-77,000
Income tax	2	-	-	-	-
Profit/loss for the period		-13,067	-27,112	-59,994	-77,000
Other comprehensive income					
<i>Items that may be reclassified to profit or loss</i>					
Translation differences on foreign subsidiaries		-2	-2	-3	3
Total comprehensive income for the period		-13,069	-27,114	-59,997	-76,997
Loss for the period attributable to:					
Parent company shareholders		-13,063	-27,107	-59,989	-76,994
Non-controlling interests		-4	-5	-5	-6
		-13,067	-27,112	-59,994	-77,000
Total comprehensive income for the period					
Parent company shareholders		-13,065	-27,110	-59,992	-76,991
Non-controlling interests		-4	-4	-5	-6
		-13,069	-27,114	-59,997	-76,997
Earnings per share before and after dilution(SEK) based on average number of shares		-0.04	-0.15	-0.24	-0.45

Consolidated Statement of Financial Position

Financial position

The equity/assets ratio was 93 (86) percent as of 31 December 2020, and equity was KSEK 140 362 (127,795). The equity includes funds from the in May completed rights issue, which provided the company with KSEK 54,064 after deduction of issue costs and compensation for guarantee commitments of KSEK 12,913 and funds from the in July completed directed issue with KSEK 18,500 less expenses KSEK 1,500. Cash and cash equivalents amounted to KSEK 61,643 (58,319) as of 31 December 2020, an increase of KSEK 3,324 from the beginning of the year. Total assets as of 31 December 2020 were KSEK 150,663 (148,492).

The board continuously monitors and evaluates the company's funding need and financial position. The board has initiated a process to ensure adequate funding to enable execution of the company's strategy with the start of a registrational Phase 2/3 study in the company's KL1333 project during the second half of 2021.

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	31 Dec, 2020	31 Dec, 2019
ASSETS			
Non-current assets			
Intangible assets	1		
Development costs		51,706	51,706
Patents		20,971	21,501
Other Intangible assets		1,344	1,479
		74,021	74,686
Tangible assets			
Equipment		41	99
Righth of use asset leases		343	687
		384	786
Financial assets			
Other long-term securities		13,101	13,101
		13,101	13,101
Total non-current assets		87,506	88,573
Current assets			
Other receivables		928	1,141
Prepaid expenses and accrued income		586	459
Cash and cash equivalents		61,643	58,319
		63,157	59,919
TOTAL ASSETS		150,663	148,492

Consolidated Statement of

Financial
Position

(SEK 000)	Note	31 Dec, 2020	31 Dec, 2019
EQUITY AND LIABILITIES			
Equity attributable to the shareholders of the parent company			
Share capital		14,817	9,298
Additional paid in capital		660,025	592,980
Translation reserve		616	619
Retained earnings		-535,096	-475,107
Total equity attributable to the shareholders of the parent		140,363	127,790
Non-controlling interests		0	5
Total equity		140,363	127,795
Long-term liabilities			
Other longterm liabilities		92	361
		92	361
Short-term liabilities			
Accounts payable		4,201	14,234
Other liabilities		675	811
Accrued expenses and deferred income		5,333	5,291
		10,209	20,336
Total liabilities		10,301	20,697
TOTAL EQUITY AND LIABILITIES		150,663	148,492

Consolidated Statement of Changes in Equity

(SEK 000)	Equity attributable to the shareholders of the parent company					Non-controlling interests	Total equity
	Share-capital	Additional paid in capital	Translation reserve	Retained earnings	Total		
Opening balance, 1 January 2020	9,298	592,980	619	-475,107	127,791	5	127,795
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, net after tax	-	-	-3	-	-3	-	-3
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	-535,095	140,363	0	140,363
Opening balance, 1 January 2019	4,585	489,913	616	-398,113	97,002	11	97,012
Comprehensive profit/loss for the period							
Profit/loss for the period	-	-	-	-76,994	-76,994	-6	-77,000
Other comprehensive income							
Translation differences	-	-	3	-	3	-	3
Other comprehensive profit/loss for the period, net after tax	-	-	3	-	3	-	3
Total comprehensive profit/loss	-	-	3	-76,994	-76,991	-6	-76,997
Transactions with shareholders							
Rights Issue	4,713	103,067	-	-	107,780	-	107,780
Total transactions with shareholders	4,713	103,067	-	-	107,780	-	107,780
Closing balance, 31 December 2019	9,298	592,980	619	-475,107	127,791	5	127,795

*Total equity includes funds from the May 5, 2020 completed rights issue with KSEK 54,064 less expenses and guarantees KSEK 12,913 and funds from the July 9th completed directed issue with KSEK 18,500 less expenses KSEK 1,500.

Consolidated Statement of Cash Flows

Cash flow and investments

Operating cash flow for the fourth quarter was KSEK -11,154 (-21,096). For the full year the operating cash flow amounted -67,558 (-72,412). The cash flow effect related to investments in intangibles equals KSEK -1,407 (-2,626) for the full year. Cash flow for the fourth quarter equals KSEK -11,367 (-21,450). Cashflow for the full year equals KSEK 3,330 (32,364).

(SEK 000)	1 Oct, 2020 31 Dec, 2020	1 Oct, 2019 31 Dec, 2019	1 Jan, 2020 31 Dec, 2020	1 Jan, 2019 31 Dec, 2019
Cash flow from operating activities				
Operating income	-13,169	-27,222	-60,071	-77,074
Adjustments for non-cash items:				
Depreciation	644	879	2,558	2,379
Result from other securities and receivables related to non current assets	-1	-	107	121
Interest received	-	-	-	-
Interest paid	-5	-	-30	-46
Net cash from operating activities before changes in working capital	-12,530	-26,343	-57,436	-74,620
Changes in working capital				
Increase/decrease of other current assets	-86	316	86	1,077
Increase/decrease of other short-term liabilities	1,462	4,932	-10,208	1,131
Changes in working capital	1,376	5,248	-10,122	2,208
Cash flow from operating activities	-11,154	-21,096	-67,558	-72,412
Investing activities				
Acquisition of intangible assets	-320	-157	-1,407	-2,626
Acquisition of tangible assets	-	-	-	-69
Increase in other financial assets	-	-	-	-
Cash flow from investing activities	-320	-157	-1,407	-2,695
Financing activities				
New share issue	-	-	72,564	107,780
Amortization lease	-	-	-269	-309
Cash flow from financing activities	-	-	72,295	107,471
Cash flow for the period	-11,367	-21,450	3,330	32,364
Cash and cash equivalents at the beginning of the period	73,013	79,773	58,319	25,951
Effect of exchange rate changes on cash	-4	-4	-6	4
Cash and cash equivalents at end of period	61,643	58,319	61,643	58,319

Parent Company

Income Statement

Parental company

Company earnings after tax for the fourth quarter amounts to KSEK -13,043 (-27,079). Earnings after tax for the full year amounts to KSEK -59,961 (-76,947). Most of the Group's operations are conducted within the parent company. Accordingly, no further specific information regarding the parent company is presented.

Parent Company

Statement of Comprehensive Income

(SEK 000)	Note	1 Oct, 2020 31 Dec, 2020	1 Oct, 2019 31 Dec, 2019	1 Jan, 2020 31 Dec, 2020	1 Jan, 2019 31 Dec, 2019
Net sales		112	49	216	134
Other operating income		1,603	1,000	1,648	3,500
		1,715	1,049	1,864	3,634
Operating expenses					
Other external expenses		-11,508	-23,525	-46,411	-63,469
Personnel cost		-2,799	-4,168	-13,305	-14,872
Depreciation and write-down of tangible and intangible assets		-558	-536	-2,215	-2,036
Other operating expenses		-	-20	-	-325
		-14,865	-28,250	-61,931	-80,702
Operating income		-13,150	-27,201	-60,067	-77,068
Profit/loss from financial items					
Result from other securities and receivables related to non current assets		107	122	107	122
Interest expenses and other similar loss items		-	-	-1	-1
		107	122	106	121
Profit/loss before tax		-13,043	-27,079	-59,961	-76,947
Income tax	2	-	-	-	-
Profit/loss for the period		-13,043	-27,079	-59,961	-76,947

(SEK 000)	Note	1 Oct, 2020 31 Dec, 2020	1 Oct, 2019 31 Dec, 2019	1 Jan, 2020 31 Dec, 2020	1 Jan, 2019 31 Dec, 2019
Profit/loss for the period		-13,043	-27,079	-59,961	-76,947
Other comprehensive income		-	-	-	-
Total comprehensive profit/loss for the period		-13,043	-27,079	-59,961	-76,947

Parent Company
Balance Sheet

(SEK 000)	Note	31 Dec, 2020	31 Dec, 2019
ASSETS			
Non-current assets			
<i>Intangible assets</i>	1		
Development costs		51,706	51,706
Patents		20,971	21,501
Other intangible assets		1,344	1,479
		74,021	74,686
Tangible assets			
Equipment		41	99
		41	99
Financial assets			
Other long-term placement		13,101	13,101
Shares in subsidiaries	3	23,625	23,625
		36,726	36,726
Total non-current assets		110,788	111,511
Current assets			
<i>Short term receivables</i>			
Other receivables		926	1,138
Prepaid expenses and accrued income		585	459
		1,511	1,597
Cash and bank balances		61,634	58,272
Total current assets		63,145	59,869
TOTAL ASSETS		173,933	171,380

Parent Company
Balance Sheet

(SEK 000)	Note	31 Dec, 2020	31 Dec, 2019
EQUITY AND LIABILITIES			
Equity			
<i>Restricted equity</i>			
Share capital		14,817	9,298
Statutory reserve		1,856	1,856
Development expenditure reserve		13,576	14,106
		30,249	25,260
Unrestricted equity			
Share premium reserve		170,111	103,067
Retained earnings		23,609	100,026
Profit/loss for the period		-59,961	-76,947
		133,759	126,146
Total equity		164,009	151,406
Short-term liabilities			
Accounts payable		4,201	14,234
Other liabilities		406	467
Accrued expenses and deferred income		5,317	5,273
		9,924	19,974
TOTAL EQUITY AND LIABILITIES		173,932	171,380

Notes

Note 1 — Intangible assets

(SEK 000)	Development costs	Patents	Other	Total
ACCUMULATED COST				
Opening balance 1 Jan. 2020	51,706	32,279	2,864	86,849
Additions	-	1,492	-	1,492
Closing balance 31 Dec. 2020	51,706	33,771	2,864	88,341
ACCUMULATED DEPRECIATION				
Opening balance 1 Jan. 2020	-	-10,778	-1,385	-12,163
Depreciation for the period	-	-2,022	-134	-2,156
Closing balance 31 Dec. 2020	-	-12,800	-1,519	-14,319
Residual value 31 Dec. 2020	51,706	20,971	1,345	74,022
(SEK 000)				
ACCUMULATED COST				
Opening balance 1 Jan. 2019	51,706	29,107	2,864	83,677
Additions	-	3,172	-	3,172
Closing balance 31 Dec. 2019	51,706	32,279	2,864	86,849
ACCUMULATED DEPRECIATION				
Opening balance 1 Jan. 2019	-	-8,986	-1,251	-10,237
Depreciation for the period	-	-1,792	-134	-1,926
Closing balance 31 Dec. 2019	-	-10,778	-1,385	-12,163
Residual value 31 Dec. 2019	51,706	21,501	1,479	74,686

Note 2 – Tax

The group's total loss carry-forwards amounts to KSEK 618,957 as of 31 December 2020 (544,635). The parent company's total loss carry-forwards amounts to SEK 593,098 as of 31 December 2020 (518,809). 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.

Other disclosures

Transactions with related parties

Transactions between the company and its subsidiaries, 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. 2020 30 Sep. 2020	1 Jan. 2019 31 Dec. 2019
Eskil Elmér, CSO	6	6
Magnus Hansson, CMO	4	3
Total	10	9

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 occurred.

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 December 2020 was 9 (9), of which 5 (4) are women.

Incentive programs/share warrants

Currently there is no incentive program.

Audit review

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

Upcoming financial statements

Annual Report	Week 17
Q1 Report January-March 2021	May 20, 2021
Q2 Report January-June 2021	August 19, 2021
Q3 Report January-September 2021	November 19, 2021
Year-End Report 2021	February 22, 2022

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

Annual General Meeting 2021

Abliva's Annual General Meeting will be held at Medicon Village, Scheelevägen 2, in Lund on Thursday 20 May 2021 at 4 pm CEST.

Please note that the time of the Annual General Meeting has changed compared to what has previously been communicated. The postponement is done for timewise practical reasons.

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. The Board of Directors works continuously to secure the business operation's need for financing. A way to spread risks is through continuous development activities, to out-license projects or enter strategic partnerships.

Impact of COVID-19 on the Company's clinical trials

The Company estimates there is a risk that COVID-19 will further delay Abliva's ongoing Phase Ia/b study with KL1333, since healthcare authorities and healthcare providers will prioritize available resources, care locations and healthcare professionals to better meet the possible influx of COVID-19 patients. At present, the planned final part of the Phase I a/b study with KL1333 against PMD started recruiting patients and seven of a total of eight patients have been dosed. There is a risk that completion from this part of the study will be further delayed. There is a risk that the start of the upcoming Phase 2/3 study, which is expected to continue in the second half of 2021 will be delayed.

Abliva's preparations in the form of preclinical safety studies to apply for permission to initiate a clinical study for the drug candidate, NV354 for Leigh syndrome, in 2021 are currently not considered to be affected to a greater extent by the COVID-19 pandemic. In Abliva's assessment, it is currently difficult to assess the actual effects of COVID-19 over the longer term and the degree to which they will affect the Company's operations and clinical studies.

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.

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 2019 on pages 52-68.

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 financial 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, February 19, 2021

David Laskow-Pooley

Chairman of the Board

David Beijker

Board member

Roger Franklin

Board member

Denise Goode

Board member

Jan Törnell

Board member

Ellen Donnelly

Chief Executive Officer



David Laskow-Pooley



David Beijker



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 08:30 a.m. CET on February 19, 2021.

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.

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 stroke-like 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 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 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 is focused on two projects. KL1333, a powerful NAD⁺ regulator, is in clinical development and has been granted orphan drug designation in Europe and the US. NV354, an energy replacement (succinate) therapy, is in preclinical development. Abliva is based in Lund, Sweden.

What is primary mitochondrial disease?

Primary mitochondrial diseases are metabolic diseases that affect the ability of cells to convert energy. The diseases can manifest very differently depending on the organs in which the genetic defects are located and have historically been viewed as clinical syndromes, and more recently as disease spectra caused by genetic defects affecting mitochondrial function. It is estimated that 125 persons per million have a primary mitochondrial disease.

Abliva's discovery projects focus on deeper understanding of the mechanisms for our unique chemistry platforms, and the development of next-generation compounds for primary mitochondrial diseases.

Stock exchange

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

Abliva AB (publ)

Medicon Village, SE-223 81 Lund
Phone: +46 46 275 62 20 (switchboard)
ir@abliva.com
www.abliva.com

