




Interim Report

January - March 2021

A photograph of a woman with long, wavy blonde hair, seen from the side, kissing a baby on the forehead. The baby is wearing gold-rimmed sunglasses and is secured in a blue denim baby carrier. The background is a soft-focus outdoor setting, possibly a beach or a field with dry grass.

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

First quarter summary

KL1333 Phase 1a/b study completed.

Directed issue of SEK 80 million.

Important events first quarter (Jan - Mar 2021)

- Ellen Donnelly was appointed new CEO, and she will be based at Abliva Inc., in the Boston area.
- The clinical Phase 1a/b study with KL1333, Abliva's drug candidate for chronic oral treatment of primary mitochondrial diseases, was completed. No serious adverse events (SAEs) have been reported.
- Abliva carried out a directed issue of SEK 80m, including to company lead investor Hadean Ventures. The subscription price, SEK 0.75, corresponded approximately to market price. SEK 24.5m was received immediately. 55.5 was received after approval at the Extraordinary General Meeting on 29 April, 2021.
- The license agreement with Fortify Therapeutics, regarding a development of a local treatment for Leber's Hereditary Optic Neuropathy (LHON), was terminated.

Important events after the reporting period

- Positive safety and pharmacokinetic data from the double-blind, randomized, placebo-controlled Phase 1a/b study with KL1333 was reported, as well as signals of efficacy in patients with primary mitochondrial diseases. In a cohort of eight patients (six dosed with KL1333, two with placebo), there were signs of efficacy across well-established relevant clinical endpoints including two patient-reported fatigue endpoints and a functional endpoint.
- Extraordinary General Meeting was held on 29 April 2021. The Board of Director's resolution to issue shares with deviation from the shareholder's preferential rights was approved.



Financial information

January-March 2021*

- Net revenues: SEK 0,000 (8,000)
- Other operating income: SEK 0,000 (0,000)
- Loss before tax: SEK 21,456,000 (16,537,000)
- Loss per share: SEK 0.07 (0.10)
- Diluted loss per share: SEK 0.07 (0.10)

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



Positive safety results and signs of efficacy

Abliva had a strong first quarter. We completed key activities for KL1333, Abliva's drug candidate for chronic, oral treatment of primary mitochondrial disease. We delivered a directed share issue, the proceeds of which will allow us to finalize the preparations for the upcoming global KL1333 Phase 2/3 study and progress NV354 towards the clinic. And we took a significant step of expanding our geographical footprint. These are key steps as we work to establish Abliva as a well-known and recognized world leader in mitochondrial medicine, developing medicines for patients suffering from primary mitochondrial diseases (PMD).

World Leader in Mitochondrial Medicine

I speak often of our goal to become a world leader in Mitochondrial Medicine so I thought I would start out this Q1 report with a review of the internal and external factors that support this vision.

Abliva is clearly differentiated from the other players in this space. First, we have a clear strategy that is focused on diseases of mitochondrial dysfunction. Abliva is not a one-product company and we could have two clinical stage candidates by next year. This is fueled by the fact that the CSO and CMO have been working in the area of mitochondrial medicine for over two decades. We have built the foundation here at Abliva to become the premier biotech company in this area.

Externally it is the competitive landscape and the financial environment that provide support for our vision. The current landscape provides an opportunity as there are no clear leaders in the fields of Mitochondrial Medicine or Primary Mitochondrial Diseases. Second, traditional biotech investors are indicating their interest in this area with significant investment in the space. Attracting the interest of international investors will be important as we look to raise additional capital to finance our vision.

Pave the way for a 2021 Phase 2/3 commence for KL1333

The most important of these data readouts is the Phase 1a/b study which completed dosing in mid March. The top-line safety data was communicated in mid-March and another press release, issued this morning, provides additional information on the study results. We are extremely pleased with the Phase

1a/b data and look forward to presenting more details during the United Mitochondrial Disease Foundation (UMDF) Mitochondrial Medicine Symposium in late June. 2021 promises to be busy with KL1333 Phase 2/3 study by the end of the year. There are multiple of activities that must happen on time to achieve this goal and the team is working aggressively to ensure that the data is delivered on time. One key area of focus is the finalization of the clinical protocol and there are several activities ongoing and data readouts that will support this.

A core element of our strategy involves securing regulators' support to best position the program for regulatory success upon completion of the clinical program. In the first quarter of the year, we discussed our Phase 2/3 clinical plan with the European Medicines Agency, EMA. This most recent feedback supplements the feedback previously received from US FDA and UK MHRA with respect to the development program for KL1333. The team will consider all of the regulatory advice as we aim to finalize our clinical design in the second quarter.

Expanding Our Geographical Reach

Expansion of our global footprint is a key goal and Abliva took its first step towards this goal in early March when we signed the Certificate of Incorporation for Abliva Inc., establishing a presence for Abliva in the Boston area, MA, an important center of biotech drug development in the United States.

There are many benefits to establishing a US presence. It brings us closer to the American capital market which offers many opportunities for biotech companies like Abliva with a compelling value proposition. Equally important, our US base will facil-

itate the communication with sites, physicians and patients as we commence our Phase 2/3 study. Finally, as we prepare for the future potential launch of KL1333 to the market, Boston area is likely to become the center of our commercial operations.

Attracting New Investors

In March, Abliva successfully completed a directed share issue which raised SEK 80 million in gross proceeds. This new financing will be used to complete the Phase 1 studies and prepare for the Phase 2/3 study for KL1333, advance NV354 towards the clinic, and cover operational costs in the company. I would like to thank both present and new investors for their participation in this round. Going forward, we will continue to tell our story broadly, increasing our interactions with European and American specialist and institutional investors as we work to secure the additional financing necessary to run the KL1333 registrational Phase 2/3 study.

Going Forward: Delivering on our commitments

The Abliva team had a strong first quarter with the completion of the Phase 1a/1b study and the important round of financing. These activities provide the foundation for the more substantial milestones that are to come – from the determination of NV354 as a clinical candidate, to the filing of regulatory documentation to support the KL1333 study, to the first patient dosed in our registrational study. It continues to be an exciting year for Abliva and I am thankful to be working with this team which is passionately invested in our work.

Ellen Donnelly
CEO



Primary mitochondrial disorders are metabolic diseases that affect the cells' ability to convert energy. The diseases can manifest very differently depending on the organs in which the genetic defects are located. They 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.

PROJECT (partner)	DISEASE	DISCOVERY	PRECLINICAL	PHASE 1	PHASE 2/3	MARKET
KL1333* (Yungjin)	(PMD) MELAS-MIDD, KSS-CPEO					
NV354	(PMD) Leigh syndrome					
Early programs	(PMD)					

*Orphan drug designation in the US and Europe

Strategic Focus: Primary Mitochondrial Diseases (PMD)

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

Building the Premier Mitochondrial Medicine Company

Abliva's long-term goal is to become the leading global biopharmaceutical 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 (PMD)

Mitochondria function as the powerhouses of our cells and are crucial for the cells' energy metabolism. PMD 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 for patients. 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 late 2021. 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 \$1B/year in annual sales.

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 PMD Leigh Syndrome initially with potential to expand to other PMD indications that have a dysfunctional complex I in the electron transport chain.

Additionally, 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 reg-

ulatory 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^{1,2}.

In addition, we have sought advice from pharmaceutical regulators in the US, UK and Europe. This advice has been extremely important to the company, as is clearly demonstrated with the 2020 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 the company in 2020 was the first step to bringing specialist investors into the company and the company aims to continue to attract new specialist and institutional investors across Sweden, Europe and America as the financial needs of the company increase with the KL1333 registrational study, the progression of the portfolio, and the build of a commercial organization.

KL1333

Blockbuster candidate heading to registrational Phase 2/3 study

Phase 1a/b study: Positive safety results and signs of efficacy
Registrational Phase 2/3 study planned to start during late 2021
Orphan drug designation in both the United States and Europe

Events in the first quarter. The company's clinical Phase 1a/b study was completed. No serious adverse events (SAEs) have been reported. The DDI study (Drug-Drug Interaction study) entered the final phase. FDA has informed that they support the main aspects of Abliva's proposed qualitative interview study in patients suffering from fatigue. The Phase 2/3 clinical plan was discussed with the EMA.

Events after the end of the period. Positive safety and pharmacokinetic data from the double-blind, placebo-controlled, randomized Phase 1a/b study with KL1333 was reported, as well as signals of efficacy in patients with PMD. In a cohort of eight patients (six dosed with KL1333, two with placebo), there were signs of efficacy across well-established relevant clinical endpoints including two patient-reported fatigue endpoints and a functional endpoint. The drug-drug interaction study was completed.

Objectives for 2021

- Conclude the Phase 1a/b study and report results. ✓
- Conclude the drug-drug interaction study and report results. ✓
- 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.

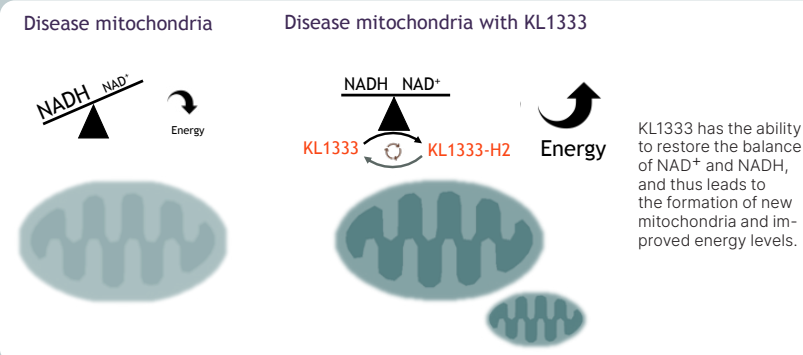
DISEASE AREA

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.

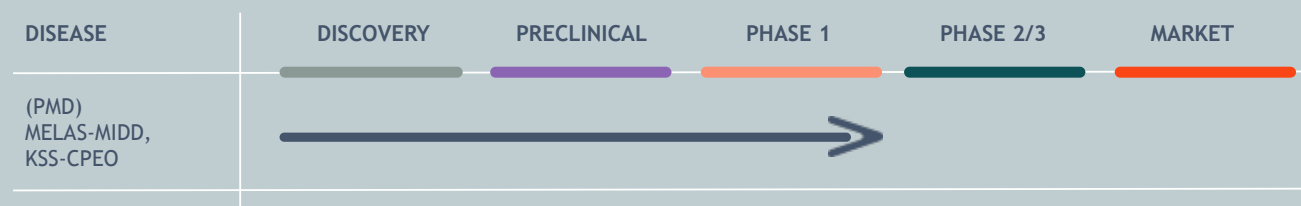
MODE OF ACTION



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



NV354

First-in-class therapeutic approach heading towards clinical development

Finalizing safety studies
Preparing for healthy volunteer studies

Events in the first 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
- Produce NV354 clinical trial material for clinical studies.
- Complete regulatory documentation to support clinical entrance.

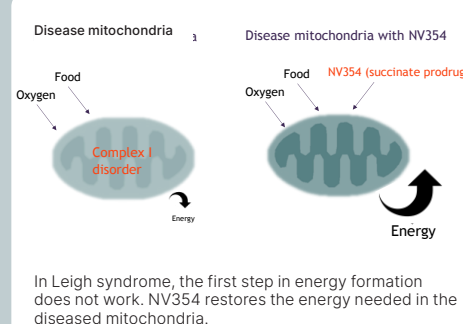
PRIMARY INDICATION

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.

MODE OF ACTION



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



Non-core asset

The company is 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 first quarter of 2021 was SEK 0,000 (8,000). Other operating revenues for the first quarter were SEK 0,000 (0,000).

Results of operations

The operating loss for the first quarter was SEK 21,451,000 (16,528,000). The net loss before tax for the first quarter amounted to SEK 21,456,000 (16,537,000).

The operating loss was affected by other external expenses, which for the full were SEK 15,540,000 (11,957,000). During the first quarter, expenses related to development projects, as a part of external expenses, have affected the result with SEK 12,318,000 (7,035,000) whereof SEK 11,328,000 (3,845,000) relates to project in clinical phase. Personnel expenses during the first quarter amount to SEK 5,047,000 (3,550,000). Other operating expenses amount to, SEK 207,000 (403,000) and pertains to exchange-rate losses. Expenses related to the previous CEO, including notice period and severance pay, will amount to approximately SEK 2,881,000 in total.

(SEK 000)	Note	1 Jan, 2021 31 Mar, 2021	1 Jan, 2020 31 Mar, 2020	1 Jan, 2020 31 Dec, 2020
Net sales		-	8	216
Other operating income		0	-	1,648
		0	8	1,864
Operating expenses				
Other external expenses		-15,540	-11,957	-46,072
Personnel cost		-5,047	-3,550	-13,305
Depreciation and write-down of tangible and intangible assets		-658	-626	-2,558
Other operating expenses		-207	-403	-
		-21,451	-16,536	-61,935
Operating income		-21,451	-16,528	-60,071
Profit/loss from financial items				
Result from other securities and receivables related to non current assets		-	-	107
Financial income		-	-	-
Financial costs		-5	-9	-30
		-5	-9	77
Profit/loss before tax		-21,456	-16,537	-59,994
Income tax	2	-	-	-
Profit/loss for the period		-21,456	-16,537	-59,994
Other comprehensive income				
<i>Items that may be reclassified to profit or loss</i>				
Translation differences on foreign subsidiaries		1	2	-3
Total comprehensive income for the period		-21,455	-16,535	-59,997
Loss for the period attributable to:				
Parent company shareholders		-21,456	-16,537	-59,989
Non-controlling interests		0	0	-5
		-21,456	-16,537	-59,994
Total comprehensive income for the period				
Parent company shareholders		-21,455	-16,535	-59,992
Non-controlling interests		0	0	-5
		-21,455	-16,535	-59,997
Earnings per share before and after dilution(SEK) based on average number of shares		-0.07	-0.10	-0.45

Consolidated Statement of Financial Position

Financial position

The equity/assets ratio was 87 (93) percent as of 31 March 2021, and equity was SEK 118,908,000 (140,363,000) compared to beginning of the year. Cash and cash equivalents amounted to SEK 47,976,000 (29,569,000) as of 31 March 2021, a decrease of SEK 13,667,000 from the beginning of the year. Total assets as of 31 March 2021 were SEK 137,048,000 (119,895,000).

The Abliva Board of Directors has completed a Directed Issue of 106,666,666 shares to several Swedish and international qualified investors, including Hadean Ventures. The subscription price in the Directed Issue is SEK 0.75 per share. Abliva thus receives proceeds of SEK 80.0 million before issue costs of approximately SEK 4 million through the Directed Issue, whereof SEK 24.5 million, i.e. Tranche 1, is received by the Company in April 2021 and SEK 55.5 million, i.e. Tranche 2, is received by the Company after approval at the Extraordinary General Meeting on April 29th 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 Mar, 2021	31 Mar, 2020	31 Dec, 2020
ASSETS				
Non-current assets				
Intangible assets	1			
Development costs		51,706	51,706	51,706
Patents		20,536	21,560	20,971
Other Intangible assets		1,311	1,445	1,344
		73,553	74,711	74,021
Tangible assets				
Equipment		30	83	41
Righth of use asset leases		258	601	343
		287	684	384
Financial assets				
Other long-term securities		13,101	13,101	13,101
		13,101	13,101	13,101
Total non-current assets		86,942	88,496	87,506
Current assets				
Other receivables		1,071	1,211	928
Prepaid expenses and accrued income		1,059	620	586
Cash and cash equivalents		47,976	29,568	61,643
		50,106	31,399	63,157
TOTAL ASSETS		137,048	119,895	150,663

Consolidated Statement of Financial Position

(SEK 000)	Note	31 Mar, 2021	31 Mar, 2020	31 Dec, 2020
EQUITY AND LIABILITIES				
Equity attributable to the shareholders of the parent company				
Share capital		14,817	9,298	14,817
Additional paid in capital		660,025	592,980	660,025
Translation reserve		617	621	616
Retained earnings		-556,551	-491,644	-535,096
Total equity attributable to the shareholders of the parent		118,908	111,255	140,363
Non-controlling interests		0	6	0
Total equity		118,908	111,261	140,363
Long-term liabilities				
Other longterm liabilities		-	448	92
		-	448	92
Short-term liabilities				
Accounts payable		9,049	1,769	4,201
Other liabilities		640	615	675
Accrued expenses and deferred income		8,451	5,802	5,333
		18,140	8,187	10,209
Total liabilities		18,140	8,635	10,301
TOTAL EQUITY AND LIABILITIES		137,048	119,895	150,663

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 2021	14,817	660,025	616	-535,095	140,362	0	140,362
Comprehensive profit/loss for the period							
Profit/loss for the period	-	-	-	-21,455	-21,455	0	-21,456
Other comprehensive income							
Translation differences	-	-	1	-	1	-	1
Other comprehensive profit/loss for the period, net after tax	-	-	1	-	1	-	1
Total comprehensive profit/loss	-	-	1	-21,455	-21,454	0	-21,455
Transactions with shareholders							
Total transactions with shareholders	-	-	-	-	-	-	-
Closing balance, 31 March 2021	14,817	660,025	617	-556,551	118,908	0	118,908
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	-	-	-	-16,537	-16,537	0	-16,536
Other comprehensive income							
Translation differences	-	-	2	-	2	-	2
Other comprehensive profit/loss for the period, net after tax	-	-	2	-	2	-	2
Total comprehensive profit/loss	-	-	2	-16,537	-16,535	0	-16,534
Transactions with shareholders							
Total transactions with shareholders	-	-	-	-	-	-	-
Closing balance, 31 March 2020	9,298	592,980	621	-491,643	111,255	6	111,261
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	140,362	0	140,362

Consolidated Statement of Cash Flows

Cash flow and investments

Operating cash flow for the first quarter was SEK -13,542,000 (-28,147,000). The cash flow effect related to investments in intangibles equals SEK -34,000 (-525,000) for the first quarter. Cash flow for the first quarter equals SEK 13,667,000 (-28,756,000).

(SEK 000)	1 Jan, 2021 31 Mar, 2021	1 Jan, 2020 31 Mar, 2020	1 Jan, 2020 31 Dec, 2020
Cash flow from operating activities			
Operating income	-21,451	-16,528	-60,071
Adjustments for non-cash items:			
Depreciation	658	626	2,558
Result from other securities and receivables related to non current assets	-	-	107
Interest received	-	-	-
Interest paid	-5	-9	-30
Net cash from operating activities before changes in working capital	-20,797	-15,911	-57,436
Changes in working capital			
Increase/decrease of other current assets	-617	-230	86
Increase/decrease of other short-term liabilities	7,873	-12,006	-10,208
Changes in working capital	7,256	-12,237	-10,122
Cash flow from operating activities	-13,542	-28,147	-67,558
Investing activities			
Acquisition of intangible assets	-34	-525	-1,407
Acquisition of tangible assets	-	-	-
Increase in other financial assets	-	-	-
Cash flow from investing activities	-34	-525	-1,407
Financing activities			
New share issue	-	-	72,564
Amortization lease	-92	-84	-269
Cash flow from financing activities	-92	-84	72,295
Cash flow for the period	-13,667	-28,756	3,330
Cash and cash equivalents at the beginning of the period	61,643	58,319	58,319
Effect of exchange rate changes on cash	1	5	-6
Cash and cash equivalents at end of period	47,976	29,568	61,643

Parent Company

Income Statement

Parental company

Company earnings after tax for the first quarter amounts to SEK -21,456,000 (-16,533,000). Accordingly, no further specific information regarding the parent company is presented.

Parent Company

Statement of Comprehensive Income

(SEK 000)		1 Jan, 2021	1 Jan, 2020	1 Jan, 2020
	Note	31 Mar, 2021	31 Mar, 2020	31 Dec, 2020
Net sales		-	8	216
Other operating income		0	-	1,648
		0	8	1,864
Operating expenses				
Other external expenses		-15,630	-12,047	-46,411
Personnel cost		-5,047	-3,550	-13,305
Depreciation and write-down of tangible and intangible assets		-572	-540	-2,215
Other operating expenses		-207	-403	-
		-21,456	-16,541	-61,931
Operating income		-21,456	-16,533	-60,067
Profit/loss from financial items				
Result from other securities and receivables related to non current assets		-	-	107
Interest expenses and other similar loss items		-	-	-1
		-	-	106
Profit/loss before tax		-21,456	-16,533	-59,961
Income tax	2	-	-	-
Profit/loss for the period		-21,456	-16,533	-59,961

(SEK 000)		1 Jan, 2021	1 Jan, 2020	1 Jan, 2020
	Note	31 Mar, 2021	31 Mar, 2020	31 Dec, 2020
Profit/loss for the period		-21,456	-16,533	-59,961
Other comprehensive income		-	-	-
Total comprehensive profit/loss for the period		-21,456	-16,533	-59,961

Parent Company

Balance Sheet

(SEK 000)	Note	31 Mar, 2021	31 Mar, 2020	31 Dec, 2020
ASSETS				
Non-current assets				
<i>Intangible assets</i>	1			
Development costs		51,706	51,706	51,706
Patents		20,536	21,560	20,971
Other intangible assets		1,311	1,445	1,344
		73,553	74,711	74,021
Tangible assets				
Equipment		30	83	41
		30	83	41
Financial assets				
Other long-term placement		13,101	13,101	13,101
Shares in subsidiaries	3	23,625	23,625	23,625
		36,726	36,726	36,726
Total non-current assets		110,308	111,521	110,788
Current assets				
<i>Short term receivables</i>				
Other receivables		1,068	1,207	926
Prepaid expenses and accrued income		1,059	620	585
		2,127	1,827	1,511
Cash and bank balances		47,966	29,517	61,634
Total current assets		50,093	31,344	63,145
TOTAL ASSETS		160,402	142,865	173,933

Parent Company

Balance Sheet

(SEK 000)	Note	31 Mar, 2021	31 Mar, 2020	31 Dec, 2020
EQUITY AND LIABILITIES				
Equity				
<i>Restricted equity</i>				
Share capital		14,817	9,298	14,817
Statutory reserve		1,856	1,856	1,856
Development expenditure reserve		13,141	14,164	13,576
		29,815	25,319	30,249
Unrestricted equity				
Share premium reserve		67,045	103,067	67,045
Retained earnings		67,149	23,021	126,676
Profit/loss for the period		-21,456	-16,533	-59,961
		112,738	109,554	133,759
Total equity		142,553	134,873	164,009
Short-term liabilities				
Accounts payable		9,049	1,769	4,201
Other liabilities		368	444	406
Accrued expenses and deferred income		8,432	5,780	5,317
		17,849	7,992	9,924
TOTAL EQUITY AND LIABILITIES		160,402	142,865	173,933

Notes

Note 1 — Intangible assets

(SEK 000)	Development costs	Patents	Other	Total
ACCUMULATED COST				
Opening balance 1 Jan. 2021	51,706	33,771	2,864	88,341
Additions	-	93	-	93
Closing balance 31 Mar. 2021	51,706	33,864	2,864	88,434
ACCUMULATED DEPRECIATION				
Opening balance 1 Jan. 2021	-	-12,800	-1,519	-14,319
Depreciation for the period	-	-528	-34	-562
Closing balance 31 Mar. 2021	-	-13,328	-1,553	-14,881
Residual value 31 Mar. 2021	51,706	20,536	1,311	73,553
(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

Note 2 – Tax

The group's total loss carry-forwards amounts to SEK 638,330,000 as of 31 March 2021 (561,101,000). The parent company's total loss carry-forwards amounts to SEK 612,472,000 as of 31 March 2021 (535,272,000). 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 Company signed Certificate of Incorporation for Abliva Inc on March 3, 2021 with the aim of establishing presence in the US.

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. 2021 31 Mar. 2020	1 Jan. 2020 31 Dec. 2020
Eskil Elmér, CSO	-	6
Magnus Hansson, CMO	-	4
Total	-	10

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 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

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

In light of the extraordinary situation due to the COVID-19 pandemic, Abliva's AGM will be conducted through advance voting (postal voting) in accordance with temporary legislation. No meeting will be held that allows attendance in person or by proxy. The CEO's speech will be recorded and posted on the website. Information about the decisions taken at the Annual General Meeting and the CEO's speech will be published on May 20, 2021, as soon as the out-come of the voting is compiled.

The full notice to attend is available at:

<https://abliva.com/investors/general-meeting/>

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 develop-

ment activities, to out-license projects or enter strategic partnerships.

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

Due to COVID-19 Abliva's ongoing Phase 1a/b study with KL1333 was delayed, since healthcare authorities and healthcare providers prioritized available resources, care locations and healthcare professionals to better meet the influx of COVID-19 patients. However, the study could be resumed in the autumn and the last patient was dosed in March 2021. The Company estimates that COVID-19 will not have an impact of the start of the upcoming registrational Phase 2/3 study, which is expected to start in the second half of 2021. The preclinical safety studies

required to support the further development of NV354 are currently not considered to be affected by the COVID-19 pandemic.

COVID-19 may, among other things, cause 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. In light of the fact that the pandemic is not over, there is a material risk that COVID-19 may negatively affect the Company's operations.

Abliva is not involved in any disputes.

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 2020 on pages 46-61.

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, 20 May, 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. CEST on 20 May, 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 disorders are metabolic diseases that affect the cells' ability to convert energy. The diseases can manifest very differently depending on the organs in which the genetic defects are located. They 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).

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