ABLIVA

Interim Report January - September 2020

We want to give patients with primary mitochondrial disease a better life.

Erik Kinnman, CEO

Delivering mitochondrial health

Third quarter summary

KL1333 is on its way to pivotal clinical study.
Pivotal study planned for the second half of 2021.

Important events, third quarter (July- September 2020)

- Abliva receives positive feedback from the US Food and Drug Administration ("FDA") on the KL1333 clinical development plan for the treatment of primary mitochondrial disease.
- Abliva takes the decision that the company will conduct a cohesive pivotal Phase II/III study with KL1333 starting in the second half of 2021.
- Directed issue of SEK 20 million to Hadean Ventures completed.
- Abliva ran a Mitochondria Day in September.

Important events after the reporting period

- Abliva doses the first patients in the Phase Ia/b clinical study with KL1333.
- Magnus Persson leaves the Board of Directors of Abliva AB to focus on his role as founding partner in Eir Ventures.
- Abliva doses the first healthy volunteers in the company's drug-drug interaction study (DDI study) with KL1333.
- Abliva receives positive feedback from the UK MHRA on KL1333 Phase II/III study plan.

Financial information

July-September 2020*

- Net revenues: KSEK 0 (0)
- Other operating income: KSEK 11 (1,500)
- Loss before tax: KSEK 10,078 (15,297)
- Loss per share: SEK 0.03 (0.08)
- Diluted loss per share: SEK 0.03 (0.08)

January-September 2020*

- Net revenues: KSEK 105 (85)
- Other operating income: KSEK 45 (2,500)
- Loss before tax: KSEK 46,927 (49,888)
- Loss per share: SEK 0.20 (0.30)
- Diluted loss per share: SEK 0.20 (0.30)

* APM Alternative perfomance measures, see definition on page 19.

KL1333's clinical development is advancing at a rapid pace
Pivotal study scheduled for second half of 2021

Many patients with primary mitochondrial diseases suffer from a combination of pronounced fatigue, muscle weakness and metabolic dysfunction, mainly in the form of severe and difficult to treat diabetes. The number of patients in Europe and the US in total is estimated to be approximately 40,000[1]. There are currently no approved medical therapies to offer this group of chronically ill patients. Thus, there is a substantial need to offer these patients new and effective treatment options as quickly as possible.

Erik Kinnman
CEO Abliva

The previous feedback from the US FDA, now complemented by UK MHRA feedback, on Abliva's study plan for KL1333 supports significantly accelerating the clinical development of this drug candidate. As a result, Abliva has made the decision that the company should conduct a coherent pivotal phase II/III study instead of two separate sequential studies. This strengthens our ability to successfully meet the major medical needs that characterize the care of patients with mitochondrial diseases. The application for market approval will be submitted after the phase II/III study has been successfully completed.

A unique opportunity to accelerate development
Since the announcement from the FDA, which we received with great enthusiasm, the level of activity has been very high at Abliva. After an intensive period, we have now redesigned the final clinical program for KL1333 in line with the FDA recommendations with the ambition to start the pivotal phase II/III study in the second half of 2021. To achieve this, we will conduct a study for validation of patient-reported endpoints, initiate a dose escalation study and complete a drug interaction study, where we have already started dosing of healthy volunteers. In addition, the regulators allowed Abliva to conduct mandatory long-term toxicological studies in parallel with the pivotal phase II/III study. I would also like to mention that the patient part of the ongoing phase Ia/b study is ongoing and that we thus have dosed patients with KL1333 for the first time. So far, we've dosed half of the patients.

KL1333 enters a resource-intensive phase
As the KL1333 project approaches the final part of the clinical development, the project is entering a resource-intensive phase. A cohesive phase II/III study like this is estimated to cost $30-40 million up to the application for market approval, which is estimated to be some $10-15 million lower compared to a program with separate Phase II and phase III studies. In parallel with the preparations for the pivotal study, we are also increasing our communication activities with public equity investors to ensure that the company's achievements are monitored, appreciated, and that Abliva has access to funds to support its long-term corporate strategy. We will be evaluating various possibilities of seeking additional financing, including accessing the international capital market.

Significant commercial potential
All in all, the updated study program means that the path to market for KL1333 could be shorter. This in turn means that in the near future we will begin planning how best to commercialize this very promising project. We believe there are approximately 40,000 patients with the relevant diseases for KL1333 in Europe and the US combined, of which around 12,000 are the most likely to be treated if there were an available therapy. At typical rare disease pricing, this translates into a major blockbuster opportunity.

Abliva's Mitochondria Day
The World Mitochondrial Disease Week took place from September 13-19 with events across the globe. Just as last year, Abliva arranged a Mitochondria Day where we brought together representatives from patients and relatives as well as treating physicians who shared their perspectives on what it is really like for patients to live with mitochondrial diseases. It was made painfully clear that the need for new and effective therapies is enormous, and that there is hope that treatments could be developed in the near future.

Another aspect that was highlighted at our Mitochondria Day is the increased investor interest for orphan drug projects. Companies like Abliva, who focus on rare disorders, are attractive to investors because of new science, high medical need, and the regulatory support provided for orphan drugs. This often means that orphan drug projects often reach the market, faster and more successfully compared to other drug projects, and on the market there is the added potential of market exclusivity and premium price for orphan drug status.

The ambition for NV354 is to enter clincical development in 2021
NV354 is being developed for the treatment of Leigh syndrome, a severe primary mitochondrial disease that typically begins in children between one and two years old. Our activities in this project are proceeding with the aim to enter clinical phase in 2021.

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

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 Phase I in patients 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 designation[1)2)]

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 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

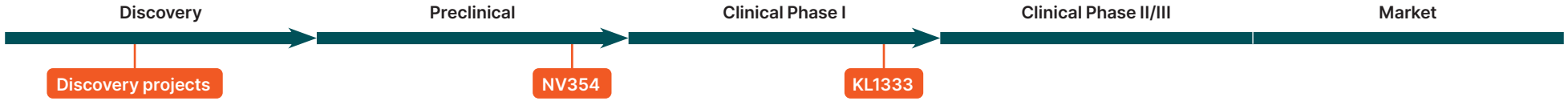
Abliva works under two main scenarios for establishing future revenue: sales revenue for the drugs the company intends to bring all the way to market, and revenue from out-licensing, milestone payments and royalties from out-licensed drug candidates.

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 are described as clinical syndromes. 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 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.

PROJECTS WITHIN PRIMARY MITOCHONDRIAL DISEASE



KL1333

First-in-class disease modifying treatment to improve the lives of patients with PMD

Ongoing Phase Ia/b study: dosing in healthy volunteers concluded
DDI study commenced
Phase II/III pivotal study planned to start H2 2021
Orphan drug designation in both the United States and Europe

Events in the third quarter. The US Food and Drug Administration ("FDA") has issued positive feedback on the KL1333 clinical development plan. Following the information from FDA, Abliva's Board of Directors has decided to accelerate the KL1333 clinical program, with the intention to start a pivotal Phase II/III clinical study, in H2 2021.

Events after the end of the period. The first primary mitochondrial disease patient in Abliva's ongoing KL1333 Phase Ia/b study has been dosed. In this third part of the study, the pharmaceutical properties of KL1333 will, for the first time, be evaluated in patients. DDI study (Drug-Drug Interaction study) initiated.

Objectives for 2020/2021

- Start DDI study ✓
- Conclude DDI study and report results (Q1 2021)
- Conclude the Phase Ia/b study and report results (H1 2021)
- Preparatory activities for the Phase II/III study: conduct a patient registry study, a validation study of endpoints, and a clinical dosing study; initiate long-term toxicological studies
- Initiate pivotal clinical Phase II/III efficacy study (H2 2021)

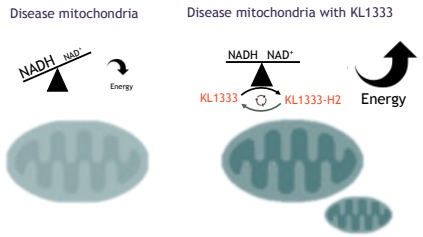
DISEASE AREA

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

These diseases cause a wide range of severe symptoms and shortened life expectancy.

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

MODE OF ACTION



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

ROAD TO MARKET

The recommendation from the FDA to make a coherent, Phase II/III pivotal study brings significant benefits to the KL1333 project. This type of project is estimated to cost USD 30-40 million up to the application for market approval, which is approximately USD 10-15 million less than the cost of conducting separate Phase II and Phase III studies. The FDA guidance also indicates shortend timeline to market approval.

POTENTIAL MARKET

The number of patients in the target group for treatment with KL1333 is approximately 40,000[1)] in Europe and the US, of which 12,000 are the most likely to be treated if there was an available therapy. At typical rare disease pricing, this translates into a major 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 I	Clinical Phase II/III	Market
Primary mitochondrial diseases			Phase Ia (healthy volunteers) ✓ Dose-dependent exposure ✓ Phase Ib with patients started ✓ DDI study started ✓	Registration-based study in the US and Europe. Start 2021.	With or without partner

NV354

First-in-class energy replacement therapy for disease modifying treatment of Leigh syndrome

The project is in preparation for clinical phase
Ongoing safety studies

Events in the third quarter
NV354 preclinical pharmacology and safety studies continues.

Objectives for 2020/2021
- Complete preclinical pharmacology and safety studies (H1 2021)
- Produce NV354 clinical trial material for clinical studies (H1 2021)
- Initiate Phase I study (H2 2021)

DISEASE AREA I

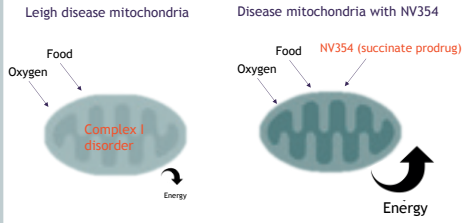
NV354 is developed for the treatment of Leigh syndrome, a severe primary mitochondrial disease that usually debuts at one to two years of age. Patients usually die within two to three years.

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

DISEASE AREA II

In a second step, NV354 may also be developed for the treatment of MELAS and LHON, a Complex I disease. 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 I	Clinical Phase II/III	Market
Leigh disease		Ongoing safety studies	Initiate Phase I study (H2 2021)	Registration-based study in the US and Europe. Start 2021.	With or without partner

Non-core assets

The company has been seeking a strategic partner for the continued development of NeuroSTAT. It has now initiated preliminary discussions with the TRACK-TBI network on a potential collaboration for a phase II 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 TRAUMATIC BRAIN INJURY

Traumatic brain injury (TBI) is caused by external force to the head resulting in immediate damage to nerve cells. The damage continues to worsen for several days after the acute trauma.

Treatment objective

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

Project status: candidate drug in clinical Phase II

NeuroSTAT has shown favorable properties in a Phase Ib/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 is engaging in preliminary discussions with the TRACK-TBI network regarding a potential collaboration within the scope of the so called Precision Medicine project[1) 2)] for a phase II 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 this news and TRACK-TBI as a partner, the company will review possible options and structures that may enable developing the NeuroSTAT program further.

NV556 – FOR TREATMENT OF NASH

Project status: no further investment

Abliva will not invest further in the NV556 project, and has adopted an opportunistic approach to continued licensing activities.

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.

Out-licensed projects and commercial partnerships

Abliva has currently out-licensed compounds developed within NVP015 project to US company BridgeBio/ Fortify. The compounds are being developed for the treatment of the eye disorder LHON. In addition, Abliva has a distribution agreement for research substances with the Austrian company Oroboros.

PROJECT FOR LOCAL TREATMENT OF LHON

In 2018, Abliva out-licensed molecules from the NVP015 project to BridgeBio Pharma's subsidiary Fortify Therapeutics. Fortify develops the in-licensed NVP015 chemistry further to a local therapy for the mitochondrial eye disorder Leber's Hereditary Optic Neuropathy (LHON).

Project status

The project is in discovery phase and is currently paused for evaluation as the molecules selected have not reached sustainable concentrations in the eye.

PARTNERSHIP WITH OROBOROS INSTRUMENTS

In 2019, Abliva announced that the company has entered into an exclusive agreement with Oroboros Instruments, a leading global supplier of mitochondrial research technologies. Abliva have agreed to provide, at scale, two research compounds, originating from its NVP015 program, on an exclusive basis to Oroboros. Oroboros has initiated commercialization and distributes the compounds under the product name MitoKit-CII.

Consolidated Statement of

Comprehensive Income

Revenues

The consolidated turnover during the third quarter of 2020 was KSEK 0 (0). Other operating revenues for the third quarter were KSEK 63 (1,500) and pertains to compensation for sick pay. During the first nine months of 2020 the consolidated turnover was 105 (85) KSEK. Other operating revenues for the first six months amounted 45 (2,500) KSEK.

Results of operations

The operating loss for the third quarter was KSEK 10,070 (15,286) and for the first nine months the operating loss amounted KSEK -46,902 (-49,852). The net loss before tax for the third quarter amounted to KSEK 10,078 (-15,297). For the fist nine months the loss before tax was -46,927 (-49,888).

The operating loss was affected by other external expenses, which for the first nine months were KSEK 34,606 (39,671). Expenses related to development projects, as a part of external expenses, have affected the result with KSEK 21,256 (27,178) whereof KSEK 15,722 (12,765) relates to project in clinical phase. Personnel expenses during the first nine months amounts to KSEK 10,506 (10,704). Other operating expenses amount to, KSEK 26 (304) and pertains to exchange-rate losses.

(SEK 000)	Note	1 Jul, 2020 30 Sep, 2020	1 Jul, 2019 30 Sep, 2019	1 Jan, 2020 30 Sep, 2020	1 Jan, 2019 30 Sep, 2019	1 Jan, 2019 31 Dec, 2019
Net sales		-	-	105	85	134
Other operating income		63	1,500	45	2,500	3,500
		63	**1,500**	**150**	**2,585**	**3,634**
Operating expenses						
Other external expenses		-6,760	-13,094	-34,606	-39,671	-63,133
Personnel cost		-2,722	-2,893	-10,506	-10,704	-14,872
Depreciation and write-down of tangible and intangible assets		-651	-612	-1,914	-1,757	-2,379
Other operating expenses		-	-187	-26	-304	-325
		-10,133	**-16,786**	**-47,052**	**-52,437**	**-80,709**
Operating income		**-10,070**	**-15,286**	**-46,902**	**-49,852**	**-77,075**
Profit/loss from financial items						
Result from other securities and receivables related to non current assets		-	-	-	-	121
Financial income		-	-	-	-	-
Financial costs		-8	-11	-24	-37	-46
		-8	**-11**	**-24**	**-37**	**75**
Profit/loss before tax		**-10,078**	**-15,297**	**-46,927**	**-49,888**	**-77,000**
Income tax	2	-	-	-	-	-
Profit/loss for the period		**-10,078**	**-15,297**	**-46,927**	**-49,888**	**-77,000**
Other comprehensive income						
Items that may be reclassified to profit or loss						
Translation differences on foreign subsidiaries		-	4	-1	5	3
Total comprehensive income for the period		**-10,078**	**-15,293**	**-46,928**	**-49,883**	**-76,997**
Loss for the period attributable to:						
Parent company shareholders		-10,078	-15,297	-46,926	-49,887	-76,994
Non-controlling interests		-	-	-1	-1	-6
		-10,078	**-15,297**	**-46,927**	**-49,888**	**-77,000**
Total comprehensive income for the period						
Parent company shareholders		-10,078	-15,295	-46,927	-49,882	-76,991
Non-controlling interests		-	-	-1	-1	-6
		-10,078	**-15,295**	**-46,928**	**-49,883**	**-76,997**
Earnings per share before and after dilution(SEK) based on average number of shares		-0.03	-0.08	-0.20	-0.30	-0.45

Consolidated Statement of

Financial Position

Financial position

The equity/assets ratio was 94 (91) percent as of 30 September 2020, and equity was KSEK 153,431 (154,910). 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 73,188 (79,773) as of 30 September 2020, an increase of KSEK 14,869 from the beginning of the year. Total assets as of 30 September 2020 were KSEK 162,477 (170,182).

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 pivotal Phase II/III 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	30 Sep, 2020	30 Sep, 2019	31 Dec, 2019
ASSETS				
Non-current assets				
Intangible assets	1			
Development costs		51,706	51,706	51,706
Patents		21,194	21,274	21,501
Other Intangible assets		1,378	1,512	1,479
		74,278	**74,492**	**74,686**
Tangible assets				
Equipment		53	126	99
Rigth of use asset leases		429	773	687
		483	**899**	**786**
Financial assets				
Other long-term securities		13,101	13,101	13,101
		13,101	**13,101**	**13,101**
Total non-current assets		**87,862**	**88,492**	**88,573**
Current assets				
Other receivables		1,101	1,312	1,141
Prepaid expenses and accrued income		327	605	459
Cash and cash equivalents		73,188	79,773	58,319
		74,616	**81,690**	**59,919**
TOTAL ASSETS		**162,477**	**170,182**	**148,492**

Consolidated Statement of

Financial Position

(SEK 000)	Note	30 Sep, 2020	30 Sep, 2019	31 Dec, 2019
EQUITY AND LIABILITIES				
Equity attributable to the shareholders of the parent company				
Share capital		14,817	9,298	9,298
Additional paid in capital		660,025	592,980	592,980
Translation reserve		618	621	619
Retained earnings		-522,032	-448,000	-475,107
Total equity attributable to the shareholders of the parent		**153,427**	**154,899**	**127,790**
Non-controlling interests		4	11	5
Total equity		**153,431**	**154,910**	**127,795**
Long-term liabilities				
Other longtrem liabilities		92	448	361
		92	**448**	**361**
Short-term liabilities				
Accounts payable		1,736	3,915	14,234
Other liabilities		742	841	811
Accrued expenses and deferred income		6,476	10,068	5,291
		8,954	**14,824**	**20,336**
Total liabilities		**9,046**	**15,720**	**21,058**
TOTAL EQUITY AND LIABILITIES		**162,477**	**170,182**	**148,492**

Consolidated Statement of

Changes in Equity

	Equity attributable to the shareholders of the parent company						
(SEK 000)	Share-capital	Additional paid in capital	Translation reserve	Retained earnings	Total	Non-controlling interests	Total equity
Opening balance, 1 January 2020	**9,298**	**592,980**	**619**	**-475,107**	**127,791**	**5**	**127,795**
Comprehensive profit/loss for the period							
Profit/loss for the period	-	-	-	-46,926	-46,926	-1	-46,927
Other comprehensive income							
Translation differences	-	-	-1	-	-1	-0	-1
Other comprehensive profit/loss for the period, net after tax	**-**	**-**	**-1**	**-**	**-1**	**-0**	**-1**
Total comprehensive profit/loss	**-**	**-**	**-1**	**-46,926**	**-46,927**	**-1**	**-46,928**
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, 30 September 2020	**14,817**	**660,025**	**618**	**-522,033**	**153,427**	**4**	**153,431**
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	-	-	-	-49,887	-49,887	-1	-49,888
Other comprehensive income							
Translation differences	-	-	5	-	5	-	5
Other comprehensive profit/loss for the period, net after tax	**-**	**-**	**5**	**-**	**5**	**-**	**5**
Total comprehensive profit/loss	**-**	**-**	**5**	**-49,887**	**-49,882**	**-1**	**-49,883**
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, 30 September 2019	**9,298**	**592,980**	**621**	**-448,000**	**154,899**	**11**	**154,910**
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 second quarter was KSEK -14,182 (-18,245). For the first nine months the operating cash flow amounted -56,511 (-51,429). The cash flow effect related to investments in intangibles equals KSEK -1,088 (-2,469) for the first nine months. Cash flow for the third quarter equals KSEK 3,907 (-19,311). Cashflow for the first nine months equals KSEK 14,697 (53,814).

(SEK 000)	1 Jul, 2020 30 Sep, 2020	1 Jul, 2019 30 Sep, 2019	1 Jan, 2020 30 Sep, 2020	1 Jan, 2019 30 Sep, 2019	1 Jan, 2019 31 Dec, 2019
Cash flow from operating activities					
Operating income	-10,070	-15,286	-46,902	-49,852	-77,074
Adjustments for non-cash items:					
Depreciation	651	354	1,914	1,500	2,379
Result from other securities and receivables related to non current assets	-1	-	-	-	121
Interest received	-	-	-	-	-
Interest paid	-8	-	-24	-37	-46
Net cash from operating activities before changes in working capital	**-9,426**	**-14,932**	**-45,013**	**-48,388**	**-74,620**
Changes in working capital					
Increase/decrease of other current assets	1,590	238	172	761	1,077
Increase/decrease of other short-term liabilities	-6,345	-3,539	-11,670	-3,801	1,131
Changes in working capital	**-4,755**	**-3,301**	**-11,498**	**-3,040**	**2,208**
Cash flow from operating activities	**-14,182**	**-18,235**	**-56,511**	**-51,429**	**-72,412**
Investing activities					
Acquisition of intangible assets	-283	-1,238	-1,088	-2,469	-2,626
Acquisition of tangible assets	-1	-	-	-69	-69
Increase in other financial assets	-	-	-	-	-
Cash flow from investing activities	**-283**	**-1,238**	**-1,088**	**-2,538**	**-2,695**
Financing activities					
New share issue	18,467	-	72,564	107,780	107,780
Amoritization lease			-269	-	-309
Cash flow from financing activities	**18,371**	**-**	**72,295**	**107,780**	**107,471**
Cash flow for the period	3,907	-19,311	14,697	53,814	32,364
Cash and cash equivalents at the beginning of the period	69,109	99,079	58,319	25,951	25,951
Effect of exchange rate changes on cash	-3	5	-3	8	4
Cash and cash equivalents at end of period	**73,013**	**79,773**	**73,013**	**79,773**	**58,319**

Parent Company

Income Statement

Parent company

Company earnings after tax for the third quarter amounts to KSEK -10,087 (-15,291). Earnings after tax for the first nine months amount to KSEK -46,917 (-49,867). Most of the Group's operations are conducted within the parent company. Accordingly, no further specific information regarding the parent company is presented.

(SEK 000)	Note	1 Jul, 2020 30 Sep, 2020	1 Jul, 2019 30 Sep, 2019	1 Jan, 2020 30 Sep, 2020	1 Jan, 2019 30 Sep, 2019	1 Jan, 2019 31 Dec, 2019
Net sales		-	-	105	85	134
Other operating income		52	1,500	45	2,500	3,500
		52	**1,500**	**150**	**2,585**	**3,634**
Operating expenses						
Other external expenses		-6,850	-13,185	-34,878	-39,944	-63,469
Personnel cost		-2,722	-2,893	-10,506	-10,704	-14,872
Depreciation and write-down of tangible and intangible assets		-566	-526	-1,656	-1,500	-2,036
Other operating expenses		-	-187	-26	-304	-325
		-10,034	**-16,791**	**-47,066**	**-52,452**	**-80,702**
Operating income		**-10,086**	**-15,291**	**-46,916**	**-49,866**	**-77,068**
Profit/loss from financial items						
Result from other securities and receivables related to non current assets		-	-	-	-	122
Interest expenses and other similar loss items		-1	-	-1	-1	-1
		-1	**-**	**-1**	**-1**	**121**
Profit/loss before tax		**-10,087**	**-15,291**	**-46,917**	**-49,867**	**-76,947**
Income tax	2	-	-	-	-	-
Profit/loss for the period		**-10,087**	**-15,291**	**-46,917**	**-49,867**	**-76,947**

Parent Company

Statement of Comprehensive Income

(SEK 000)	Note	1 Jul, 2020 30 Sep, 2020	1 Jul, 2019 30 Sep, 2019	1 Jan, 2020 30 Sep, 2020	1 Jan, 2019 30 Sep, 2019	1 Jan, 2019 31 Dec, 2019
Profit/loss for the period		-10,087	-15,291	-46,917	-49,867	-76,947
Other comprehensive income		-	-	-	-	-
Total comprehensive profit/loss for the period		**-10,087**	**-15,291**	**-46,917**	**-49,867**	**-76,947**

Parent Company

Balance Sheet

(SEK 000)	Note	30 Sep, 2020	30 Sep, 2019	31 Dec, 2019
ASSETS				
Non-current assets				
Intangible assets	1			
Development costs		51,706	51,706	51,706
Patents		21,194	21,274	21,501
Other intangible assets		1,378	1,512	1,479
		74,278	**74,492**	**74,686**
Tangible assets				
Equipment		53	126	99
		53	**126**	**99**
Financial assets				
Other long-term placement		13,100	13,101	23,625
Shares in subsidiaries	3	23,625	23,625	13,101
		36,726	**36,726**	**36,726**
Total non-current assets		**111,057**	**111,345**	**111,511**
Current assets				
Short term receivables				
Other receivables		1,098	1,308	1,138
Prepaid expenses and accrued income		327	605	459
		1,425	**1,913**	**1,597**
Cash and bank balances		73,163	79,707	58,272
Total current assets		**74,587**	**81,620**	**59,869**
TOTAL ASSETS		**185,644**	**192,965**	**171,380**

Parent Company

Balance Sheet

(SEK 000)	Note	30 Sep, 2020	30 Sep, 2019	31 Dec, 2019
EQUITY AND LIABILITIES				
Equity				
Restricted equity				
Share capital		14,817	9,298	9,298
Statutory reserve		1,856	1,856	1,856
Development expenditure reserve		13,799	10,610	14,106
		30,472	**21,764**	**25,260**
Unrestricted equity				
Share premium reserve		170,111	103,067	103,067
Retained earnings		23,386	103,523	100,026
Profit/loss for the period		-46,917	-49,867	-76,947
		146,580	**156,723**	**126,146**
Total equity		**177,052**	**178,487**	**151,406**
Short-term liabilities				
Accounts payable		1,736	3,914	14,234
Other liabilities		386	502	467
Accrued expenses and deferred income		6,470	10,062	5,273
		8,592	**14,478**	**19,974**
TOTAL EQUITY AND LIABILITIES		**185,644**	**192,965**	**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	-	1,203	-	1,203
Closing balance 31 Sep. 2020	**51,706**	**33,482**	**2,864**	**88,052**
ACCUMULATED DEPRECIATION				
Opening balance 1 Jan. 2020	**-**	**-10,778**	**-1,385**	**-12,163**
Depreciation for the period	-	-1,510	-101	-1,611
Closing balance 31 Sep. 2020	**-**	**-12,288**	**-1,486**	**-13,774**
Residual value 31 Sep. 2020	**51,706**	**21,194**	**1,378**	**74,278**

(SEK 000)	Development costs	Patents	Other	Total
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 605,900 as of 30 September 2020 (517,572). The parent company's total loss carry-forwards amounts to SEK 580,065 as of 30 September 2020 (491,777). 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 subsidiarie, which are related parties to the company, have been eliminated on consolidation, and accordingly, no disclosures are made regarding these transactions.

Transactions with related parties

(SEK 000)	1 Jan. 2020 30 Sep. 2020	1 Jan. 2019 31 Dec. 2019
Eskil Elmér, CSO	3	6
Magnus Hansson, CMO	2	3
Total	**5**	**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 occured.

Segment information

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

Human resources

The average number of employees of the group for the period January to September 2020 was 9 (8), of which 5 (4) are women.

Incentive programs/share warrants

Currently there is no incentive program.

Audit review

This Interim Report has been subject to review by the company's auditors in accordance with the Standard on Review Engagements (ISRE) 2410, Review of Interim Financial Information Performed by the Independent Auditor of the Entity.

Upcoming financial statements

Year-End Report, 2020	February 19, 2021
Q1 Report, 2021	May 20, 2021
Q2 Report, 2021	August 19, 2021
Q3 Report, 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 22 April 2021 at 4 pm

The Nomination Committee for the 2020 AGM comprises:

- Florian Eckhardt – for Hadean Ventures
- Kristina Ingvar – for John Fällström
- Andreas Inghammar – Rothesay Ltd

In total, the Nomination Committee represents some 14.35 % of the votes in Abliva as of 30 September 2020.

The Nomination Committee's task ahead of the AGM 2021 is to prepare proposals on the following matters to present to the AGM for resolution:

-Propose the Chairman of the AGM
-Propose the number of Board members
-Propose remuneration to Board members and remuneration to Committee members
-Propose remuneration to the Auditors
-Propose the Chairman of the Board, other Board members and Auditor.
-Propose guidelines for appointing members of the Nomination Committee and instructions for the Nomination Committee
-Propose remuneration to the members of the Nomination Committee

Shareholders wishing to make proposals on the above matters can contact the Committee by email at: valberedningen@abliva.com, or by post at: Abliva AB, FAO: Nomination Committee, Medicon Village, 223 81 Lund, Sweden.

In order for the Nomination Committee to consider the proposals received with due care, proposals should be received by the Nomination Committee by no later than 1 February 2021.

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 continious 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 four 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, but if that would occur this will not have impact on the start of the upcoming Phase II/III study, which is expected to start in the second half of 2021. Abliva's preparations in the form of preclinical safety studies to be able to take the drug candidate, NV354 for Leigh syndrome, into clinical phase in 2021 are currently not considered to be affected 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.

Abliva is not involved in any disputes.

For more detail of risks and uncertainty factors, refer to the Statutory Administration Report in the Annual Report 2019 and the prospectus published April 3, 2020 for the preferential rights issue carried out in April/May 2020.

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
Profi/loss before tax	Operating income after profit/loss from finacial items and allocations	Measures the result in the business after profit/loss from financial items and allocations
Earnings per share before dilution(SEK) based on average number of shares	Profit/loss for the period divided by avarage 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 avarage 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, November 20, 2020

David Laskow-Pooley
Chairman of the Board

David Bejker
Board member

Roger Franklin
Board member

Denise Goode
Board member

Jan Törnell
Board member

Erik Kinnman
Chief Executive Officer


David Laskow-Pooley


David Bejker


Roger Franklin


Denise Goode


Jan Törnell


Erik Kinnman

For more information concerning this report, please contact CEO Erik Kinnman. 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 November 20, 2020.

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.

Auditor's review report

TO THE BOARD OF ABLIVA AB (PUBL),
CORP.ID.NO 556595-6538

Introduction
We have performed a review of the condensed interim financial statements (the interim report) for Abliva AB (publ) at September 30, 2020 and the nine months' period then ended. The Board of Directors and the President are responsible for the preparation and presentation of this interim report in accordance with IAS 34 and the Swedish Annual Accounts Act. Our responsibility is to express a conclusion on this interim report based on our review.

Scope of review
We conducted our review in accordance with the Standard on Review Engagements ISRE 2410 Review of Interim Financial Information Performed by the Independent Auditor of the Entity. A review consists of making inquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with the International Standards on Auditing and other generally accepted auditing practices.

The procedures performed in a review do not enable us to obtain a level of assurance that would make us aware of all significant matters that might be identified in an audit. Therefore, the conclusion expressed based on a review does not give the same level of assurance as a conclusion expressed based on an audit.

Conclusion
Based on our review, nothing has come to our attention that causes us to believe that the interim report, in all material aspects, is not prepared for the Group in accordance with IAS 34 and the Swedish Annual Accounts Act and for the Parent company in accordance with the Swedish Annual Accounts Act.

Emphasis of matter
As described on page 9 in the section Financial position the board has initiated a process to ensure adequate funding to enable execution of the company's strategy.

Stockholm, November 20th, 2020
Mazars AB

Michael Olsson
Authorized Public Accountant

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 I, phase II, phase III. Phase II is usually divided into an early phase (phase IIa) and a later phase (phase IIb). See also "phase (I, II and III)".
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.
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 strokelike episodes.
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 (I, II and III). The various stages of trials on the efficacy of a pharmaceutical in humans. See also "clinical trial." Phase I examines the safety on healthy human subjects, phase II examines efficacy in patients with the relevant disease and phase III 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 II is often divided between phase IIa and phase IIb.
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 disorders can manifest differently depending on the organs affected by the genetic defects and are viewed as clinical syndromes. An estimated 125 in every 1,000,000 people suffer from 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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