ABLIVA

Interim Report

January - March

2023

Delivering mitochondrial health

First Quarter Summary

Patient screening ongoing in the FALCON study | Orphan Drug Designation for NV354

Important events January – March 2023

- Abliva appointed Dag Nesse as Vice President of Clinical Operations. Mr. Nesse has joined the company's management team.
- The U.S. Patent and Trademark Office granted a composition of matter patent for the NV354 compound.
- An Extraordinary General Meeting was held on March 8.

Important events after the reporting period

- Abliva's drug candidate NV354 was granted Orphan Drug Designation (ODD) in the U.S. for the treatment of mitochondrial disease.
- Abliva's Annual General Meeting was held on May 5. All proposals were passed by the general meeting. For more information, see https://abliva.com/news/resolutions-from-annual-general-meeting-in-abliva-ab-publ-on-may-5-2023/.

Financial information

January-March 2023*

- Net revenues: SEK 0 (0)
- Other operating income: SEK 1,055,000 (0)
- Loss before tax: SEK 16,092,000 (22,028,000)
- Loss per share before dilution: SEK 0.02 (0.05)
- Diluted loss per share: SEK 0.02 (0.05)

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

Focusing on FALCON

The Abliva team is laser-focused on the Phase 2 FALCON study which is designed to evaluate the efficacy of KL1333 in adult patients with mitochondrial disease. This global study started in December of 2022 and is on track to recruit the first 40 patients this year.

All Attention on FALCON
Clinical operations have been the focus of the team during the first quarter of 2023. Today we have full approval for five countries (Denmark, France, UK, Spain, and the U.S.), and sites activated in all these countries. The Abliva team was onsite for many of the activation visits and welcomed the opportunity to meet with the physicians and site staff who will be conducting the study.

Many of our sites are now screening their patients to identify those patients who fulfil the study requirements. Interested patients are then more formally 'screened' to ensure they fulfil the study requirements. In the FALCON study the screening period of 8-12 weeks ensures that the patients have significant enough levels of fatigue and myopathy in order to see a robust effect from KL1333. This screening period also allows us to collect baseline information on the primary endpoints and train both the sites and the patients on the use of mobile devices to collect data for the primary endpoints.

Because of the length of the screening period, our sites will be focused on screening patients in the first half of the year, with the first patients expected to be dosed towards the end of Q2. Given the status of the program, we are on track to recruit 40 patients into the study in the second half of the year with the interim analysis on track for the first half of 2024.

Dag Nesse Announced as VP Clinical Operations
In the first quarter we welcomed Dag Nesse to the Abliva team. Dag, as our Vice President of Clinical Operations, has ultimate accountability for the operational aspects of the study. Dag's experience in clinical operations across all stages of development, including market authorization and launch, will be extremely beneficial as we work to ensure Abliva has the quality systems in place to support the launch of KL1333 subject to study results.

New U.S. Patent and Orphan Drug Designation for NV354
In January, Abliva received news from the U.S. Patent Court that our patent "Succinate Prodrug, Compositions Containing the Succinate Prodrug and Uses Thereof" would be issued as Patent No. 11,565,998. This important patent covers isolated forms of NV354 and joins several previously granted patents focused on the protection of NV354-related compounds.

Another key benefit was secured last week with the approval of Orphan Drug Designation for NV354 in the U.S. This important designation will give NV354 a number of benefits for the company including giving NV354 seven years of exclusivity in the U.S. upon market launch, separate to the protection we expect from our patent position.

Ongoing Partnership with Patients and Patient Organizations
At Abliva we have always prioritized our work with patients, and the current FALCON study design reflects our focus on the patients – from the mitochondrial disease-specific fatigue questionnaire that was designed and validated with mitochondrial disease patient input, to our patient-friendly study design that allows most of the study visits to be completed at home with a home healthcare provider. Patient advocacy organizations across the globe have been extremely helpful in spreading the word about our study and we are thankful for their partnership, as well as the important work that they do supporting patients with mitochondrial disease.

"Many of our sites are now screening their patients to identify those patients who fulfil the study requirements"

Best wishes,

Ellen Donnelly
CEO

Innovative Portfolio in Rare and Severe Mitochondrial Disease

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

Primary mitochondrial disease often presents 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.

*KL1333 has Orphan Drug Designation (ODD) in the U.S. and Europe, and NV354 has ODD in the U.S.
**mtDNA-related mitochondrial disorders caused by mutation(s) in mitochondrial DNA (as opposed to nuclear DNA).
***Given that mitochondrial disease is an orphan disease, a Phase 2 study in these patients, if successful, can have the potential for market approval.

Strategic focus: Mitochondrial Disease

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

Building the Premier Mitochondrial Medicine Company
Abliva's long-term goal is to become the leading global biotech company focused on the discovery of therapeutics for mitochondrial disease. Abliva has the foundation to do this with a clear strategy, a strong portfolio of assets, a research and development 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 aim to augment our strong research and development capabilities and build a commercial organization. We will bring new innovative therapeutics to the patients 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 Disease
Mitochondria function as the powerhouses of our cells and are crucial for the cells' energy metabolism. Primary mitochondrial disease is a rare orphan disease 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 disease lead to premature mortality. Mitochondrial medicine has become an area of ever increasing focus for the pharmaceutical industry as there are currently no effective treatment options. Through Abliva's research and development, we have an opportunity to improve the health and quality of life of 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 different types of mitochondrial disease.

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 that enabled the start of a potentially registrational Phase 2 study in 2022. KL1333 is protected by both a composition of matter patent as well as Orphan Drug Designation (ODD) in the U.S. and in Europe. The commercial opportunity is significant with even conservative estimates exceeding USD 1 billion per year in annual sales[1)].

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

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

Leveraging Opportunities in Rare Diseases
Abliva is continually working to take advantage of the opportunities afforded to companies working in the rare disease space. The company requested, and was granted, orphan drug designation (ODD) for both KL1333 and NV354. ODD is a regulatory designation that provides sponsors with a several advantages including more regulatory assistance and scientific advice during the development process, lower development costs, attractive pricing, and market exclusivity (10 years in the EU and 7 years in the US). The outlook for reaching the market is also better than for traditional medicines[2,3].

In addition, we have sought scientific advice for KL1333 from pharmaceutical regulators across the U.S., U.K., and Europe. This advice has been extremely important to the company, as is clearly demonstrated with the advice from the FDA that led us to move to a single, potentially registrational Phase 2 study, allowing us to get to market more quickly. We have also received valuable and positive feedback from the U.K. regulatory agency on our NV354 program, validating its potential to move into studies in humans.

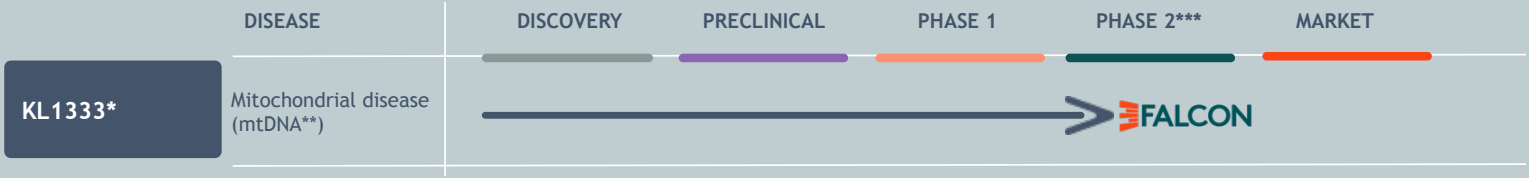
Building a World Class Organization
The key to the success of any company is the people who work there, and the leadership at Abliva is committed to attracting and retaining a group of bright, innovative scientists, clinicians, and drug development experts. We will continue to support development opportunities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

Accessing Capital to Finance the Vision
Abliva is a public company traded on NASDAQ Stockholm (ABLI, Small cap). The company appreciates the continued commitment of our shareholders and looks to attract new investors as we advance our portfolio and build the company. The investment of Hadean Ventures in 2020 was the first step to bringing specialist investors into the company; 2022 brought investment from life science specialist IP Group plc and Norweigan institutional investor Oslo Pensionsförsäkringar. The company aims to continue to attract new specialist and institutional investors.

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

KL1333 Innovative therapy in clinical development

The FALCON study is screening patients
Positive safety results and signs of dose-dependeefficacy from Phase 1a/b study
Clarity on regulatory pathway



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**mtDNA-related mitochondrial disorders caused by mutation(s) in mitochondrial DNA (as opposed to nuclear DNA).
***Given that mitochondrial disease is an orphan disease, a Phase 2 study in these patients, if successful, can have the potential for market approval.

Events since the start of the first quarter

- The first patients in the FALCON study have been screened and are now undergoing their mandatory 8-12 week screening period before dosing of KL1333 can start.

Objectives for 2023

- Full recruitment of Wave 1 of the FALCON study.
- Preparation of sites and documentation for Wave 2 of the FALCON study.

DISEASE AREA

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

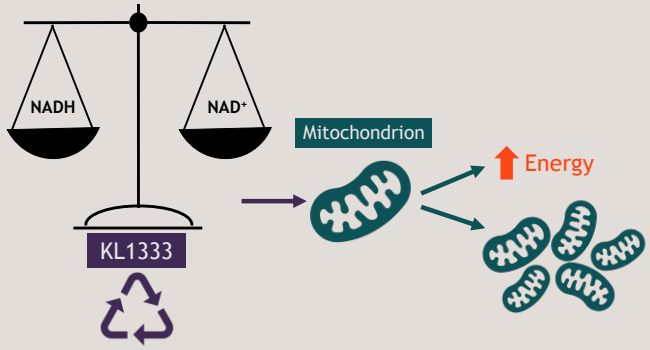
THE FALCON STUDY

The FALCON study is a global, randomized, placebo-controlled, potentially registrational, clinical Phase 2 study with KL1333. Through the study, the company will evaluate the safety and efficacy of KL1333 on primary mitochondrial disease in adult patients with mitochondrial DNA mutations, with a focus on chronic fatigue and muscle weakness which are the most common and debilitating disease expressions in these patients. The company will recruit 120 – 180 patients, in two waves, who will be given KL1333 or placebo twice daily for 12 months. An interim analysis will take place after the completion of Wave 1 and will give important statistical information on safety and powering in Wave 2.

PATH TO MARKET

The recommendation from the FDA to make a coherent, potentially registrational study brings significant benefits to the KL1333 project, and Abliva's intention is to apply for market approval during 2026. The number of patients in the target group for treatment with KL1333 is approximately 40,000[1] in Europe and the US. At typical orphan drug pricing, this translates into a blockbuster opportunity.

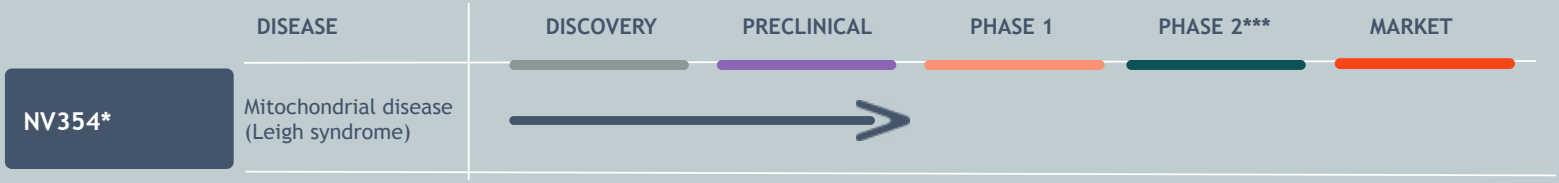
1) Gorman et al.,Prevalence of Nuclear and Mitochondrial DNA Mutations Related to Adult Mitochondrial Disease, 2015



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

NV354 First-in-class therapeutic targeting high unmet need

Increased patent protection and orphan drug designation in the U.S.



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**mtDNA-related mitochondrial disorders caused by mutation(s) in mitochondrial DNA (as opposed to nuclear DNA).
***Given that mitochondrial disease is an orphan disease, a Phase 2 study in these patients, if successful, can have the potential for market approval.

Events during the first quarter

- The U.S. Patent and Trademark Office granted a composition of matter patent (Succinate Prodrug, Compositions Containing the Succinate Prodrug and Uses Thereof) for the NV354 compound.

Events after the reporting period

- NV354 was granted Orphan Drug Designation (ODD) for the treatment of mitochondrial disease by the FDA.

Objectives

- Given the prioritization of KL1333, the progression of NV354 to Phase 1 continues at a reduced speed.

PRIMARY INDICATION

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

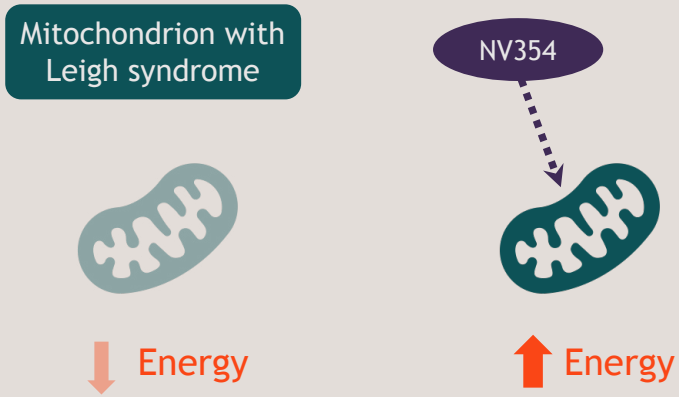
Symptoms include developmental delay, psychomotor regression and hypotonia. There are currently no approved medicines. The drug candidate is intended for long-term oral treatment.

EXPANSION OPPORTUNITY

The unique mechanism of action and high brain uptake may be utilized to develop NV354 for the treatment of MELAS in children and adolescents with neurological symptoms, and for the treatment of LHON. MELAS is a serious disease with symptoms such as muscle weakness, diabetes, fatigue, epilepsy, other severe neurological effects, and shortened life span. LHON is a disease that causes sudden severe permanent visual impairment and can lead to blindness on both eyes.

PATH TO MARKET

Given the orphan drug designation and the high unmet medical need, NV354 is expected to have an expedited path to market and a substantial commercial opportunity. Internal analyses suggest a launch in Leigh syndrome followed by expansion in LHON and MELAS could result in annual peak sales approaching USD 1 billion.



In Leigh syndrome and related mitochondrial diseases, the first step in energy production (complex 1) does not work properly. NV354, a succinate prodrug, bypasses this deficiency and restores the energy needed.

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

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

Treatment objective

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

Project status

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

Abliva continues 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 of traumatic brain injury with NeuroSTAT. TRACK-TBI has updated its timelines, hence the study, if authorized by US Department of Defense (DOD), would commence in 2023 at the earliest, 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 2023 was SEK 0 (0). Other operating revenues for the first quarter were SEK 1,055 (0) and pertain to net exchange-raite gains.

Results of operations

The operating loss for the first quarter was SEK 16,216,000 (21,550,000). The net loss before tax for the first quarter amounted to SEK 16,092,000 (22,028,000). The operating loss was affected by other external expenses, which for the full were SEK 11,840,000 (17,350,000). During the first quarter, expenses related to development projects, as a part of external expenses, have affected the result with SEK 8,307,000 (15,702,00000) whereof SEK 8 038,000 (15,264,000) relates to project in clinical phase. The cost for Projects in the clinical phase are less, compared to the same period last year, due to predetermined payment schedules to suppliers. Personnel expenses during the first quarter amount to SEK 4,720,000 (3,448,000) and are higher compared to last year due to bonus reservations. Other operating expenses amount to SEK 0 (145,000).

Profit/loss from financial items

Financial items for the first quarter amount to SEK 123,000 (-478,000) and refers mainly to accrued interest for short term placements.

(SEK 000)	Note	1 Jan, 2023 31 Mar, 2023	1 Jan, 2022 31 Mar, 2022	1 Jan, 2022 31 Dec, 2022
Net sales		-	-	31
Other operating income		1,055	-	1,716
		1,055	**0**	**1,746**
Operating expenses				
Other external expenses		-11,840	-17,350	-68,298
Personnel cost		-4,720	-3,448	-14,028
Depreciation and write-down of tangible and intangible assets		-711	-608	-2,610
Other operating expenses		-	-145	-
		-17,271	**-21,550**	**-84,937**
Operating income		**-16,216**	**-21,550**	**-83,190**
Profit/loss from financial items				
Result from other securities and receivables related to non current assets		-	-	298
Financial income		143	-	392
Financial costs		-20	-478	-2,764
		123	**-478**	**-2,073**
Profit/loss before tax		**-16,092**	**-22,028**	**-85,264**
Income tax	2	-	-	-
Profit/loss for the period		**-16,092**	**-22,028**	**-85,264**
Other comprehensive income				
Items that may be reclassified to profit or loss				
Translation differences on foreign subsidiaries		-6	23	147
Total comprehensive income for the period		**-16,098**	**-22,005**	**-85,117**
Loss for the period attributable to:				
Parent company shareholders		-16,092	-22,028	-85,262
Non-controlling interests		-	-1	-2
		-16,092	**-22,028**	**-85,264**
Total comprehensive income for the period				
Parent company shareholders		-16,098	-22,004	-85,117
Non-controlling interests		-	-1	-
		-16,098	**-22,005**	**-85,117**
Earnings per share before and after dilution(SEK) based on average number of shares		-0.02	-0.05	-0.12
Average number of shares before and after dilution		1,056,299,165	403,006,798	739,486,960

Consolidated Statement of

Financial Position

Financial position

The equity/assets ratio was 95 (33) percent as of 31 March 2023, and equity was SEK 149,007,000 (20,114,000) compared to beginning of the year. Long term liabilities refers to long term part of the rigth of use asset leases. Current liabilities amounted to SEK 6,932,000 (17,348,000) as of March 31, 2023, and mainly refers to activities realted to the FALCON study. Other short-term recivables amounts to 59,466 (0) and refer to the investment of surplus liquidity.Cash and cash equivalents amounted to SEK 59,518,000 (23,880,000) as of 31 March 2023, a decrease of SEK 6,874,000 from the beginning of the year. Total assets as of 31 March 2023 were SEK 156,650,000 (61,686,000).

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 about 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, 2023	31 Mar, 2022	31 Dec, 2022
ASSETS				
Non-current assets				
Intangible assets	1			
Patents		18,469	20,083	18,928
Other Intangible assets		1,042	1,176	1,075
		19,511	**21,259**	**20,004**
Tangible assets				
Equipment		42	49	49
Rigth of use asset leases		1,046	-	859
		1,088	**49**	**908**
Financial assets				
Other long-term securities		13,101	13,101	13,101
		13,101	**13,101**	**13,101**
Total non-current assets		**33,700**	**34,409**	**34,013**
Current assets				
Other receivables		1,265	1,328	849
Prepaid expenses and accrued income		2,701	2,070	3,626
Other short term recivables		59,466	-	78,949
Cash and cash equivalents		59,518	23,880	66,392
		122,950	**27,278**	**149,816**
TOTAL ASSETS		**156,650**	**61,686**	**183,829**

Consolidated Statement of

Financial Position

(SEK 000)	Note	31 Mar, 2023	31 Mar, 2022	31 Dec, 2022
EQUITY AND LIABILITIES				
Equity attributable to the shareholders of the parent company				
Share capital		52,815	20,150	52,815
Additional paid in capital		905,823	730,560	905,221
Translation reserve		827	711	833
Retained earnings*		-810,458	-731,316	-794,582
Total equity attributable to the shareholders of the parent		**149,007**	**20,106**	**164,287**
Non-controlling interests		-	8	-
Total equity		**149,007**	**20,114**	**164,287**
Long-term liabilities				
Other longtrem liabilities		711	24,223	534
		711	**24,223**	**534**
Short-term liabilities				
Accounts payable		2,922	9,289	4,860
Other liabilities		674	1,393	548
Accrued expenses and deferred income		3,337	6,667	13,599
		6,932	**17,348**	**19,007**
Total liabilities		**7,643**	**41,571**	**19,541**
TOTAL EQUITY AND LIABILITIES		**156,650**	**61,686**	**183,828**

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 2022	**20,150**	**730,560**	**688**	**-709,879**	**41,519**	**9**	**41,528**
Comprehensive profit/loss for the period		**-**	**-**	**-**	**-**	**-**	**-**
Profit/loss for the period	-	-	-	-85,262	-85,262	-2	-85,264
Other comprehensive income		-	-	-	-	-	-
Translation differences	-	-	145	-	145	2	147
Other comprehensive profit/loss for the period, net after tax	**-**	**-**	**145**	**-**	**145**	**2**	**147**
Total comprehensive profit/loss	**-**	**-**	**145**	**-85,262**	**-85,117**	**-**	**-85,117**
Transactions with shareholders		**-**	**-**	**-**	**-**	**-**	**-**
Rights Issue	32,665	174,661	-	-	207,326	-	207,326
Share-based payment	-	-	-	550	550	-	550
Change of ownership in share issue	-	-	-	9.00	9.00	-9.00	-
Total transactions with shareholders	**32,665**	**174,661**	**-**	**559**	**207,885**	**-9**	**207,876**
Closing balance, 31 December 2022	**52,815**	**905,221**	**833**	**-794,582**	**164,287**	**0**	**164,287**
Opening balance, 1 January 2022	**20,150**	**730,560**	**688**	**-709,879**	**41,519**	**9**	**41,528**
Comprehensive profit/loss for the period							
Profit/loss for the period	-	-	-	-22,028	-22,028	-1	-22,028
Other comprehensive income							
Translation differences	-	-	23	-	23	-	23
Other comprehensive profit/loss for the period, net after tax	**-**	**-**	**23**	**-**	**23**	**-**	**23**
Total comprehensive profit/loss	**-**	**-**	**23**	**-22,028**	**-22,005**	**-1**	**-22,005**
Transactions with shareholders							
Rights Issue*	-	-	-	-	-	-	-
Share-based payment	-	-	-	591	591	-	591
Total transactions with shareholders	**-**	**-**	**-**	**591**	**591**	**-**	**591**
Closing balance, 31 March 2022	**20,150**	**730,560**	**711**	**-731,316**	**20,106**	**8**	**20,114**
Opening balance, 1 January 2023	**52,815**	**905,221**	**833**	**-794,582**	**164,287**	**0**	**164,287**
Comprehensive profit/loss for the period							
Profit/loss for the period	-	-	-	-16,092	-16,092	-	-16,092
Other comprehensive income							
Translation differences	-	-	-6	-	-6	-	-6
Other comprehensive profit/loss for the period, net after tax	**-**	**-**	**-6**	**-**	**-6**	**-**	**-6**
Total comprehensive profit/loss	**-**	**-**	**-6**	**-16,092**	**-16,098**	**-**	**-16,098**
Transactions with shareholders							
Rights Issue*	-	-	-	-	-	-	-
Share-based payment	-	602	-	-	602	-	602
Change of ownership in share issue	-	-	-	217	217	-	217
Total transactions with shareholders	**-**	**602**	**-**	**217**	**819**	**-**	**819**
Closing balance, 31 March 2023	**52,815**	**905,823**	**827**	**-810,457**	**149,008**	**-0**	**149,008**

Consolidated Statement of

Cash Flows

Cash flow and investments

Operating cash flow for the first quarter was SEK -7,330,000 (-22,718,000). The cash flow effect related to investments in intangibles equals SEK -65,000 (13,000) for the first quarter. Cash flow for the first quarter equals SEK -6,875,000 (1,519,000).

(SEK 000)	1 Jan, 2023 31 Mar, 2023	1 Jan, 2022 31 Mar, 2022	1 Jan, 2022 31 Dec, 2022
Cash flow from operating activities			
Operating income	-16,216	-21,550	-83,190
Adjustments for non-cash items:			
Depreciation	711	608	2,610
Currency differences on intercompany items	-4	14	193
Impaired Value	-11	-	-
Share-based payments	217	591	551
Result from other securities and receivables related to non current assets	-	-	298
Interest received	143	-	392
Interest paid	-20	-	-25
Net cash from operating activities before changes in working capital	**-15,179**	**-20,337**	**-79,172**
Changes in working capital			
Increase/decrease of other current assets	19,991	-1,483	-81,506
Increase/decrease of other short-term liabilities	-12,142	-898	1,118
Changes in working capital	**7,849**	**-2,381**	**-80,388**
Cash flow from operating activities	**-7,330**	**-22,718**	**-159,560**
Investing activities			
Acquisition of intangible assets	-65	13	-882
Acquisition of tangible assets	-	-	-23
Cash flow from investing activities	**-65**	**13**	**-905**
Financing activities			
New share issue	602	-	180,364
Amoritization lease	-82	-	-170
Increase/decrease of long-term liabilities	-	24,223	24,223
Cash flow from financing activities	**520**	**24,223**	**204,417**
Cash flow for the period	-6,875	1,519	43,952
Cash and cash equivalents at the beginning of the period	66,392	22,339	22,339
Effect of exchange rate changes on cash	1	22	101
Cash and cash equivalents at end of period	**59,518**	**23,880**	**66,392**

Parent Company

Income Statement

Parental company

Company earnings after tax for the first quarter amounts to SEK -15,268,000 (-21,434,000). Accordingly, no further specific information regarding the parent company is presented.

(SEK 000)	Note	1 Jan, 2023 31 Mar, 2023	1 Jan, 2022 31 Mar, 2022	1 Jan, 2022 31 Dec, 2022
Net sales		-	-	31
Other operating income		1,045	-	1,716
		1,045	**0**	**1,746**
Operating expenses				
Other external expenses		-13,091	-18,218	-72,875
Personnel cost		-3,109	-1,987	-8,580
Depreciation and write-down of tangible and intangible assets		-616	-608	-2,439
Other operating expenses		-	-145	-
		-16,816	**-20,957**	**-83,894**
Operating income		**-15,772**	**-20,956**	**-82,148**
Profit/loss from financial items				
Result from other securities and receivables related to non current assets		-	-	298
Interest income and other similar profit items		143	-	392
Interest expenses and other similar loss items		-	-478	-2,738
		143	**-478**	**-2,048**
Profit/loss before tax		**-15,628**	**-21,434**	**-84,196**
Income tax	2	-	-	-
Profit/loss for the period		**-15,628**	**-21,434**	**-84,196**

Parent Company

Statement of Comprehensive Income

(SEK 000)	Note	1 Jan, 2023 31 Mar, 2023	1 Jan, 2022 31 Mar, 2022	1 Jan, 2022 31 Dec, 2022
Profit/loss for the period		-15,628	-21,434	-84,196
Other comprehensive income		-	-	-
Total comprehensive profit/loss for the period		**-15,628**	**-21,434**	**-84,196**

Parent Company

Balance Sheet

(SEK 000)	Note	31 Mar, 2023	31 Mar, 2022	31 Dec, 2022
ASSETS				
Non-current assets				
Intangible assets	1			
Patents		18,469	20,083	18,928
Other intangible assets		1,042	1,176	1,075
		19,511	**21,259**	**20,004**
Tangible assets				
Equipment		42	49	49
		42	**49**	**49**
Financial assets				
Other long-term placement		13,101	13,101	13,101
Shares in subsidiaries	3	24,557	24,557	24,557
		37,658	**37,658**	**37,658**
Total non-current assets		**57,211**	**58,966**	**57,711**
Current assets				
Short term receivables				
Receivables from group companies		602	-	-
Other receivables		1,241	1,306	825
Prepaid expenses and accrued income		2,646	2,070	3,626
		4,488	**3,376**	**4,451**
Other short term recievables		59,466	-	78,949
Cash and bank balances		58,614	23,607	65,123
Total current assets		**122,568**	**26,984**	**148,522**
TOTAL ASSETS		**179,779**	**85,950**	**206,234**

Parent Company

Balance Sheet

(SEK 000)	Note	31 Mar, 2023	31 Mar, 2022	31 Dec, 2022
EQUITY AND LIABILITIES				
Equity				
Restricted equity				
Share capital		52,815	20,150	52,815
Statutory reserve		1,856	1,856	1,856
Development expenditure reserve**		788	2,402	1,247
		55,459	**24,409**	**55,919**
Unrestricted equity				
Share premium reserve		175,263	70,534	174,661
Retained earnings		-41,892	-29,845	41,844
Profit/loss for the period		-15,628	-21,434	-84,196
		117,742	**19,255**	**132,309**
Total equity		**173,201**	**43,664**	**188,228**
Long-term liabilities				
Other longtrem liabilities		-	24,223	-
		-	**24,223**	**-**
Short-term liabilities				
Accounts payable		2,891	9,268	4,602
Liabilities subsidiary		749	1,783	1,290
Other liabilities		326	1,389	213
Accrued expenses and deferred income		2,612	5,623	11,901
		6,578	**18,063**	**18,006**
TOTAL EQUITY AND LIABILITIES		**179,779**	**85,950**	**206,234**

Notes

Note 1 — Intangible assets

(SEK 000)	Patents	Other	Total
ACCUMULATED COST			
Opening balance 1 Jan. 2023	**36,086**	**2,864**	**38,950**
Additions	116	-	116
Impaired value	-	-	-
Closing balance 31 Mar. 2023	**36,202**	**2,864**	**39,066**
ACCUMULATED DEPRECIATION			
Opening balance 1 Jan. 2023	**-17,158**	**-1,789**	**-18,947**
Depreciation for the period	-575	-34	-609
Impaired value	-	-	-
Closing balance 31 Mar. 2023	**-17,734**	**-1,822**	**-19,556**
Residual value 31 Mar. 2023	**18,468**	**1,042**	**19,510**

(SEK 000)	Patents	Other	Total
ACCUMULATED COST			
Opening balance 1 Jan. 2022	**35,180**	**2,864**	**38,044**
Additions	906	-	906
Impaired value	-	-	-
Closing balance 31 Dec. 2022	**36,086**	**2,864**	**38,950**
ACCUMULATED DEPRECIATION			
Opening balance 1 Jan. 2022	**-14,887**	**-1,654**	**-16,541**
Depreciation for the period	-2,271	-134	-2,406
Impaired value	-	-	-
Closing balance 31 Dec. 2022	**-17,158**	**-1,789**	**-18,947**
Residual value 31 Dec. 2022	**18,928**	**1,075**	**20,003**

Note 2 – Tax

The group's total loss carry-forwards amounts to SEK 825,819,000 as of 31 March 2023 (767,871,000). The parent company's total loss carry-forwards amounts to SEK 799,190,000 as of 31 March 2023 (741,933,000). 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 in the subsidiary NeuroVive Pharmaceutical Asia Ltd., domiciled in Hong Kong, the american subsidiary Abliva Inc., Boston and the Swedish subsidiary Abliva Incentive AB, holding option program for the CEO.

Other disclosures

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

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.

At the EGM on March 8, 2023, the meeting resolved on a bonus to Board Member Edwin Moses to subsidize the participant's tax costs for participation in Warrant program for the board member 2023/2027 through a bonus payment in cash. The bonus payment amounted to SEK 340,000.

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 March 2023 was 8 (8), of which 6 (6) are women.

Important events during the first quarter (Jan-Mar 2023)
For further information, see page 2.

Important events after the reporting period
For further information, see page 2.

Incentive programs/share warrants
Stock option programs
The annual general meeting on 20 May, 2021, decided on a four-year incentive stock option program 2021/2025 for the Company's CEO. The incentive stock option program entitles the holder to a new share in Abliva AB up to a maximum of 4,600,000 ordinary shares. The redemption price amounts to SEK 0.27. The program is vested at 25% per year on 1 June, 2022, 1 June, 2023, 1 June, 2024 and 1 June, 2025. Latest redemption date is 31 December, 2025.

The general meeting on 8 March, 2023, decided on a second four-year incentive stock option program 2023/2027 for the Company's CEO. The incentive stock option program entitles the holder to a new share in Abliva AB up to a maximum of 17,500,000 ordinary shares. The redemption price amounts to SEK 0.27. The program is vested at 25% per year on 1 April, 2024, 1 April, 2025, 1 April, 2026 and 1 April, 2027. Latest redemption date is 31 December, 2027.

Warrant Programs
At the general meeting on 8 March, 2023, it was decided on a warrant program 2023/2027 to management and other key employees of a maximum of 23.5 million warrants at a price of SEK 0.06 per warrant, corresponding to a subscription price of SEK 0.67 per share. One warrant entitles the holder to one new share in Abliva AB. In total, approx. 10 million options have been subscribed in the warrant program for management and other key employees. Redemption date is 1 June - 31 December 2027.

At the general meeting on 8 March, 2023, it was decided on a warrant program 2023/2027 to board member Edwin Moses of 8.5 million warrants. The warrants have been assigned to the participant free of charge. On 4 May, 2023, Edwin Moses declined re-election due to personal reasons and has thus returned all warrants. The program is in the process of being cancelled.

On 5 May the AGM resolved on a warrant program 2023/2027 for certain board members of a maximum of 4.5 million warrants at a price of SEK 0.05 per warrant and a subscription price of SEK 0.5767 per share. One warrant entitles the holder to one new share in Abliva AB Redemption date is June 1 - December 31, 2027.

In case of full utilization of all incentive programs, warrant program to Edwin Moses excluded, the maximum dilution amounts to 4.55 per cent on a fully diluted basis. The dilution effects have been calculated as the number of additional shares and votes in relation to the number of existing shares and votes plus the number of additional shares and votes. The dilution is only expected to have a marginal effect on the Company's key performance indicator "Earnings (loss) per share".

For further information, please see www.abliva.com and the Annual Report for 2022, note 12.

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

Upcoming financial statements

Q2 Report January-June 2023	August 18, 2023
Q3 Report January-September 2023	November 17, 2023
Year-End Report 2023	February 23, 2024

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

Risks and uncertainty factors

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

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

Macroeconomic and geopolitical factors
The Russian invasion of Ukraine in Febraury 2022 has worsened the political security situation in the rest of the world and created significant uncertainty in the financial markets, which may affect the company. The company has no direct business in, nor does it conduct any preclinical or clinical studies in Ukraine or Russia, but sees a risk that the company eventually will suffer from increased raw material and energy prices, which are likely to translate into both increased prices for goods and services as well as a change in strategy by investors and potential partners.

Disputes
Abliva is not involved in any disputes.

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

Principles of preparation of the Interim Report

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

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 2022 on pages 41-56.

Definitions alternative performance measures

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

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

The declaration of the Board of Directors and the CEO

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

Lund, Sweden, May 23, 2023

David Laskow-Pooley
Chair of the Board

David Bejker
Board member

Roger Franklin
Board member

Denise Goode
Board member

Jan Törnell
Board member

Ellen Donnelly
Chief Executive Officer


David Laskow-Pooley


David Bejker


Roger Franklin


Denise Goode


Jan Törnell


Ellen Donnelly

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

The information was submitted for publication, through the agency of the contact person set out above, at 8:30 a.m. CEST on May 23, 2023.

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

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)".
(The) **FALCON study.** Abliva's global potentially registrational Phase 2 clinical trial with the drug candidate KL1333. The study will evaluate the efficacy of KL1333 on fatigue and muscle weakness in adult patients with primary mitochondrial diseases caused by inherited mutations in the mitochondrial DNA.
Fatigue. Extreme tiredness. Often includes muscle fatigue with exercise intolerance.
FDA. The United States Federal Food and Drug Administration.
Hypotonia. An abnormally low level of tension, important for posture, in the resting muscle.
Indication. A disease condition requiring treatment, such as traumatic brain injury or fatty liver, NASH.
Interim analysis. The analysis of data in a clinical trial comparing intervention groups before the formal completion of the trial, typically before patient recruitment is complete. Can be used for various purposes, such as assessing the statistical strength of the study to meet the predetermined endpoints.
KSS. Mitochondrial disease, Kearns-Sayre's syndrome. The disease debuts before the age of 20 and is characterized by eye related symptoms with pigment retention in the retina and paralysis of the outer eye muscles, as well as the effects on the cardiac retinal system and the cerebellum with disorders in the coordination of muscle movements (ataxia).
Leigh syndrome. Leigh syndrome is a serious condition with characteristic changes to the brain that usually affects small children. This disease is caused by faults in energy-producing mitochondria and is also known as subacute (fast onset) necrotizing (tissue destroying) encephalomyopathy (a disease of the brain and muscles).
LHON. Mitochondrial disease, Leber Hereditary Optic Neuropathy. Affects the retina and the optic nerve, but in rare cases symptoms can be found in other parts of the central nervous system. There is no cure, but treatments are focused primarily on compensating for the visual impairment.
MELAS. MELAS is an acronym of mitochondrial encephalomyopathy (brain and muscle disease) with lactic acidosis (increased lactic acid levels in the blood) and strokelike episodes.
MERRF. (Myoclonic epilepsy with ragged-red fibers). Primary mitochondrial disease with symptoms such as epilepsy, involuntary muscle twitching and difficulty coordinating muscle movements, but the disease can affect many functions. When examined under a microscope, muscle tissue has characteristic changes.
MHRA. The UK Medicines and Healthcare products Regulatory Agency.
MIDD. Maternally Inherited Diabetes and Deafness
Mitochondria. That part of each cell that provides effective energy production in the form of conversion of oxygen and nutrients in the body into chemical energy.
Mitochondrial medicine. Field of research and development of pharmaceuticals that protect the mitochondria.
Mitochondrial myopathy. Primary mitochondrial disease which affects the muscles.
mtDNA. Mitochondrial DNA. Mitochondria's own genome that is inherited only on the maternal line. Separate from the cells' genome (nuclear DNA = nDNA) inherited by both parents.
NAD^+/NADH. A coenzyme involved in metabolism. NAD^+ and NADH have central roles in cell- and mitochondrial metabolism and energy production.
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.
Phase (1,2 and 3). The various stages of trials on the efficacy of a pharmaceutical in humans. See also "clinical trial." Phase 1 examines the safety on healthy human subjects, Phase 2 examines efficacy in patients with the relevant disease and Phase 3 is a large-scale trial that verifies previously achieved results. In the development of new pharmaceuticals, different doses are trialed and safety is evaluated in patients with relevant disease, Phase 2 is often divided between Phase 2a and Phase 2b.
Preclinical. That stage of drug development that occurs before a candidate drug is trialed on humans.
Primary mitochondrial diseases. Metabolic diseases that affect the ability of cells to convert energy. An estimated 12 in every 100,000 people affected. Often present in early childhood and lead to severe symptoms, such as mental retardation, heart failure and rhythm disturbances, dementia, movement disorders, severe diabetes, stroke-like episodes, deafness, blindness, limited mobility of the eyes, vomiting and seizures.
Psychomotor regression. When the development of the ability to perform will-driven movements is initially normal but deteriorates during infancy or early childhood.
TBI. Traumatic Brain Injury. An injury to the brain where some nerve cells are subjected to immediate damage. The injury then continues to exacerbate several days after the incident, which significantly impacts the final extent of damage.

About Abliva

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

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

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

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

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