ABLIVA

Interim Report

January - June 2023

2023

Delivering mitochondrial health

Second Quarter Summary

The first patient was dosed in the FALCON study | Orphan Drug Designation for NV354

Important events April – June 2023

- The first patient was dosed in Abliva's global, potentially registrational, clinical Phase 2 study with lead drug candidate KL1333 - the FALCON study.
- 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 Abliva's website www.abliva.com.

Financial information

April-June 2023*

- Net revenues: SEK 0 (0)
- Other operating income: SEK 2,711,000 (0)
- Loss before tax: SEK 21,226,000 (20,535,000)
- Loss per share before dilution: SEK 0.02 (0.04)
- Diluted loss per share: SEK 0.02 (0.04)

January-June 2023*

- Net revenues: SEK 0 (0)
- Other operating income: SEK 3,766,000 (0)
- Loss before tax: SEK 37,318,000 (42,564,000)
- Loss per share before dilution: SEK 0.04 (0.09)
- Diluted loss per share: SEK 0.04 (0.09)

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

First Patient Dosed in Phase 2 FALCON Study

Abliva recognized an important milestone in June with the dosing of the first patient in our global, potentially registrational Phase 2 study, the FALCON study, and thus closed the quarter on a strong note. At the completion of the first two months of dosing patients, the study remains on track to recruit the patients required for Wave 1 of the study by the end of the year with the interim analysis expected towards the middle of 2024.

Milestone Achieved in FALCON

During the second quarter, the team was focused on gaining full approval of the FALCON study in all countries included in the first wave of the study, while also directing their attention to site initiations. By the end of the quarter the team had successfully received ethics and regulatory approval in the six countries (Belgium, Denmark, France, UK, Spain, U.S.) that will contribute patients to the first wave of the study. The most important milestone in the quarter was the initiation of dosing, with our first patient dosed by Dr. Rita Horvath and her team at the Department of Clinical Neurosciences, Addenbrooke's Hospital in Cambridge, UK.

The second quarter offered our team important insights into the baseline characteristics of incoming patients. When a patient is considered for the study, they spend 8-12 weeks in a screening phase to ensure that they have moderate to severe levels of both fatigue and myopathy that persist over time. This period allows us to confirm that we have the right patient population in the study and provides us with important baseline data. The importance of this screening and its utility for ensuring the robustness of our study has, as expected, been demonstrated over the past few months where some patients didn't meet the stringent criteria and thus were not included in the trial

Mingling with the Mito Community

In June, the team had the opportunity to meet with physicians, patients, and other mitochondrial disease experts during two global mitochondria meetings. The first, Euromit, was held in Bologna, Italy and brought together the European mitochondrial community. During the meeting the Abliva team held meetings with FALCON study investigators as well as patient advocacy groups across Europe, the U.S., and Australia. The team also presented three preclinical posters, all of which received great attention.

"...the study remains on track to recruit the patients required for Wave 1 of the study by the end of the year..."

Two weeks later, Magnus Hansson and I attended the leading mitochondrial medicine meeting in the U.S., UMDF's Mitochondrial Medicine Symposium 2023. The UMDF meeting was unique in catering to patients, and we had the opportunity to meet with numerous patients and hear their stories. During this meeting we also presented posters and released, for the first time, the 'PROMIS® Fatigue Mitochondrial Disease Short Form, a patient reported outcome that has been acknowledged by the FDA as an approvable endpoint in our study. This scale was developed to address the fatigue experienced by primary mitochondrial disease patients and is the first validated fatigue scale for this disease.

NV354 Receives Orphan Drug Designation in the U.S.

Although mentioned previously, it would be remiss of me to neglect mentioning the approval of Orphan Drug Designation for NV354 in the U.S. that was received in May. Not only does this designation give NV354, our second drug candidate, the potential for an additional seven years of exclusivity upon market launch, but it also brings tax credits for qualified clinical trials and an exemption from user fees.

I hope that all of you have had a relaxing summer.

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 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 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 few 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 leads 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 levels 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 candidate 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 efforts ongoing to identify additional portfolio opportunities focused on the regulation and stabilization of cellular 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.

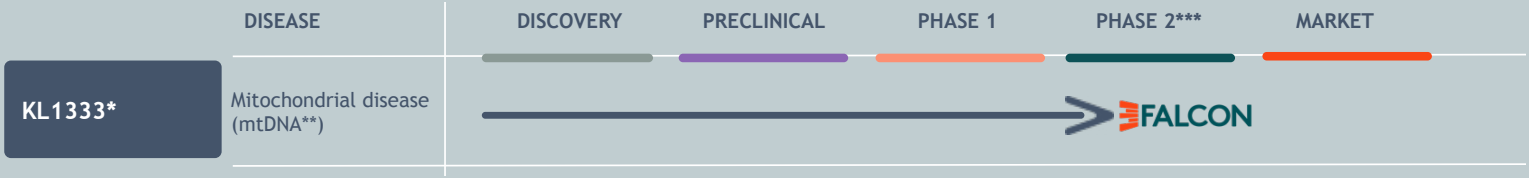
Building a World Class Organization
The key to the success of any company is the people who work there, and the leadership at Abliva is committed to attracting and retaining a group of bright and innovative scientists, clinicians, and drug development experts. We will continue to support development 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 late-stage development

Dosing in patients is ongoing in the FALCON study
Positive safety results and signs of dose-dependent efficacy 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 during the second quarter
- The first patient was dosed in the FALCON study.

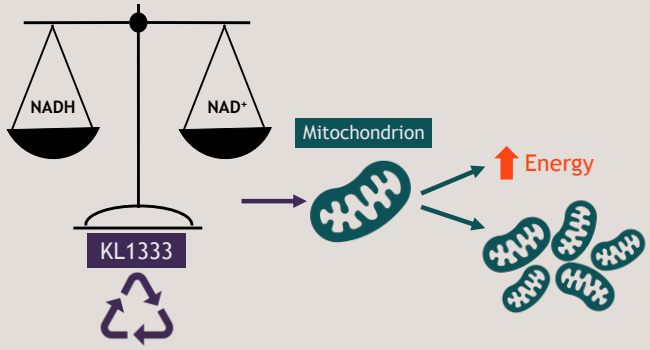
Objectives for 2023
- Full recruitment of Wave 1 of the FALCON study.
- Preparation of sites and documentation for Wave 2 of the FALCON study.

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.

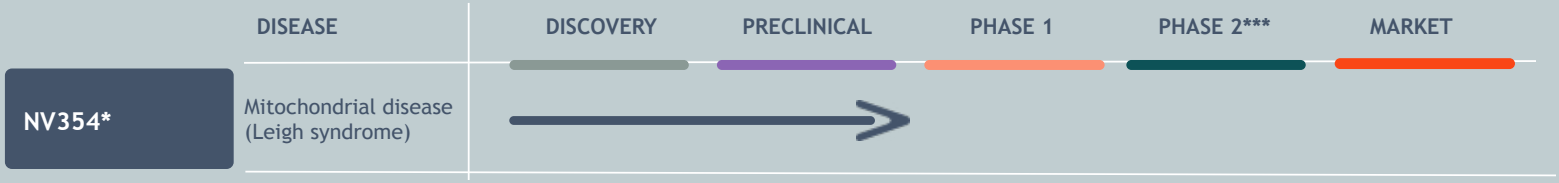
1) Gorman et al.,Prevalence of Nuclear and Mitochondrial DNA Mutations Related to Adult Mitochondrial Disease, 2015



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 granted orphan drug designation in the U.S.



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***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 second quarter

- 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 initially 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.

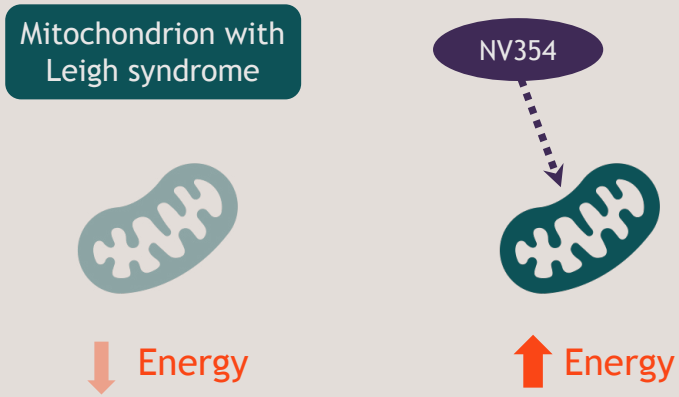
Symptoms include developmental delay, psychomotor regression and hypotonia. There are currently no approved medicines. The drug candidate is intended for long-term oral treatment.

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 neu-

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 second quarter of 2023 was SEK 0 (0). Other operating revenues for the second quarter were SEK 2,711,000 (0) and pertain to exchange-rate gains. During the first six months of 2023 the consolidated turnover was KSEK 0 (0). Other operating revenues for the first six months amounted SEK 3,766,000 (0) and pertain to exchange-rate gains.

Results of operations

The operating loss for the second quarter was SEK 21 289,000 (18,275,000) and for the first six months the operating loss amounted SEK 37,505,000 (39,825,000). The net loss before tax for the second quarter amounted to KSEK 21,226,000 (20,535,000). For the first six months the loss before tax was 37,318,000 (42,564,000).

The operating loss was affected by other external expenses, which for the first six months were SEK 30,040,000 (30,236,000). Expenses related to development projects, as a part of external expenses, have affected the result with SEK 21,610,000 (26,092,000) whereof SEK 21,178,000 (25,832,000) 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 six months amount to SEK 9,805,000 (7,935,000) and are higher compared to last year due to bonus reservations and new recruitment. Other operating expenses amount to SEK 0 (439,000) and pertained to exchange-rate losses.

Profit/loss from financial items

Financial items for the six months amounted to SEK 186,000 (-2,739,000) and refers mainly to accrued interest for short term placements. Comparative figures (2022) refer to 10% interest and set-up costs related to convertible loan from Hadean Ventures.

(SEK 000)	Note	1 Apr, 2023 30 Jun, 2023	1 Apr, 2022 30 Jun, 2022	1 Jan, 2023 30 Jun, 2023	1 Jan, 2022 30 Jun, 2022	1 Jan, 2022 31 Dec, 2022
Net sales		-	-	-	-	31
Other operating income		2,711	-	3,766	-	1,716
		2,711	**-**	**3,766**	**-**	**1,746**
Operating expenses						
Other external expenses		-18,200	-12,886	-30,040	-30,236	-68,298
Personnel cost		-5,086	-4,487	-9,805	-7,935	-14,028
Depreciation and write-down of tangible and intangible assets		-714	-607	-1,425	-1,215	-2,610
Other operating expenses		-	-294	-	-439	-
		-23,999	**-18,275**	**-41,270**	**-39,825**	**-84,937**
Operating income		**-21,289**	**-18,275**	**-37,505**	**-39,825**	**-83,190**
Profit/loss from financial items						
Result from other securities and receivables related to non current assets		-	-	-	-	298
Financial income		87	-	231	-	392
Financial costs		-25	-2,261	-44	-2,739	-2,764
		63	**-2,261**	**186**	**-2,739**	**-2,073**
Profit/loss before tax		**-21,226**	**-20,535**	**-37,318**	**-42,564**	**-85,264**
Income tax	2	-	-	-	-	-
Profit/loss for the period		**-21,226**	**-20,535**	**-37,318**	**-42,564**	**-85,264**
Other comprehensive income						
Items that may be reclassified to profit or loss						
Translation differences on foreign subsidiaries		32	154	26	177	147
Total comprehensive income for the period		**-21,193**	**-20,381**	**-37,292**	**-42,387**	**-85,117**
Loss for the period attributable to:						
Parent company shareholders		-21,226	-20,535	-37,318	-42,563	-85,262
Non-controlling interests		-	-1	-	-1	-2
		-21,226	**-20,536**	**-37,318**	**-42,564**	**-85,264**
Total comprehensive income for the period						
Parent company shareholders		-21,193	-20,382	-37,292	-42,387	-85,117
Non-controlling interests		-	-	-	-	-
		-21,193	**-20,382**	**-37,292**	**-42,387**	**-85,117**
Earnings per share before and after dilution(SEK) based on average number of shares		-0.02	-0.04	-0.04	-0.09	-0.12
Average number of shares before and after dilution		1,056,299,165	459,311,736	1,056,299,165	459,311,736	739,486,960

Consolidated Statement of

Financial Position

Financial position

The equity/assets ratio was 90 (90) percent as of 30 June 2023, and equity was SEK 128,386,000 (163,766,000). Long term liabilities refers to long term part of the rigth of use asset leases and amount to 617,000 (704,000). Current liabilities amounted to SEK 13,018,000 (18,136,000) as of June 30, 2023, and mainly refers to activities realted to the FALCON study. Other short-term recivables amounts to 41,271,000 (0) and refer to the investment of surplus liquidity. Total assets as of 30 June 2023 were SEK 142,021,000 (182,606,000).

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

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

(SEK 000)	Note	30 Jun, 2023	30 Jun, 2022	31 Dec, 2022
ASSETS				
Non-current assets				
Intangible assets	1			
Patents		17,990	19,689	18,928
Other Intangible assets		1,008	1,143	1,075
		18,998	**20,832**	**20,004**
Tangible assets				
Equipment		35	42	49
Rigth of use asset leases		951	1,030	859
		986	**1,072**	**908**
Financial assets				
Other long-term securities		13,101	13,101	13,101
		13,101	**13,101**	**13,101**
Total non-current assets		**33,085**	**35,005**	**34,013**
Current assets				
Other receivables		1,266	9,815	849
Prepaid expenses and accrued income		2,629	2,627	3,626
Other short term recivables		41,271	-	78,949
Cash and cash equivalents		63,770	135,159	66,392
		108,936	**147,602**	**149,816**
TOTAL ASSETS		**142,021**	**182,606**	**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	45,488	52,815
Additional paid in capital		906,048	869,495	905,221
Translation reserve		859	864	833
Retained earnings*		-831,336	-752,090	-794,582
Total equity attributable to the shareholders of the parent		**128,386**	**163,757**	**164,287**
Non-controlling interests		-	9	-
Total equity		**128,386**	**163,766**	**164,287**
Long-term liabilities				
Other longtrem liabilities		617	704	534
		617	**704**	**534**
Short-term liabilities				
Accounts payable		5,440	11,990	4,860
Other liabilities		824	1,877	548
Accrued expenses and deferred income		6,754	4,270	13,599
		13,018	**18,136**	**19,007**
Total liabilities		**13,635**	**18,840**	**19,541**
TOTAL EQUITY AND LIABILITIES		**142,020**	**182,606**	**183,829**

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	-	-	-	551	551	-	551
Change of ownership in share issue	-	-	-	9	9	-9	-
Total transactions with shareholders	**32,665**	**174,661**	**-**	**560**	**207,886**	**-9**	**207,877**
Closing balance, 31 December 2022	**52,815**	**905,221**	**833**	**-794,581**	**164,287**	**-**	**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	-	-	-	-42,563	-42,563	-1	-42,564
Other comprehensive income							
Translation differences	-	-	176	-	176	1	177
Other comprehensive profit/loss for the period, net after tax	**-**	**-**	**176**	**-**	**176**	**1**	**177**
Total comprehensive profit/loss	**-**	**-**	**176**	**-42,563**	**-42,387**	**-**	**-42,387**
Transactions with shareholders							
Rights Issue*	25,338	138,935	-	-	164,273	-	164,273
Share-based payment	-	-	-	351	351	-	351
Total transactions with shareholders	**25,338**	**138,935**	**-**	**351**	**164,624**	**-**	**164,624**
Closing balance, 30 June 2022	**45,488**	**869,495**	**864**	**-752,090**	**163,757**	**9**	**163,765**
Opening balance, 1 January 2023	**52,815**	**905,221**	**833**	**-794,581**	**164,287**	**0**	**164,287**
Comprehensive profit/loss for the period							
Profit/loss for the period	-	-	-	-37,318	-37,318	-	-37,318
Other comprehensive income							
Translation differences	-	-	26	-	26	-	26
Other comprehensive profit/loss for the period, net after tax	**-**	**-**	**26**	**-**	**26**	**-**	**26**
Total comprehensive profit/loss	**-**	**-**	**26**	**-37,318**	**-37,292**	**-**	**-37,292**
Transactions with shareholders							
Share-based payment	-	827	-	-	827	-	827
Change of ownership in share issue	-	-	-	564	564	-	564
Total transactions with shareholders	**-**	**827**	**-**	**564**	**1,391**	**-**	**1,391**
Closing balance, 30 June 2023	**52,815**	**906,048**	**859**	**-831,336**	**128,386**	**-**	**128,386**

Consolidated Statement of

Cash Flows

Cash flow and investments

Operating cash flow for the second quarter was SEK 4 222,000 (-25,785,000). For the first six months the operating cash flow amounted SEK -3,109,000 (-48,503,000). The cash flow effect related to investments in intangibles equals SEK -214,000 (-336,000) for the first six months. Cashflow for the first six months equals SEK -2,663,000 (112,745,000).

(SEK 000)	1 Apr, 2023 30 Jun, 2023	1 Apr, 2022 30 Jun, 2022	1 Jan, 2023 30 Jun, 2023	1 Jan, 2022 30 Jun, 2022	1 Jan, 2022 31 Dec, 2022
Cash flow from operating activities					
Operating income	-24,796	-18,275	-37,505	-39,825	-83,190
Adjustments for non-cash items:					
Depreciation	714	607	1,425	1,215	2,610
Currency differences on intercompany items	60	156	56	170	192
Impaired Value	1	-	-10	-	-
Share-based payments	346	-240	564	351	551
Result from other securities and receivables related to non current assets	-	-	-	-	298
Interest received	87	-	231	-	392
Interest paid	-25	-	-44	-	-25
Net cash from operating activities before changes in working capital	**-23,612**	**-17,751**	**-35,283**	**-38,088**	**-79,172**
Changes in working capital					
Increase/decrease of other current assets	18,268	-9,043	38,258	-10,525	-81,506
Increase/decrease of other short-term liabilities	9,566	1,009	-6,084	111	1,118
Changes in working capital	**27,834**	**-8,034**	**32,174**	**-10,414**	**-80,388**
Cash flow from operating activities	**4,222**	**-25,785**	**-3,109**	**-48,503**	**-159,560**
Investing activities					
Acquisition of intangible assets	-150	-349	-214	-336	-882
Acquisition of tangible assets	-	-	-	-	-23
Cash flow from investing activities	**-150**	**-349**	**-214**	**-336**	**-905**
Financing activities					
New share issue	225	137,361	827	137,361	180,364
Amoritization lease	-84	-	-166	-	-170
Increase/decrease of long-term liabilities	-	-	-	24,223	24,223
Cash flow from financing activities	**141**	**137,361**	**661**	**161,584**	**204,417**
Cash flow for the period	4,213	111,226	-2,663	112,745	43,952
Cash and cash equivalents at the beginning of the period	59,518	23,880	66,392	22,339	22,339
Effect of exchange rate changes on cash	39	53	41	75	101
Cash and cash equivalents at end of period	**63,770**	**135,159**	**63,770**	**135,159**	**66,392**

Parent Company

Income Statement

Parental company

Company earnings after tax for the second quarter amount to SEK -21,359,000 (-20,284,000). Loss after tax for the first six months amount to SEK 36,987,000 (42,259,000). Most of the Group's operations are conducted within the parent company. Accordingly, no further specific information regarding the parent company is presented.

(SEK 000)	Note	1 Apr, 2023 30 Jun, 2023	1 Apr, 2022 30 Jun, 2022	1 Jan, 2023 30 Jun, 2023	1 Jan, 2022 30 Jun, 2022	1 Jan, 2022 31 Dec, 2022
Net sales		-	-	-	-	31
Other operating income		2,664	-	3,709	-	1,716
		2,664	**-**	**3,709**	**-**	**1,746**
Operating expenses						
Other external expenses		-20,430	-14,656	-33,522	-32,874	-72,875
Personnel cost		-3,056	-3,006	-6,165	-4,992	-8,580
Depreciation and write-down of tangible and intangible assets		-618	-607	-1,235	-1,215	-2,439
Other operating expenses		-	-294	-	-439	-
		-24,105	**-18,564**	**-40,921**	**-39,521**	**-83,894**
Operating income		**-21,440**	**-18,564**	**-37,212**	**-39,520**	**-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		87	-	231	-	392
Interest expenses and other similar loss items		-6	-2,260	-6	-2,738	-2,738
		81	**-2,260**	**225**	**-2,738**	**-2,048**
Profit/loss before tax		**-21,359**	**-20,824**	**-36,987**	**-42,259**	**-84,196**
Income tax	2	-	-	-	-	-
Profit/loss for the period		**-21,359**	**-20,824**	**-36,987**	**-42,259**	**-84,196**

Parent Company

Statement of Comprehensive Income

(SEK 000)	Note	1 Apr, 2023 30 Jun, 2023	1 Apr, 2022 30 Jun, 2022	1 Jan, 2023 30 Jun, 2023	1 Jan, 2022 30 Jun, 2022	1 Jan, 2022 31 Dec, 2022
Profit/loss for the period		-21,359	-20,824	-36,987	-42,259	-84,196
Other comprehensive income		-	-	-	-	-
Total comprehensive profit/loss for the period		**-21,359**	**-20,824**	**-36,987**	**-42,259**	**-84,196**

Parent Company

Balance Sheet

(SEK 000)	Note	30 Jun, 2023	30 Jun, 2022	31 Dec, 2022
ASSETS				
Non-current assets				
Intangible assets	1			
Patents		17,990	19,689	18,928
Other intangible assets		1,008	1,143	1,075
		18,998	**20,832**	**20,004**
Tangible assets				
Equipment		35	42	49
		35	**42**	**49**
Financial assets				
Other long-term placement		13,100	13,100	13,101
Shares in subsidiaries	3	25,160	24,558	24,557
		38,260	**37,658**	**37,658**
Total non-current assets		**57,293**	**58,532**	**57,711**
Current assets				
Short term receivables				
Receivables from group companies		-	-	-
Other receivables		1,241	9,791	825
Prepaid expenses and accrued income		2,602	2,627	3,626
		3,842	**12,418**	**4,451**
Other short term recievables		41,271	-	78,949
Cash and bank balances		62,961	134,789	65,123
Total current assets		**108,074**	**147,207**	**148,522**
TOTAL ASSETS		**165,367**	**205,739**	**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	45,488	52,815
Statutory reserve		1,856	1,856	1,856
Development expenditure reserve**		309	2,008	1,247
		54,980	**49,352**	**55,919**
Unrestricted equity				
Share premium reserve		175,488	209,520	174,661
Retained earnings		-41,414	-29,451	41,844
Profit/loss for the period		-36,987	-42,259	-84,196
		97,087	**137,810**	**132,309**
Total equity		**152,067**	**187,162**	**188,228**
Long-term liabilities				
Other longtrem liabilities		-	-	-
		-	**-**	**-**
Short-term liabilities				
Accounts payable		5,423	11,951	4,602
Liabilities subsidiary		1,968	1,813	1,290
Other liabilities		466	1,551	213
Accrued expenses and deferred income		5,444	3,262	11,901
		13,300	**18,577**	**18,006**
TOTAL EQUITY AND LIABILITIES		**165,367**	**205,739**	**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	215	-	215
Impaired value	-	-	-
Closing balance 31 Jun. 2023	**36,301**	**2,864**	**39,165**
ACCUMULATED DEPRECIATION			
Opening balance 1 Jan. 2023	**-17,158**	**-1,789**	**-18,947**
Depreciation for the period	-1,152	-67	-1,219
Impaired value	-	-	-
Closing balance 30 Jun. 2023	**-18,310**	**-1,856**	**-20,166**
Residual value 30 Jun. 2023	**17,990**	**1,008**	**18,998**

(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-forward amount to SEK 889,255,000 as of 30 June 2023 (775,529,000). The parent company's total loss carry-forwards amounts to SEK 863,106,000 as of 30 June 2023 (749,710,000). 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.

The AGM on 5 May, 2023 resolved on a bonus payment in cash to David Laskow-Pooley of SEK 937,500. David Laskow-Pooley is required to use the full amount of the Bonus, net after income tax to acquire Abliva shares on the stock market. The company will pay the social security costs. The shares acquired for the Bonus will be locked in for a period of three (3) years after the acquisition.

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

Human resources
The average number of employees of the group for the period January to June 2023 was 8 (8), of which 6 (6) are women.

Important events during the second quarter (Apr-Jun 2023)
For further information, see page 2.

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

Incentive programs/share warrants
The Company has two option programs and two warrant programs

Option Programs
The annual gneral 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 and 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. In total, approx. 10 million options have been subscribed in the warrant program for management and other and key employees. Redemption date is 1 June - 31 December 2027.

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 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 2022 annual report, note 12.

Audit review
This interim report has not been subject to review by the company's auditors.

Upcoming financial statements

Q3 Report January-September 2023	November 17, 2023
Year-End Report 2023	February 23, 2024

The interim reports and the annual 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, August 18, 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 August 18, 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.
Succinate. Endogenous substance that plays an important role in mitochondrial energy production. Succinate is used by mitochondrial protein complex II.
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, has entered late-stage development. NV354, an energy replacement therapy, has completed preclinical development. Abliva is based in Lund, Sweden.

What is primary mitochondrial disease?
Primary mitochondrial 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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