

2023 Summary

40 Patients Enrolled in Wave 1 of the FALCON Study | Fast Track Designation for KL1333 Orphan Drug Designation for NV354 in both US and Europe

Important events during 2023

KL1333

- The first patient in Abliva's global, potentially registrational, clinical Phase 2 study the FALCON study was dosed in June.
- Fast Track designation was received in September from the U.S. Food and Drug Administration (FDA), facilitating KL1333's clinical development and path forward to market.
- The goal of enrolling 40 patients for Wave 1 of the FALCON study was met in December. The interim analysis remains on track for summer of 2024.

NV354

- The U.S. Patent and Trademark Office granted a composition of matter patent in February.
- Orphan Drug Designation (ODD) was granted in April in the U.S. for the treatment of mitochondrial disease.
- Orphan designation was granted by the European Commission in December for the treatment of Leigh syndrome.

Other

- Abliva appointed Dag Nesse as Vice President of Clinical Operations in February.
- World Mitochondrial Disease Week, Septermber 18 24, was recognized by Abliva by the release of videos highlighting the ongoing activities at the company. The videos can be found at Abliva's website www.abliva.com.
- A licensing and collaboration agreement for Abliva's NeuroSTAT®, for the treatment of moderate to severe traumatic brain injury (TBI), was signed by Abliva and Owl Therapeutics of San Antonio, Texas (US) in November. See page 17 for more information.

Important events after the reporting period

- The Board of Directors of Abliva AB has on 22 February resolved on a capital raise totalling app. SEK 88 million through a fully guaranteed rights issue of app. SEK 46 million, and a directed issue of convertible bonds of app. SEK 42 million. The convertible loan amount shall be paid and immediately converted into shares in the Company after the announcement of the interim data from the KL 1333 Phase 2 study provided the results from the study is positive, i.e. non futile. The Transaction is conditional upon approval by an Extraordinary General Meeting intended to be held on March 26, 2024. For further information, see page 10.
- Abliva convened an Extraordinary General Meeting to be held at 3 p.m. on Tuesday 26 March 2024 at Medicon Village, Scheeletorget 1, in Lund, Sweden, with admission for registration from 2.30 p.m.

Financial information

October-December 2023*

- Net revenues: SEK 137,000 (0)
- Other operating income: SEK 0 (1,504,000)
- Loss before tax: SEK 25,258,000 (17,576,000)
- Loss per share before dilution: SEK 0.02 (0.04)
- Diluted loss per share: SEK 0.02 (0.04)

January-December 2023*

- Net revenues: SEK 137.000 (31.000)
- Other operating income: SEK 1,345,000 (1,716,000)
- Loss before tax: SEK 95,518,000 (85,264,000)
- Loss per share before dilution: SEK 0.09 (0.12)
- Diluted loss per share: SEK 0.09 (0.12)

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

Execute and Deliver

During the fourth quarter of 2023, the Abliva team focused on the execution of the ongoing Phase 2 study and delivered a key corporate goal with the successful enrollment of Wave 1 of the FALCON study as targeted in December. With this milestone achieved, the team shifts attention to the interim analysis which is on track for mid-2024.

The Flock Has Taken Flight

The fourth quarter started with good momentum with the announcement that over 90 patients had been identified for inclusion in Wave 1 of the FALCON study. This number supports what we believe to be the high unmet medical need in primary mitochondrial disease and a trust from the investigators in our mechanism of action, while also providing comfort that we would be able to recruit the required number of patients into Wave 2 of this rare disease study. Each patient was evaluated in depth for eight to twelve weeks, and only the patients who satisfied our stringent inclusion criteria were dosed in the study. We are hopeful that this comprehensive approach to patient selection will ensure that the right patients are included in the study, increasing our chances for a successful study.

On December 20 we announced that we had reached our patient enrollment goal for Wave 1 of the FALCON study, randomizing 40 patients. The Wave 1 patients are now being dosed with KL1333 or placebo, and their 24-week data will be used in the interim analysis. The team has already begun to prepare for that analysis, ensuring that data cleaning is done now to provide high quality data at the time of interim analysis. This work will support an expeditious lock of the data base so that the Independent Data Monitoring Committee (DMC) can review the data as soon as possible after the last 24-week visit. As a reminder, at the time of the interim analysis, the DMC will evaluate the likelihood that the study could be positive and will then communicate the final size of

the study (between 120 – 180 patients) based on the analysis of the conditional power of both endpoints.



"The Wave 1 patients are now being dosed with KL1333 or placebo, and their 24-week data will be used in the interim analysis"

An Impactful Change in the Mito Disease Landscape

On December 14, 2023, Reneo Pharmaceuticals announced negative results from their pivotal STRIDE study of their drug candidate, mavodelpar, in primary mitochondrial myopathies. The program was the most advanced program in primary mitochondrial disease, and the results were obviously disappointing to our entire community given the high unmet medical need. The failure does, however, present an opportunity for Abliva as the competitive landscape has improved and thus may positively impact the annual sales potential for KL1333, which we already believe may be over \$1B US. Thankfully, both the mechanisms of actions of our drugs and the clinical programs were very different, so the outcome of the Reneo study has had no impact on our ongoing program.

\$43M Deal Done for NeuroSTAT® in TBI

In November we were pleased to announce that Owl Therapeutics would in-license our NeuroSTAT program for the treatment of traumatic brain injury. Owl Therapeutics, a bio-

tech company based out of the 'Military City', San Antonio, Texas, is focused on diagnostics and therapeutics for traumatic brain injury and brain health. Through the agreement, Abliva is eligible to receive over \$43M in clinical and commercial milestones with additional royalties in the mid-single digits. The Abliva team is working with the team at Owl to ensure a successful transition for the program.

Preferential Rights Issue & Convertible Loan Announced in February

In June 2022, the company raised SEK 200 million to fund Wave 1 of the FALCON study and provide 24 months of runway. To ensure adequate runway after the interim analysis, we were pleased on Thursday to announce a new financing round with a novel structure that provides an attractive option for both investors and the company. The preferential rights issue will, if approved by the EGM, provide short term capital while the convertible loan, due with a non-futile readout of the interim analysis, will provide capital later in the year. The proceeds from both are intended to be used to further support KL1333 (clinical, nonclinical and manufacturing) and provide additional runway for the company. The team remains thankful for our engaged and supportive shareholders, with greater than 50% providing pre-commitments to the round and voting commitments in the upcoming EGM.

In conclusion. 2023 was a year of execution and delivery, reaching a pinnacle in the fourth quarter with on-time recruitment of Wave 1 and a deal for NeuroSTAT. With our additional funding in place, all eyes now shift to the interim analysis which is expected mid-2024.

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 child-hood 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.

PROGRAM	DISEASE	DISCOVERY	PRECLINICAL	PHASE 1	PHASE 2***	MARKET
KL1333*	Mitochondrial disease (mtDNA**)				FALCON	
NV354*	Mitochondrial disease (Neurology)		── >			
Early programs	Mitochondrial disease	\longrightarrow				

^{*}KL1333 and NV354 have Orphan Drug Designation (ODD) in the U.S. and Europe, and KL1333 has Fast Track designation 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

At Abliva, we are focused on becoming the leading company in mitochondrial medicine, developing therapeutics for mitochondrial disease, orphan indications of high unmet medical need. We intend 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. We will do this with our clear strategy, strong portfolio of assets, research and development organization, and team with decades of experience in mitochondrial medicine and 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.
- Bring new innovative therapeutics to the patients and fuel our pipeline with new candidates from discovery.
- Attract and retain talented colleagues with a passion for drug development.
- 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.
- Generate future revenues through two paths: sales revenue for the drugs we intend to bring to market, and revenue from out-licensing assets (through milestone payments and royalties).

Addressing Primary Mitochondrial Disease

Primary mitochondrial disease is a rare orphan disease where the energy metabolism in the cells, by the power-houses of our cells – the mitochondria, is impaired. This causes deterioration that leads to multifaceted disorders and great suffering for patients. 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 is being developed as a treatment for primary mitochondrial disease patients suffering from multiple debilitating symptoms, including chronic fatigue and myopathy. KL1333 has completed several key Phase 1 studies that enabled the start of a potentially registrational Phase 2 study in 2022. KL1333 is protected by a composition of matter patent and Orphan Drug Designation (ODD) in the US and in Europe. It has also received Fast Track Designation in the US. The commercial opportunity is significant with even conservative estimates exceeding USD 1 billion per year in annual sales¹⁾.

NV354 is being developed for mitochondrial disease with neurologic complications, including Leigh syndrome, MELAS (Mitochondrial encephalomyopathy, lactic acidosis and stroke-like episodes), and LHON (Leber's hereditary optic neuropathy). NV354 has completed preclinical development and is supported by a strong group of patents as well as ODD in the US and Europe.

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 committed to taking advantage of rare disease opportunities, successfully attaining ODD for both KL1333 and NV354. ODD provides significant benefits, includ-

ing regulatory assistance, cost reduction, attractive pricing, and an additional layer of market exclusivity (10 years in the EU, 7 in the US). The outlook for reaching the market is also better than for traditional medicines^{2,3)}. KL1333 has also secured Fast Track designation in the US, streamlining development and marketing application reviews.

Seeking scientific advice from regulators in the US, UK, and Europe has been invaluable, resulting in a shift toward a single, potentially registrational, Phase 2 study for KL1333, expediting its path to market.

Building a World Class Organization

The key to the success of any company is the people who work there, and we are committed to attracting and retaining 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). We appreciate the continued commitment of our shareholders and look 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, and, since that time, they have been joined by life science specialist IP Group plc and Norwegian institutional investor Oslo Pensjonsforsikring AS. We aim to continue to attract new specialist and institutional investors.

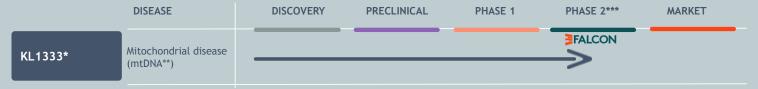
- Gorman et al., Prevalence of Nuclear and Mitochondrial DNA Mutations Related to Adult Mitochondrial Disease, 2015.
- Jayasundra et al. Orphanet J of Rare Dis. Estimating the clinical cost of drug development for orphan versus non-orphan drugs. 2019.3) EvaluatePharma, Orphan Drug Report 2019.



KL1333 Innovative therapy in late-stage development

Patient recruitment to Wave 1 of the FALCON study completed Interim analysis planned for summer of 2024

Positive safety results and signs of dose-dependent efficacy from Phase 1a/b study



- *KL1333 has Orphan Drug Designation (ODD) in the U.S. and Europe and Fast Track designation 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.

Events during the fourth quarter

 The goal of enrolling 40 patients for Wave 1 of the FALCON study was met. The interim analysis remains on track for summer of 2024.

Objectives for 2023

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

Objectives for 2024

- Interim readout of the KL1333 FALCON study.
- Commencement of Wave 2 of the KL1333 FALCON study.
- Progression of commercial production of KL1333.

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

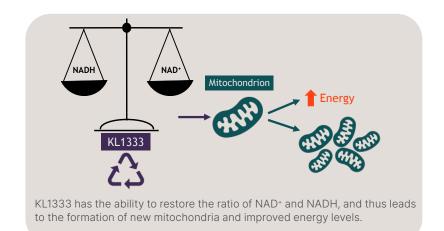
The FALCON study is a global, randomized, placebo-controlled, potentially registrational, clinical Phase 2 study with KL1333. Through the study, the company evaluates the safety and efficacy of KL1333 on primary mitochondrial disease in adult patients with mitochondrial DNA mutations, with a focus on 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 48 weeks. 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

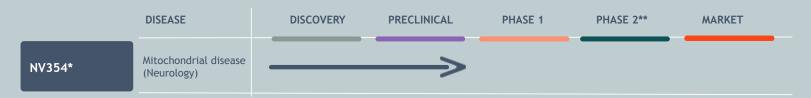
KL1333's Orphan Drug- and Fast Track designations and the possibility to make a coherent, potentially registrational, study bring significant benefits, and Abliva's intention is to apply for market approval at the conclusion of the study. The number of patients in the target group for treatment with KL1333 is approximately 40,000¹¹ in Europe and the US. At typical orphan drug pricing, this translates into a blockbuster opportunity.

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



NV354 First-in-class the rapeutic targeting high unmet need

Orphan drug designation in both the U.S. and Europe



^{*}NV354 has Orphan Drug Designation (ODD) in the U.S. and Europe.

 Given the prioritization of KL1333, no significant cost-intensive operational activities are planned for NV354 at this time.

INITIAL FINDINGS

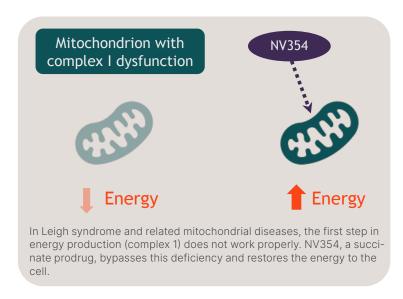
NV354 was discovered due to its ability to increase mitochondrial activity in cells from Leigh syndrome patients. Leigh syndrome is a severe mitochondrial disease that usually debuts at one to two years of age. The disease is fatal, and children usually die before age 5.

TREATMENT OBJECTIVE

Brain penetrable NV354 is being developed for mitochondrial diseases with neurologic complications due to a dysfunctional complex I in the electron transport chain. Mitochondrial diseases with dysfunctional complex I include Leigh syndrome, MELAS, and LHON.

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 the potential for significant commercial sales.



^{**}Given that mitochondrial disease is an orphan disease, a Phase 2 study in these patients, if successful, can have the potential for market approval.

Comprehensive Income

Revenues

The consolidated turnover during the fourth quarter of 2023 was SEK 137,000 (0). Other operating revenues for the fourth quarter were SEK 0 (1,504,000) and pertainen to exchange-rate gains. During the full year of 2023 the consolidated turnover was SEK 137,000 (31,000). Other operating revenues for the full year amounted to SEK 1,345,000 (1,716,000) and pertain to exchange-rate gains.

Results of operations

The operating loss for the fourth quarter was SEK 26,106,000 (17,825,000) and for the full year the operating loss amounted SEK 96,548,000 (-83,190,000). The net loss before tax for the fourth quarter amounted to SEK 25,258,000 (17,576,000). For the full year the loss before tax was 95,518,000 (-85,264,000).

The operating loss was affected by other external expenses, which for the full year were SEK 68,819,000 (68,298,000). Expenses related to development projects, as a part of external expenses, have affected the result with SEK 53,638,000 (58,884) whereof SEK 53,215,000 (57,890,000) relates to project in clinical phase. Expenses during 2023 compared to 2022 is lower due to decreased development rate during first part of 2023 pending funding. Personnel expenses for the full year 2023 amounts to KSEK 18,785,000 (14,028,000) and are higher compared to last year due to bonus reservations and exchange rate differences. Depreciation and impairment of intangible and tangible assets for the full year amount to SEK 10,426,000 (-2,610,000) whereof SEK 8,592,000 refers to impairment of patents. For further information see Note 1 Intangible assets.

Profit/loss from financial items

Financial items for the full year 2023 amounted to SEK 1,030,000 (-2,073,000) 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.

		1 Oct, 2023	1 Oct, 2022	1 Jan, 2023	1 Jan, 2022
(SEK 000)	Note	31 Dec, 2023	31 Dec, 2022	31 Dec, 2023	31 Dec, 2022
Net sales		137	-	137	31
Other operating income		-	1,504	1,345	1,716
		137	1,504	1,482	1,746
Operating expenses					
Other external expenses		-19,990	-15,884	-68,819	-68,298
Personnel cost		-4,334	-2,746	-18,785	-14,028
Depreciation and write-down of tangible and intangible assets		-481	-700	-10,426	-2,610
Other operating expenses		-1,438	-		
		-26,243	-19,329	-98,030	-84,937
Operating income		-26,106	-17,825	-96,548	-83,190
Profit/loss from financial items					
Result from other securities and receivables related to non current assets		34	60	34	298
Financial income		828	201	1,072	392
Financial costs		-14	-12	-76	-2,764
		848	249	1,030	-2,073
Profit/loss before tax		-25,258	-17,576	-95,518	-85,264
Income tax	2	21	-	9	-
Profit/loss for the period		-25,237	-17,576	-95,509	-85,264
Other comprehensive income					
Items that may be reclassified to profit or loss					
Translation differences on foreign subsidiaries		-47	-66	-30	147
Total comprehensive income for the period		-25,284	-17,642	-95,539	-85,117
Loss for the period attributable to:					
Parent company shareholders		-25,237	-17,576	-95,509	-85,262
Non-controlling interests		- 25.227	17.576	-	-2
		-25,237	-17,576	-95,509	-85,264
Total comprehensive income for the period		05.004	47.040	05.500	05.447
Parent company shareholders		-25,284	-17,642	-95,539	-85,117
Non-controlling interests		25.204	17.040	-	05 447
		-25,284	-17,642	-95,539	-85,117
Earnings per share before and after dilution(SEK) based on average number of shares		-0.02	-0.02	-0.09	-0.12
Average number of shares before and after dilution		1,056,299,165	633,882,892	1,056,299,165	739,486,960



Financial Position

Financial position

Other short-term recivables amounts to 0 (78,949) and referred to the investment of surplus liquidity. Cash and cash equivalents amounted to SEK 57,664,000 (66,392,000) as of 31 December 2023. In total, cash and cash equivalents amount to 57,664,000 a decrease of SEK 87,677,000 compared to the beginning of the year when short term receivables and cash and cash equivalents amounted to 145,341,000. Total assets as of 31 December 2023 were SEK 87,499,000 (183,828,000).

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 Dec, 2023	31 Dec, 2022
ASSETS			
Non-current assets			
Intangible assets	1		
Patents		10,505	18,928
Other Intangible assets		941	1,075
		11,446	20,004
Tangible assets			
Equipment		20	49
Right of use asset leases		761	859
		781	908
Financial assets			
Other long-term securities		13,101	13,101
Deferred tax		9	-
		13,110	13,101
Total non-current assets		25,337	34,013
Current assets			
Other receivables		1,051	849
Prepaid expenses and accrued income		3,447	3,626
Other short term recivables		-	78,949
Cash and cash equivalents		57,664	66,392
		62,162	149,816
TOTAL ASSETS		87,499	183,829

Financial Position

Financial position

The equity/assets ratio was 81 (89) percent as of 31 December 2023, and equity was SEK 70,718,000 (164,287,000). Long term liabilities refers to long term part and tax liability of the rigth of use asset leases and amount to 424,000 (534,000). Short term Liabilities amounted SEK 16,357,000 (19,007,000) as of 31 December 2023, and mainly refers to activities realted to the FALCON study.

The Board of Directors of Abliva AB has on 22 February resolved on a capital raise totalling approximately SEK 88 million. The Transaction consists of both a fully guaranteed rights issue with preferential rights for existing shareholders of approximately SEK 46 million, and a directed issue of convertible bonds to a limited number of certain existing shareholders and institutional investors of approximately SEK 42 million. The convertible loan amount shall be paid and immediately converted into shares in the Company after the announcement of the interim data from the KL 1333 Phase 2 study provided the results from the study is positive, i.e. non futile. The purpose of the Rights Issue is to fund additional clinical activities for the KL1333 program including initiating new countries for expansion of the study during Wave 2, and for general corporate purposes. Conditional upon approval by an Extraordinary General Meeting intended to be held on 26 March 2024 approx. additional 46 million before transaction costs are added to the company in connection with notification of the outcome of the rights issue at the end of April 2024 and additional funds of approx. 42 million before transaction costs are added to the company in connection with the announcement of positive, i.e. non-futile, interim data towards the middle of 2024. For further information, please see www.abliva.com.

(SEK 000) Note	31 Dec, 2023	31 Dec, 2022
EQUITY AND LIABILITIES		
Equity attributable to the shareholders of the parent company		
Share capital	52,815	52,815
Additional paid in capital	905,972	905,221
Translation reserve	803	833
Retained earnings	-888,872	-794,582
Total equity	70,718	164,287
Long-term liabilities		
Other longtrem liabilities	424	534
	424	534
Short-term liabilities		
Accounts payable	9,348	4,860
Other liabilities	699	548
Accrued expenses and deferred income	6,310	13,599
	16,357	19,007
Total liabilities	16,781	20,076
TOTAL EQUITY AND LIABILITIES	87,499	183,828

Changes in Equity

	Equity at	tributable to	the shareholde	ers of the pare	nt company		
		Additional				Non-	
	Share-	paid in	Translation	Retained		controlling	Total
(SEK 000)	capital	capital	reserve	earnings	Total	interests	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	0	164,287
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	-	-	-	-95,509	-95,509	-	-95,509
Other comprehensive income							
Translation differences	-	-	-30	-	-30	-	-30
Other comprehensive profit/loss for the period, net after tax	-	-	-30	-	-30	-	-30
Total comprehensive profit/loss	-	-	-30	-95,509	-95,539	-	-95,539
Transactions with shareholders							
Share-based payment	-	752	-	-	752	-	752
Change of ownership in share issue	-	-	-	1,218	1,218	-	1,218
Total transactions with shareholders	-	752	-	1,218	1,970	-	1,970
Closing balance, 31 December 2023	52,815	905,972	803	-888,872	70,718	0	70,718

Consolidated Statement of Cash Flows

Cash flow and investments

Operating cash flow for the fourht quarter was SEK 252,000 (-6,674,000) For the full year the operating cash flow amounted SEK -7,802,000 (159,560,000) (the comparative figure for 2022 includes SEK 93,212,000, which referred to short-term investment of surplus liquidity). The cash flow effect related to investments in intangibles equals SEK -1,290,000 (-882,000) for the full year. The cash flow effect related to investments in financing activities equals SEK 414,000 (204,417,000) for the full year. Cash flow for the fourth quarter equals SEK -867,000 (-7,001,000). Cashflow for the full year equals SEK -8,678,000 (43,952,000).

(SEK 000)	1 Oct, 2023	1 Oct, 2022	1 Jan, 2023	1 Jan, 2022
	31 Dec, 2023	31 Dec, 2022	31 Dec, 2023	31 Dec, 2022
Cash flow from operating activities				
Operating income	-26,105	-17,825	-96,547	-83,190
Adjustments for non-cash items:				
Depreciation	481	700	10,426	2,610
Currency differences on intercompany items	-101	-92	-58	192
Impaired Value	3	-	-7	-
Share-based payments	327	100	1,218	551
Result from other securities and receivables related to non current assets	34	60	34	298
Interest received	828	201	1,072	392
Interest paid	-15	-12	-76	-25
Paid taxes	-	-	-	-
Net cash from operating activities before changes in working capital	-24,547	-16,869	-83,938	-79,172
Changes in working capital Increase/decrease of other current assets	20,882	12,284	70.022	-81,506
			78,923	· · · · · · · · · · · · · · · · · · ·
Increase/decrease of other short-term liabilities	3,917	-2,090	-2,787	1,118
Changes in working capital	24,799	10,195	76,136	-80,388
Cash flow from operating activities	252	-6,674	-7,802	-159,560
Investing activities				
Acquisition of intangible assets	-957	-238	-1,290	-882
Acquisition of tangible assets	-	-	-	-23
Cash flow from investing activities	-957	-238	-1,290	-905
Financing activities				
New share issue	-75	-	752	180,364
Amoritization lease	-87	-90	-338	-170
Increase/decrease of long-term liabilities	-	-		24,223
Cash flow from financing activities	-162	-90	414	204,417
Cash flow for the period	-867	-7,001	-8,678	43,952
Cash and cash equivalents at the beginning of the period	58,637	73,444	66,392	22,339
Effect of exchange rate changes on cash	-106	-51	-50	101
Cash and cash equivalents at end of period	57,664	66,392	57,664	66,392

Parent Company

Income Statement

Parental company

Company earnings after tax for the fourth quarter amounts to SEK - 24,929,000 (-17,465,000). Earnings after tax for the full year amount to SEK -118,238,000 (-84,196,000). As of 31 August 2023, the subsidiary in Hong Kong, NeuroVive Pharmaceutial Ltd ("NVP Asia") was deregistered as Abliva no longer conducts any business in Asia. As a consequence of the closure of the subsidiary, the value of these shares has been written down in the parent company by a total of SEK 23,694,000. Most of the Group's operations are conducted within the parent company. Accordingly, no further specific information regarding the parent company is presented.

Parent Company

Statement of Comprehensive Income

(SEK 000)	1 Oct, 2023	1 Oct, 2022	1 Jan, 2023	1 Jan, 2022
Note	31 Dec, 2023	31 Dec, 2022	31 Dec, 2023	31 Dec, 2022
Net sales	137	-	137	31
Other operating income	-	1,504	1,508	1,716
	137	1,504	1,645	1,746
Operating expenses				
Other external expenses	-21,561	-16,890	-75,410	-72,875
Personnel cost	-2,915	-1,726	-11,803	-8,580
Depreciation and write-down of tangible and intangible assets	-386	-614	-10,046	-2,439
Other operating expenses	-1,068	-	-	-
	-25,930	-19,229	-97,259	-83,894
Operating income	-25,793	-17,726	-95,614	-82,148
Profit/loss from financial items				
Result from other securities and receivables related to non current assets	34	60	-23,691	298
Interest income and other similar profit items	828	201	1,072	392
Interest expenses and other similar loss items	1	-	-5	-2,738
	863	261	-22,624	-2,048
Profit/loss before tax	-24,929	-17,465	-118,238	-84,196
Income tax 2	-	-	-	-
Profit/loss for the period	-24,929	-17,465	-118,238	-84,196

(SEK 000)	1 Oct, 2023	1 Oct, 2022	1 Jan, 2023	1 Jan, 2022
Note	31 Dec, 2023	31 Dec, 2022	31 Dec, 2023	31 Dec, 2022
Profit/loss for the period	-24,929	-17,465	-118,238	-84,196
Other comprehensive income	-	-	-	-
Total comprehensive profit/loss for the period	-24,929	-17,465	-118,238	-84,196

Parent Company

Balance Sheet

(SEK 000) Note	31 Dec, 2023	31 Dec, 2022
ASSETS		
Non-current assets		
Intangible assets 1		
Patents	10,505	18,928
Other intangible assets	941	1,075
	11,446	20,004
Tangible assets		
Equipment	20	49
	20	49
Financial assets		
Shares in subsidiaries 3	1,465	24,557
Other long-term placement	13,101	13,101
	14,566	37,658
Total non-current assets	26,032	57,711
Current assets		
Short term receivables		
Other receivables	1,031	825
Prepaid expenses and accrued income	3,425	3,626
	4,456	4,451
Other short term recievables	-	78,949
Cash and bank balances	55,826	65,123
Total current assets	60,282	148,522
TOTAL ASSETS	86,314	206,234

Parent Company

Balance Sheet

(SEK 000) Note	31 Dec, 2023	31 Dec, 2022
EQUITY AND LIABILITIES		
Equity		
Restricted equity		
Share capital	52,815	52,815
Statutory reserve	1,856	1,856
Development expenditure reserve	-	1,247
	54,671	55,919
Unrestricted equity		
Share premium reserve	225	174,661
Retained earnings	134,159	41,844
Profit/loss for the period	-118,238	-84,196
	16,145	132,309
Total equity	70,816	188,228
Short-term liabilities		
Accounts payable	9,345	4,602
Liabilities subsidiary	1,620	1,290
Other liabilities	319	213
Accrued expenses and deferred income	4,213	11,901
	15,498	18,006
TOTAL EQUITY AND LIABILITIES	86,314	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	1,459	-	1,459
Impaired value	-15,933	-	-15,933
Closing balance 31 Dec. 2023	21,612	2,864	24,476
ACCUMULATED DEPRECIATION			
Opening balance 1 Jan. 2023	-17,158	-1,789	-18,947
Depreciation for the period	-1,290	-134	-1,424
Impaired value	7,341	-	7,341
Closing balance 31 Dec. 2023	-11,107	-1,923	-13,030
Residual value 31 Dec. 2023	10,505	941	11,446

(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	20,004

Note 2 - Tax

The group's total loss carry-forwards amounts to SEK 946,598,000 as of 31 Decmber 2023 (852,673,000). The parent company's total loss carry-forwards amounts to SEK 944,154,000 as of 31 December 2023 (826,291,000). 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

Shares and participations in group companies relates to the holly owned american subsidiary Abliva Inc., Boston and the Swedish subsidiary Abliva Incentive AB, holding option program for the CEO and warrant program for managment and key personnel. The subsidiary NeuroVive Pharmaceutical Asia Ltd., domiciled in Hong Kong, was deregistered as of 31 August, 2023, as Abliva does not conduct any operations in Asia. At the deregistration of NeuroVive Pharmaceutical Asia, Ltd. shares and shares in group companies was impaired with the book value of SEK 23,694,000.

Other disclosures

Licensing and collaboration agreement with Owl Therapeutics

In November 2023, Abliva and Owl Therapeutics of San Antonio, Texas, entered into a licensing and collaboration agreement for the drug candidate NeuroSTAT®, developed by Abliva, for the prevention and treatment of moderate to severe traumatic brain injury (TBI). Owl Therapeutics continues to progress the activities initiated by Abliva, and Abliva remains involved in the program on a limited basis (at no cost to Abliva).

Under the agreement, Owl Therapeutics has received a global (excluding China and South Korea) license to develop, manufacture, and commercialize NeuroSTAT. Under the terms of the agreement, Abliva is eligible to receive up to \$43.65 million in milestones (excluding royalties) as well as mid-single digit royalties (based on net sales) upon commercialization.

Transactions with related parties

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

Compensation based on sales SEK 13,000 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 8 March, 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.

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 has paid the social security costs. The shares (2,250,000) 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 December 2023 was 8 (8), of which 5 (6) are women.

Important events during the fourth quarter (Oct-Dec 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 0.725. 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. 8.8 million options have been subscribed in the warrant program. One warrant entitles the holder to one new share in Abliva AB. 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. All options have been subscribed. 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 <u>www.abliva.com</u> and the Annula report note 12.



Audit review

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

Upcoming financial statements

Annual Report 2023	The week starting
	with April 15, 2024
Q1 Report January-March 2024	May 23, 2024
Q2 Report January-June 2024	August 22, 2024
Q3 Report January-September 2024	November 21, 2024
Year-End Report 2024	February 21, 2025

The interim reports and the Annual Year Report are available at $\underline{www.abliva.com}$

Extraordinary General Meeting 2024

Extraordinary General Meeting of Abliva AB (publ) will be held at 3 p.m. on Tuesday, March 26, 2024 at Medicon Village, Scheeletorget 1, in Lund, Sweden, with admission for registration from 2.30 p.m.

Annual General Meeting 2024

Annual General Meeting of Abliva AB (publ) will be held at 1 p.m. on Thursday, May 23, 2024, at Medicon Village, Scheeletorget 1, in Lund, Sweden.

Proposed appropriation of profits

The Board of Directors proposes that Abliva does not pay dividends for the financial year 2023.



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. For a more detailed description of the risks and uncertainty factors that Abliva is facing, please refer to the risk analysis on pages 17-20 in the Annual Report for 2022.

Financing

The Board continuously monitors and evaluates the company's funding need and financial position given ongoing

development. The company announced a financing of SEK 200 million in June 2022 and additional financing in February 2024 in the form of a fully guaranteed preferential rights issue of SEK 46 million, dependent on approval from the EGM. Owners representing 49 percent of the company have entered into voting commitments to approve the financing. The Board acknowledges that further funding (equity, loan, grants and/or partnerships) will be required to recruit patients into the Wave 2 of the FALCON study. If the company is not successful in securing additional financing, there is a risk that Wave 2 of the program will be delayed. By adapting the pace of ongoing activities, with the present liquidity and the fully guaranteed preferential rights issue of SEK 46 million, there is financing support for continuing the business for the next twelve-month period. The interim

report is thus prepared on the basis of a going concern assumption.

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, February 23, 2024

David Laskow-Pooley	David Bejker	Roger Franklin
Chair of the Board	Board member	Board member

Denise Goode	Jan Törnell	Ellen Donnelly
Board member	Board member	Chief Executive Officer

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. CET on February 23, 2024.

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. **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.

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 Ophthalmople-gia/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 disease. Metabolic disease that affects the ability of cells to convert energy. An estimated 12 in every 100,000 people are affected. Often presents in early childhood and leads 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.

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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