

A close-up photograph of a smiling couple outdoors. The man, on the left, has grey hair and a beard, wearing a red and white checkered shirt. The woman, on the right, has dark hair and is wearing a blue denim shirt. They are both smiling warmly at the camera. The background is a soft-focus outdoor setting with trees and sunlight.

ABLIVA

Year-End Report

January - December

2022

Delivering mitochondrial health

2022 Summary

A successful financing enabled the start of the FALCON study with KL1333

Important events during 2022

- In June, Abliva conducted a directed issue of approximately SEK 150 million to several life science specialist and institutional investors and a preferential rights issue of approximately SEK 50 million. In total, the company received approximately SEK 180 million after issue costs.
- In December, Abliva initiated the company's global, potentially registrational Phase 2 study with KL1333 (the FALCON study) in adult patients suffering from mitochondrial DNA (mtDNA)-related primary mitochondrial diseases.



Important events after the reporting period

- Abliva appointed Dag Nesse as Vice President of Clinical Operations. Mr. Nesse has joined the company's management team.
- The U.S. Patent and Trademark Office granted a composition of matter patent for the NV354 compound.
- Abliva's Nomination Committee announced it proposes Edwin Moses as a new Board member and incoming Chair of the Board of Directors at upcoming General Meetings.
- Abliva announces notice of Extraordinary General Meeting, to be held on March 8, 2023, at 11 a.m. at Medicon Village, Scheeleorget 1, in Lund, Sweden.

Financial information

October-December 2022*

- Net revenues: SEK 0 (48,000)
- Other operating income: SEK 1,504,000 (126,000)
- Loss before tax: SEK 17,576,000 (36,871,000)
- Loss per share before dilution: SEK 0.02 (0.09)
- Diluted loss per share: SEK 0.02 (0.09)

January-December 2022*

- Net revenues: SEK 31,000 (151,000)
- Other operating income: SEK 1,716,000 (0,000)
- Loss before tax: SEK 85,264,000 (123,494,000)
- Loss per share before dilution: SEK 0.12 (0.33)
- Diluted loss per share: SEK 0.12 (0.33)

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

FALCON Takes Flight

The fourth quarter (Q4) at Abliva was defined by the start of the potentially pivotal Phase 2 FALCON clinical study to investigate the efficacy of KL1333 in adult patients suffering from Primary Mitochondrial Disease. This milestone was the culmination of two years of work and represents the movement of KL1333 into late-stage clinical development.

KL1333 Enters Late-Stage Development

The year ended on a high note with the initiation of two of our clinical sites, the start of the FALCON study, a major corporate milestone. As the first site activated, we would like to thank Dr. Nicolai Rasmus Preisler and his team at Copenhagen University Hospital, Rigshospitalet, in Denmark for their hard work in helping us accomplish this goal. Primary mitochondrial disease patients satisfying the inclusion criteria in Denmark and the UK are now being considered for entry into the study. For more information about the study and the inclusion criteria, please refer to the study page on our website (<https://abliva.com/research-and-development/clinicaltrials-falcon>).

This major milestone marked the transition of KL1333 from successful Phase 1 results to a Phase 2 clinical study. As I've highlighted previously, we have agreed with the regulators that, given that this is a rare disease, that only one pivotal study may be required to register this drug. In short, we have designed the study to serve as a 'registrational' or 'pivotal' study, but this won't be confirmed by the regulators until they are able to review the final data. For this reason, we will often refer to the study as a 'potentially' registrational study to make this clear. We will also refer to the study 'waves' (in English) going forward with Wave 1 including up to 40 patients included for interim analysis and Wave 2 consisting of the second group of 80 – 140 patients, with the potential for outcome data only after completion of Wave 2.

The Christmas vacation period extended through mid-January this year and this, coupled with shortages in some administrative departments, has led to a delay in the start-up of additional

sites and in the screening of our first patients. Things have accelerated and we can start including patients in the next few weeks to allow for the first patient to be dosed in the second quarter (this timeline includes a screening period of 8-12 weeks that provides additional baseline data for the study). The team is currently implementing additional measures with the aim of bringing the timeline back to the original projection.

Dag Nesse Joins Abliva as VP Clinical Operations

With the advancement of KL1333 into a potentially pivotal study, we are focused not only on the study, but on the establishment of the appropriate policies, procedures, and standards to support both a late-stage study, the regulatory submission and commercialization that will follow should the study be positive. We were fortunate to attract someone very experienced in these areas to Abliva, Dag Nesse, VP, Clinical Operations. With over 25 years of experience in clinical operations, Dag was instrumental in taking TARPEYO® (Calliditas) through a pivotal study to marketing application and regulatory approval. Dag and I worked together at Modus Therapeutics many years ago and I am thrilled that he has joined our team.

Sharing Our Story

We continue to work to improve the awareness of Abliva amongst a growing group of patients, physicians, investors, shareholders and rare disease companies. At the end of the year, we had a number of opportunities to present the company to a wide range of shareholders and investors including a Scandinavian audience during the Nordic Life Science Days 2022, American investors at the DNB meeting in New York City in December, and Aktiespararna investors in Olofström, Tommarp and Stockholm. In addition, our clinical and research colleagues presented our science during Mitocon's Mitochondrial Diseases Conference in Italy in October and during the Mitochondrial Medicine – Therapeutic Development meeting in Cambridge in November. And, as a capstone to the year, we were pleased to catch the attention of Van Lanschot Kempen NV as they initiated coverage on the company on December 15th. Their recog-



"This major milestone marked the transition of KL1333 from successful Phase 1 results to a Phase 2 clinical study"

nition of Abliva led to coverage by a number of Swedish media outlets including Trading Direkt Healthcare who highlighted Abliva as the biotech company in Sweden with the greatest potential increase in share price (500%) at the time the analysis was released.

Looking Back on 2022

This year marked a pivotal year for the company as we moved from an early-stage rare disease company to a late-stage company running a large, global potentially pivotal study. This study was enabled by a large financing of SEK200M in June that attracted new, European, life-science investors to the company. With money in the bank and the study started we now have one primary goal – to deliver the FALCON study to the interim analysis.

Let's do this!

Ellen Donnelly
CEO

Innovative Portfolio in Rare and Severe Mitochondrial Diseases



Primary mitochondrial diseases are metabolic diseases that affect the cells' ability to convert energy. The diseases can manifest 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 diseases has increased, improving our ability to identify and treat these patients. It is estimated that 125 persons per million have a primary mitochondrial disease.

Primary mitochondrial diseases often present in early childhood and can lead to severe symptoms, such as stunted growth, muscle weakness, pronounced fatigue, heart failure and rhythm disturbances, diabetes, movement disorders, stroke-like episodes, deafness, blindness, limited mobility of the eyes and epileptic seizures.

PROGRAM	DISEASE	DISCOVERY	PRECLINICAL	PHASE 1	PHASE 2***	MARKET
KL1333*	Mitochondrial diseases (mtDNA**)					
NV354	Mitochondrial diseases (Leigh syndrome)					
Early programs	Mitochondrial diseases					

*Orphan drug designation in the US and Europe.

**mtDNA-related mitochondrial disorders caused by mutation(s) in mitochondrial DNA (as opposed to nuclear DNA).

***Given that mitochondrial diseases are orphan diseases, a Phase 2 study in these patients, if successful, has the potential to be considered registrational.

Strategic focus: Mitochondrial Diseases

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

Building the Premier Mitochondrial Medicine Company

Abliva's long-term goal is to become the leading global biotech company focused on the discovery of therapeutics for mitochondrial diseases. Abliva has the foundation to do this with a clear strategy, a strong portfolio of assets, a research and development organization and a team that has over two decades of experience in mitochondrial medicine as well as decades of experience in drug development.

Over the next five years we will focus on the delivery of our portfolio to the market. We aim to augment our strong research and development capabilities and build a commercial organization. We will bring new innovative therapeutics to the patients and fuel our pipeline with new candidates from discovery. We will attract and retain talented colleagues with a passion for drug development. We will build a strong network of experts that will complement, enhance and support our efforts across development that will include patients, physicians, researchers, regulators, payers and technical experts. We will generate future revenues through two paths: sales revenue for the drugs Abliva intends to bring to market, and revenue from out-licensing assets (through milestone payments and royalties).

Addressing Primary Mitochondrial Diseases

Mitochondria function as the powerhouses of our cells and are crucial for the cells' energy metabolism. Primary mitochondrial diseases are rare orphan diseases where the energy metabolism in the cells is impaired, causing deterioration that leads to multifaceted disorders and great suffering for patients. The symptoms worsen over time and, in many cases, the dis-

eases lead to premature mortality. Mitochondrial medicine has become an area of ever increasing focus for the pharmaceutical industry as there are currently no effective treatment options. Through Abliva's research and development, we have an opportunity to improve the health and quality of life of these patients.

Delivering a Portfolio of First-in-Class Therapies

Abliva's in-house R&D capabilities have been instrumental in creating and delivering a portfolio that includes several projects with mechanisms of action suitable for a wide range of mitochondrial diseases.

KL1333 restores the balance of the coenzymes NAD⁺ and NADH, creating new mitochondria and improved energy levels. KL1333 has completed a number of key Phase 1 studies that enabled the start of a potentially registrational Phase 2 study in 2022. KL1333 is protected by both a composition of matter patent as well as Orphan Drug Designation (ODD) in the U.S. and in Europe. The commercial opportunity is significant with even conservative estimates exceeding USD 1 billion per year in annual sales¹⁾.

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

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

Leveraging Opportunities in Rare Diseases

Abliva is continually working to take advantage of the opportunities afforded to companies working in the rare disease space. The company requested, and was granted, orphan drug designation (ODD) for KL1333 in both the US and EU. ODD is a regulatory designation that provides sponsors with a several advan-

tages 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 US, UK 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 UK regulatory agency on our NV354 program, validating its potential to move into studies in humans.

Building a World Class Organization

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

Accessing Capital to Finance the Vision

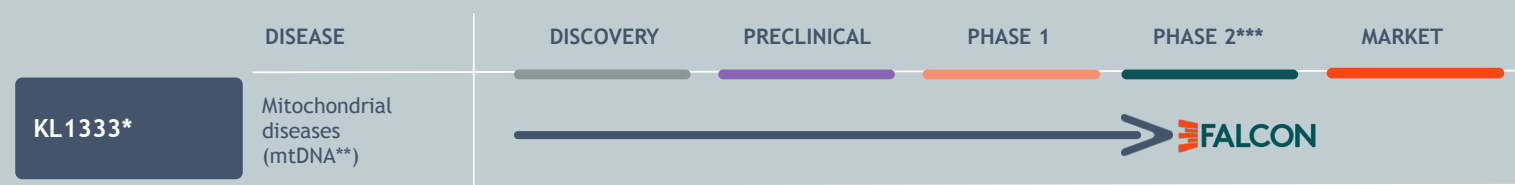
Abliva is a public company traded on NASDAQ Stockholm (ABLI, Small cap). The company appreciates the continued commitment of our shareholders and looks to attract new investors as we advance our portfolio and build the company. The investment of Hadean Ventures in 2020 was the first step to bringing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

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

2) Jayasundara 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

The FALCON study started in December 2022
Positive safety results and signs of efficacy from Phase 1a/b study
Clarity on regulatory pathway



*Orphan drug designation in the US and Europe.

**mtDNA-related mitochondrial disorders caused by mutation(s) in mitochondrial DNA (as opposed to nuclear DNA).

***Given that mitochondrial diseases are orphan diseases, a Phase 2 study in these patients, if successful, has the potential to be considered registrational.

Events since the start of the fourth quarter

- In December 2022, Abliva initiated the potentially registrational Phase 2 study with KL1333 (the FALCON study).

Objectives for 2022

- Regulatory approvals to start the FALCON study in selected countries. ✓
- Initiate the start of 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

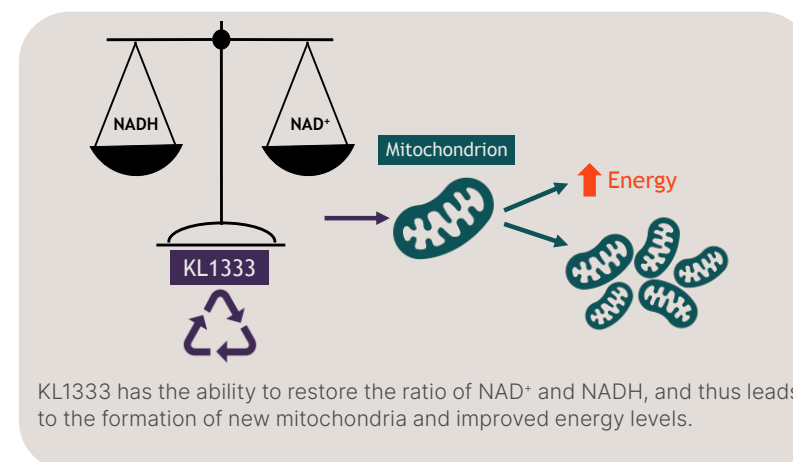
The FALCON study is a global, randomized, placebo-controlled, potentially registrational, clinical Phase 2 study with KL1333. Through the study, the company will evaluate the safety and efficacy of KL1333 on chronic fatigue and muscle weakness in adult patients with mitochondrial DNA-related primary mitochondrial diseases. 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 40,000¹⁾ in Europe and the US. At typical orphan drug pricing, this translates into a blockbuster opportunity.

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

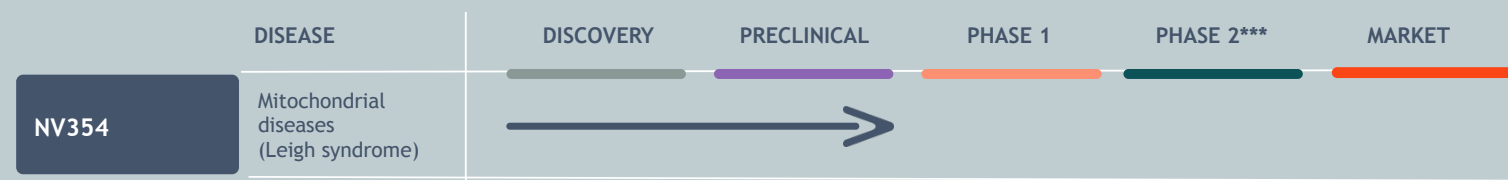


KL1333 has the ability to restore the ratio of NAD⁺ and NADH, and thus leads to the formation of new mitochondria and improved energy levels.

NV354

First-in-class therapeutic targeting high unmet need

Positive feedback from UK MHRA scientific advice meeting



**mtDNA-related mitochondrial disorders caused by mutation(s) in mitochondrial DNA (as opposed to nuclear DNA).

***Given that mitochondrial diseases are orphan diseases, a Phase 2 study in these patients, if successful, has the potential to be considered registrational.

Events since the start of the fourth quarter

- On January 31, 2023, the patent "Succinate Prodrug, Compositions Containing the Succinate Prodrug and Uses Thereof" was issued by the U.S. Patent Court as Patent No 11,565,998.

Objectives

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

PRIMARY INDICATION

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

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

EXPANSION OPPORTUNITY

The unique mechanism of action and high brain uptake may be utilized to develop NV354 for the treatment of MELAS in children and adolescents with neurological symptoms, and for the treatment of LHON. MELAS is a serious disease with symptoms such as muscle weakness, diabetes, fatigue, epilepsy, other severe neu-

rological effects, and shortened life span. LHON is a disease that causes sudden severe permanent visual impairment and can lead to blindness on both eyes.

PATH TO MARKET

Given the rarity of these conditions 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.

Mitochondrion with Leigh syndrome



↓ Energy

NV354



↑ Energy

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 fourth quarter of 2022 was SEK 0 (48,000). Other operating revenues for the fourth quarter were SEK 1,504,000 (126,000) and pertainen to exchange-rate gains. During the full year of 2022 the consolidated turnover was SEK 31,000 (151,000). Other operating revenues for the full year amounted to SEK 1,716,000 (0,000) and pertain to net exchange-raite gains.

Results of operations

The operating loss for the fourth quarter was SEK 17,825,000 (36,869,000) and for the full year the operating loss amounted SEK 83,190 (-123,482,000). The net loss before tax for the fourth quarter amounted to SEK 17,576,000 (36,871,000). For the full year the loss before tax was 85,264,000 (-123,494,000).

The operating loss was affected by other external expenses, which for the full year 2022 were SEK 68,298,000 (103,695,000). Expenses related to development projects, as a part of external expenses, have affected the result with SEK 58,884,000 (90,690,000) whereof SEK 57,890,000 (85,481,000) relates to project in clinical phase. Expenses during 2022 compared to 2021 is lower due to decreased development rate during first part of 2022 pending funding. Personnel expenses during the full year 2022 amounts to KSEK 14,028,000 (16,844,000). Personnel expenses are lower compared to 2021 when the number of employees are less in 2022 and salary during the notice period and severance pay to the former CEO were included in 2021. Other operating expenses amount to, SEK 0,000 (330,000) and pertained to exchange-rate losses in 2021.

(SEK 000)	Note	1 Oct, 2022 31 Dec, 2022	1 Oct, 2021 31 Dec, 2021	1 Jan, 2022 31 Dec, 2022	1 Jan, 2021 31 Dec, 2021
Net sales		-	48	31	151
Other operating income		1,504	126	1,716	-
		1,504	174	1,746	151
Operating expenses					
Other external expenses		-15,884	-33,314	-68,298	-103,695
Personnel cost		-2,746	-2,945	-14,028	-16,844
Depreciation and write-down of tangible and intangible assets		-700	-784	-2,610	-2,764
Other operating expenses		-	-	-	-330
		-19,329	-37,043	-84,937	-123,633
Operating income		-17,825	-36,869	-83,190	-123,482
Profit/loss from financial items					
Result from other securities and receivables related to non current assets		60	-	298	-
Financial income		201	-	392	-
Financial costs		-12	-1	-2,764	-12
		249	-1	-2,073	-12
Profit/loss before tax		-17,576	-36,871	-85,264	-123,494
Income tax	2	-	-4	-	-4
Profit/loss for the period		-17,576	-36,875	-85,264	-123,498
Other comprehensive income					
Items that may be reclassified to profit or loss					
Translation differences on foreign subsidiaries		-66	61	147	71
Total comprehensive income for the period		-17,642	-36,814	-85,117	-123,427
Loss for the period attributable to:					
Parent company shareholders		-17,576	-36,870	-85,262	-123,492
Non-controlling interests		-	-5	-2	-6
		-17,576	-36,875	-85,264	-123,498
Total comprehensive income for the period					
Parent company shareholders		-17,642	-36,809	-85,117	-123,420
Non-controlling interests		-	-5	-	-7
		-17,642	-36,814	-85,117	-123,427
Earnings per share before and after dilution(SEK) based on average number of shares		-0.02	-0.09	-0.12	-0.33
Average number of shares before and after dilution		1,056,299,165	403,006,798	739,486,960	370,168,023

Consolidated Statement of Financial Position

Financial position

The equity/assets ratio was 89 (70) percent as of 31 December 2022, and equity was SEK 164,287,000 (41,528,000). The equity includes funds from the in June completed directed share issue, which provided the company with net SEK 137,362,000 after deduction of issue costs of SEK 13,038,000 and the in July completed 100% guaranteed preferential rights issue, which provided the company with net SEK 43,003,000 after deduction of issue costs of SEK 8,289,000 wherof SEK 6,155,000 constituted compensation to the guarantors. In addition Equity includes the conversion of the convertible loan from Haeen Ventures amounting to 26,961,000 SEK. Short term Liabilities amounted SEK 19,007,000 (17,390,000) as of 31 December 2022, and mainly refers to activities realted to the FALCON study. Other short-term recivables amounts to 78,949 (0) and refer to the investment of surplus liquidity. Cash and cash equivalents amounted to SEK 66,392,000 (22,339,000) as of 31 December 2022, an increase of SEK44,053,000 from the beginning of the year. Total assets as of 31 December 2022 were SEK 183,828,000 (58,918,000).

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, 2022	31 Dec, 2021
ASSETS			
Non-current assets			
Intangible assets	1		
Patents		18,928	20,293
Other Intangible assets		1,075	1,210
		20,004	21,503
Tangible assets			
Equipment		49	60
Righ of use asset leases		859	-
		908	60
Financial assets			
Other long-term securities		13,101	13,101
		13,101	13,101
Total non-current assets		34,013	34,664
Current assets			
Other receivables		848	912
Prepaid expenses and accrued income		3,626	1,003
Other short term recivables		78,949	-
Cash and cash equivalents		66,392	22,339
		149,815	24,254
TOTAL ASSETS		183,828	58,918

Consolidated Statement of Financial Position

(SEK 000)	Note	30 Dec, 2022	31 Dec, 2021
EQUITY AND LIABILITIES			
Equity attributable to the shareholders of the parent company			
Share capital		52,815	20,150
Additional paid in capital		905,221	730,560
Translation reserve		833	688
Retained earnings		-794,582	-709,879
Total equity attributable to the shareholders of the parent		164,287	41,519
Non-controlling interests		-	9
Total equity		164,287	41,528
Long-term liabilities			
Other longterm liabilities		534	-
		534	-
Short-term liabilities			
Accounts payable		4,860	9,616
Other liabilities		548	277
Accrued expenses and deferred income		13,599	7,497
		19,007	17,390
Total liabilities		19,541	17,390
TOTAL EQUITY AND LIABILITIES		183,828	58,918

Consolidated Statement of Changes in Equity

(SEK 000)	Equity attributable to the shareholders of the parent company					Non-controlling interests	Total equity
	Share-capital	Additional paid in capital	Translation reserve	Retained earnings	Total		
Opening balance, 1 January 2021	14,817	660,025	616	-586,802	88,656	0	88,656
Comprehensive profit/loss for the period	-	-	-	-	-	-	-
Profit/loss for the period	-	-	-	-123,492	-123,492	-6	-123,498
Other comprehensive income	-	-	-	-	-	-	-
Translation differences	-	-	72	-	72	-1	71
Other comprehensive profit/loss for the period, net after tax	-	-	72	-	72	-1	71
Total comprehensive profit/loss	-	-	72	-123,492	-123,420	-7	-123,427
Transactions with shareholders	-	-	-	-	-	-	-
Rights Issue	5,333	70,535	-	-	75,868	-	75,868
Impairment in subsidiary	-	-	-	415	415	-	415
Change of ownership in share issue	-	-	-	-	-	16	16
Total transactions with shareholders	5,333	70,535	-	415	76,283	16	76,299
Closing balance, 31 December 2021	20,150	730,560	688	-709,879	41,519	9	41,528
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	164,288	0	164,287

*Total equity includes funds from the June 9th completed directed share issue with net SEK 137,362,000 less expenses SEK 13,038,000, and from the July 13th completed preferential rights issue, with net SEK 43,003,000 less expenses of SEK 8,289,000 whereof SEK 6,155,000 constituted compensation to the guarantors, and the conversion of the convertible loan to Hadean amounting to SEK 26,961,000.

Consolidated Statement of Cash Flows

Cash flow and investments

Operating cash flow for the fourth quarter was SEK -6,674,000 (-40,778,000). For the full year 2022 the operating cash flow amounted SEK -159,560,000 (-73,114,075) whereof SEK -78,949,000 relates to investment of surplus liquidity. The cash flow effect related to investments in intangibles equals SEK -882,000 (-1,024,000) for the full year. The cash flow effect related to investments in financing activities equals SEK 204,417,000 (75,792,000) for the full year and refers to the directed share issue and the preferential rights issue that affected cash flow positively by SEK 180,364,000, the conversion of the convertible loan that affected cash flow positively by SEK 24,223,000 and amortization lease with a negative effect of SEK 170,000. Cash flow for the forth quarter equals SEK -7,001,000 (-40,990,000). Cashflow for the full year 2022 equals SEK 43,952,000 (-39,372,000).

(SEK 000)	1 Oct, 2022 31 Dec, 2022	1 Oct, 2021 31 Dec, 2021	1 Jan, 2022 31 Dec, 2022	1 Jan, 2021 31 Dec, 2021
Cash flow from operating activities				
Operating income	-17,825	-36,869	-83,190	-123,482
Adjustments for non-cash items:				
Depreciation	700	680	2,610	2,660
Currency differences on intercompany items	-92	-13	192	-7
Impaired Value	-	104	-	104
Share-based payments	100	415	551	415
Result from other securities and receivables related to non current assets	60	-	298	-
Interest received	201	-	392	-
Interest paid	-12	-1	-25	-12
Paid taxes	-	-4	-	-4
Net cash from operating activities before changes in working capital	-16,869	-35,688	-79,172	-120,326
Changes in working capital				
Increase/decrease of other current assets	12,284	-83	-81,506	-400
Increase/decrease of other short-term liabilities	-2,090	-5,007	1,118	6,651
Changes in working capital	10,195	-5,090	-80,388	6,251
Cash flow from operating activities	-6,674	-40,778	-159,560	-114,075
Investing activities				
Acquisition of intangible assets	-238	-182	-882	-1,024
Acquisition of tangible assets	-	-	-23	-65
Cash flow from investing activities	-238	-182	-905	-1,089
Financing activities				
Shareholder contribution subsidiary	-	2	-	16
New share issue	-	-32	180,364	75,868
Amoritzation lease	-90	-	-170	-92
Increase/decrease of long-term liabilities	-	-	24,223	-
Cash flow from financing activities	-90	-30	204,417	75,792
Cash flow for the period	-7,001	-40,990	43,952	-39,372
Cash and cash equivalents at the beginning of the period	73,444	63,267	22,339	61,643
Effect of exchange rate changes on cash	-51	62	101	68
Cash and cash equivalents at end of period	66,392	22,339	66,392	22,339

Parent Company

Income Statement

Parental company

Company earnings after tax for the forth quarter amounts to SEK -17,465,000 (-39,727,000). Earnings after tax for the full year 2022 amount to KSEK -84,196,000 (-123,072,000). 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, 2022	1 Oct, 2021	1 Jan, 2022	1 Jan, 2021
	Note	31 Dec, 2022	31 Dec, 2021	31 Dec, 2022	31 Dec, 2021
Net sales		-	48	31	151
Other operating income		1,504	-	1,716	-
		1,504	48	1,746	151
Operating expenses					
Other external expenses		-16,890	-36,999	-72,875	-107,521
Personnel cost		-1,726	-2,203	-8,580	-12,952
Depreciation and write-down of tangible and intangible assets		-614	-698	-2,439	-2,420
Other operating expenses		-	126	-	-330
		-19,229	-39,775	-83,894	-123,223
Operating income		-17,726	-39,727	-82,148	-123,072
Profit/loss from financial items					
Result from other securities and receivables related to non current assets		60	-	298	-
Interest income and other similar profit items		201	-	392	-
Interest expenses and other similar loss items		-	-	-2,738	-
		261	-	-2,048	-
Profit/loss before tax		-17,465	-39,727	-84,196	-123,072
Income tax	2	-	-	-	-
Profit/loss for the period		-17,465	-39,727	-84,196	-123,072

(SEK 000)		1 Oct, 2022	1 Oct, 2021	1 Jan, 2022	1 Jan, 2021
	Note	31 Dec, 2022	31 Dec, 2021	31 Dec, 2022	31 Dec, 2021
Profit/loss for the period		-17,465	-39,727	-84,196	-123,072
Other comprehensive income		-	-	-	-
Total comprehensive profit/loss for the period		-17,465	-39,727	-84,196	-123,072

Parent Company

Balance Sheet

(SEK 000)	Note	31 Dec, 2022	31 Dec, 2021
ASSETS			
Non-current assets			
<i>Intangible assets</i>	1		
Patents		18,928	20,293
Other intangible assets		1,075	1,210
		20,004	21,503
<i>Tangible assets</i>			
Equipment		49	60
		49	60
<i>Financial assets</i>			
Other long-term placement		13,101	13,101
Shares in subsidiaries	3	24,557	24,557
		37,658	37,658
Total non-current assets		57,711	59,221
Current assets			
<i>Short term receivables</i>			
Receivables from group companies		-	-
<i>Other receivables</i>		825	890
Prepaid expenses and accrued income		3,626	1,003
		4,451	1,893
<i>Other short term recivables</i>		78,949	-
<i>Cash and bank balances</i>		65,123	21,696
Total current assets		148,522	23,589
TOTAL ASSETS		206,234	82,810

Parent Company

Balance Sheet

(SEK 000)	Note	31 Dec, 2022	31 Dec, 2021
EQUITY AND LIABILITIES			
Equity			
<i>Restricted equity</i>			
Share capital		52,815	20,150
Statutory reserve		1,856	1,856
Development expenditure reserve**		1,247	2,613
		55,919	24,619
<i>Unrestricted equity</i>			
Share premium reserve		174,661	70,534
Retained earnings		-41,844	93,017
Profit/loss for the period		-84,196	-123,072
		132,309	40,479
Total equity		188,228	65,098
Short-term liabilities			
Accounts payable		4,602	9,616
Liabilities subsidiary		1,290	1,253
Other liabilities		213	273
Accrued expenses and deferred income		11,901	6,570
		18,006	17,712
TOTAL EQUITY AND LIABILITIES		206,234	82,810

Notes

Note 1 — Intangible assets

(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. 2021	-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
(SEK 000)			
ACCUMULATED COST			
Opening balance 1 Jan. 2021	33,771	2,864	36,635
Additions	1,561	-	1,561
Impaired value	-153	-	-153
Closing balance 31 Dec. 2021	35,179	2,864	38,043
ACCUMULATED DEPRECIATION			
Opening balance 1 Jan. 2021	-12,800	-1,519	-14,319
Depreciation for the period	-2,136	-135	-2,271
Impaired value	49	-	49
Closing balance 31 Dec. 2021	-14,887	-1,654	-16,541
Residual value 31 Dec. 2021	20,293	1,210	21,503

Note 2 – Tax

The group's total loss carry-forwards amounts to SEK 809,484,000 as of 31 December 2022 (746,806,000). The parent company's total loss carry-forwards amounts to SEK 783,041,000 as of 31 December 2022 (720,526,000). 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.

(SEK 000)	1 Jan.2022- 30 Dec. 2022	1 Jan.2021- 31 Dec. 2021
Eskil Elmér, CSO	1	5
Magnus Hansson, CMO	1	3
Total	2	8

Compensation based on sales has been paid during the period under the agreement, in relation to mitochondrial energy regulation projects, with the Research Group at Lund University, which includes CSO Eskil Elmér and CMO Magnus Hansson. Apart from remuneration to senior executives in accordance with the table below no other transactions with related parties have occurred.

Segment information

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

Human resources

The average number of employees of the group for the period January to December 2022 was 8 (9), of which 6 (6) are women.

Important events during the fourth quarter (Oct-Dec 2022)

For further information, see page 2.

Important events after the reporting period

For further information, see page 2.

Incentive programs/share warrants

The AGM on May 20, 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 ordinary share in Abliva AB up to a maximum of 4,600,000 ordinary shares. The redemption price amounts to 0.725 öre. The program is vested at 25% per year on June 1, 2022, June 1, 2023, June 1, 2024 and June 1, 2025. Latest redemption date is December 31, 2025.

Audit review

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

Upcoming financial statements

Annual Report 2022	Week starting with March 27, 2023
Q1 Report January-March 2023	May 23, 2023
Q2 Report January-June 2023	August 18, 2023
Q3 Report January-September 2023	November 17, 2023
Year-End Report 2023	February 23, 2024

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

Extraordinary General Meeting

Extraordinary General Meeting of Abliva AB (publ) will be held on March 8, 2023, at 11 a.m. at Medicon Village, Scheeletorget 1, in Lund, Sweden.

The full notice and other documents for the general meeting are available at <https://abliva.com/investors/general-meeting/>.

Annual General Meeting 2023

Annual General Meeting of Abliva AB (publ) will be held on May 5, 2023, at 10 a.m. at Medicon Village, Scheeletorget 1, in Lund, Sweden.

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.

Impact of Covid-19 on the Company's operations

Although Covid-19 has decreased in severity and frequency, the impact of the pandemic is still felt in many geographies across

many industries, especially with the prioritization of resources and staffing due to workforce shortages and supply chain issues. The future impact of Covid-19 on the Company's operations (clinical trials, manufacturing, vendors) is unknown but there is a risk that continued outbreaks could impact the global FALCON study of KL1333 and/or the forward progression of NV354.

Macroeconomic and geopolitical factors

The Russian invasion of Ukraine in February 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 2021 Annual Report 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 2021 on pages 43-58.

Definitions alternative performance measures

Alternative Performance Measures (APM) are key figures not defined in financial reports prepared according to IFRS.

Of the below key figures, only the key figure Earnings per share before and after dilution is mandatory and defined according to IFRS.

Of the other key figures, net sales, earnings per share before and after dilution, cash flow from operating activities and cash flow for the period are defined according to IFRS.

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

The declaration of the Board of Directors and the CEO

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

Lund, Sweden, February 24, 2023

David Laskow-Pooley
Chairman of the Board

David Bejker
Board member

Roger Franklin
Board member

Denise Goode
Board member

Jan Törnell
Board member

Ellen Donnelly
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 24, 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 stroke-like episodes.

MERRF. (Myoclonic epilepsy with ragged-red fibers). Primary mitochondrial disease with symptoms such as epilepsy, involuntary muscle twitching and difficulty coordinating muscle movements, but the disease can affect many functions. When examined under a microscope, muscle tissue has characteristic changes.

MHRA. The UK Medicines and Healthcare products Regulatory Agency.

MIDD. Maternally Inherited Diabetes and Deafness

Mitochondria. That part of each cell that provides effective energy production in the form of conversion of oxygen and nutrients in the body into chemical energy.

Mitochondrial medicine. Field of research and development of pharmaceuticals that protect the mitochondria.

Mitochondrial myopathy. Primary mitochondrial disease which affects the muscles.

mtDNA. Mitochondrial DNA. Mitochondria’s own genome that is inherited only on the maternal line. Separate from the cells’ genome (nuclear DNA = nDNA) inherited by both parents.

NAD⁺/NADH. A coenzyme involved in metabolism. NAD⁺ and NADH have central roles in cell- and mitochondrial metabolism and energy production.

ODD. Orphan Drug Designation. Facilitates development and commercialization, and may, upon receiving marketing authorization, provide orphan drug status with seven or ten years of market exclusivity (in the US and Europe, respectively).

PEO/CPEO. Mitochondrial disease. Progressive External Ophthalmoplegia/Chronic Progressive External Ophthalmoplegia.

Phase (1,2 and 3). The various stages of trials on the efficacy of a pharmaceutical in humans. See also “clinical trial.” Phase 1 examines the safety on healthy human subjects, Phase 2 examines efficacy in patients with the relevant disease and Phase 3 is a large-scale trial that verifies previously achieved results. In the development of new pharmaceuticals, different doses are trialed and safety is evaluated in patients with relevant disease, Phase 2 is often divided between Phase 2a and Phase 2b.

Preclinical. That stage of drug development that occurs before a candidate drug is trialed on humans.

Primary mitochondrial diseases. Metabolic diseases that affect the ability of cells to convert energy. An estimated 12 in every 100,000 people affected. Often present in early childhood and lead to severe symptoms, such as mental retardation, heart failure and rhythm disturbances, dementia, movement disorders, severe diabetes, stroke-like episodes, deafness, blindness, limited mobility of the eyes, vomiting and seizures.

Psychomotor regression. When the development of the ability to perform will-driven movements is initially normal but deteriorates during infancy or early childhood.

TBI. Traumatic Brain Injury. An injury to the brain where some nerve cells are subjected to immediate damage. The injury then continues to exacerbate several days after the incident, which significantly impacts the final extent of damage.

About Abliva

Abliva discovers and develops medicines for the treatment of mitochondrial diseases. These rare and often very severe diseases occur when the cell's energy provider, the mitochondria, do not function properly. The company has prioritized two projects. KL1333, a powerful regulator of the essential co-enzymes NAD⁺ and NADH, is entering 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 diseases are metabolic diseases that affect the cells' ability to convert energy. The diseases can manifest 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 diseases has increased, improving our ability to identify and treat these patients. It is estimated that 125 persons per million have a primary mitochondrial disease.

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

Stock exchange

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

Abliva AB (publ)

Medicon Village, SE-223 81 Lund
Phone: +46 46 275 62 20 (switchboard)

ir@abliva.com
www.abliva.com

