ABLIVA

Interim Report

January - June 2024

2024

Delivering mitochondrial health

Second Quarter Summary

FALCON Positioned for Success Following Analysis by Independent Committee

Strong Safety Profile Confirmed, and Both Primary Endpoints Passed Futility

Important events April - June 2024

- The new share issue with preferential rights for existing shareholders, announced on 22 February 2024 and carried out in April 2024, was subscribed to 100 percent, which provided Abliva with approximately SEK 46 million before deduction for transaction costs.

Important events after the reporting period

- In July, Abliva announced a positive outcome of the interim analysis of the 24-week data of the FALCON study with KL1333, increasing the probability of a positive readout upon completion of the full study. The analysis confirmed the strong safety profile of KL1333, both primary endpoints passed futility, and the company was recommended to include a total of 180 patients.
- Following the positive outcome of the interim analysis, Abliva was provided with additional proceeds of SEK 42 million before transaction costs through the conversion of the convertible bonds pledged in the capital raise earlier this year.

Financial information

April-June 2024*

- Net revenues: SEK 0 (0)
- Other operating income: SEK 0 (2,711,000)
- Loss before tax: SEK 25,750,000 (21,226,000)
- Loss per share before dilution: SEK 0.02 (0.02)
- Diluted loss per share: SEK 0.02 (0.02)

January-June 2024*

- Net revenues: SEK 0 (0)
- Other operating income: SEK 513,000 (3,766,000)
- Loss before tax: SEK 43,933,000 (37,318,000)
- Loss per share before dilution: SEK 0.04 (0.04)
- Diluted loss per share: SEK 0.04 (0.04)

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

FALCON: Significant Interest after Positive Interim Analysis

The FALCON study was the focus in the second quarter as the company prepared for the interim analysis. In parallel, the team started preparing the path forward with several key meetings, before ending the quarter interacting with mito patients at the annual UMDF patient advocacy meeting in the US. In July, we were excited to announce the positive interim analysis of the FALCON study and dive into the details with interested investors, clinical, and commercial partners.

Positive Interim Analysis Is a First in Primary Mitochondrial Disease

The FALCON study is a global, potentially pivotal clinical study evaluating the safety and efficacy of KL1333 in adult patients with primary mitochondrial disease who experience debilitating fatigue and myopathy. The FALCON study was designed with an interim analysis (IA), conducted after 24 weeks of dosing of Wave 1 patients, to provide an early, external assessment of the safety of KL1333 and the potential for efficacy in patients after 48-weeks of dosing.

The team is extremely pleased with the results of the IA. Importantly,

- Both primary endpoints passed futility. The result confirms that both independent, alternative endpoints have the potential to be successful, only one of which is required to file for approval.
- By performing a sample size re-estimation and adapting the sample size of the study based on the weakest endpoint, the power of both endpoints has increased, making a positive study more likely.
- The strong safety profile of KL1333 has been confirmed following long-term dosing over 24 weeks, a major step forward from the previous phase 1b study with 10 days of dosing.
- The dosing strategy with evaluation of the maximally well tolerated dose in each patient has performed as expected, allowing us to test different doses without increasing the size of the study.
- Study patients' demographic profile confirms the assumptions from previous natural history studies and positions the product well for future label claims.
- Abliva is the first company in the mitochondrial disease space to readout a positive interim analysis, and thus this is an important de-risking event for investors and partners considering our strong development program.

"Abliva is the first company in the mitochondrial disease space to readout a positive interim analysis"

Interim Analysis Provides Important De-Risking to the Program

The interim analysis is a powerful tool that has proven beneficial for the company, shareholders, future partners, and the patients. The IA has ensured prudent use of capital and reflects a patient centric approach, which allowed for early study termination if review of the data had suggested that a positive study would not be possible. In addition, the IA provided an early review of the safety data to ensure the study drug is not causing harmful side effects. Finally, the IA allowed us to review the original assumptions used to power the study (based on external studies with similar patient populations or similar endpoints) and adjust these assumptions using actual FALCON patient data.

Convertible Loan Converts with Interim Results, Elongating Cash Runway

In March, the EGM approved a two-part financing round comprised of a preferential rights issue and a convertible loan that would convert with a non-futile readout of the IA. The convertible loan was converted, payments received, and shares registered last week. This additional capital allows us to continue to progress time-critical activities for KL1333 while prolonging our cash runway to allow valuable time to have discussions with parties interested in participating in the final chapter of this important study. Those discussions have already begun, and we are enjoying the attention this program is receiving due to the positive interim results. Abliva is currently working with a goal to submit the New Drug Application (NDA) at the end of 2027, and it is clear to all that the short time to market coupled with the large commercial opportunity (projected sales estimates exceed $1B annually) make this program attractive.

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 1 in 5,000 people have primary mitochondrial disease.

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

*KL1333 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 powerhouses 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 consistent 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 sales[1].

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, including regulatory assistance, cost reduction, advantageous 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.

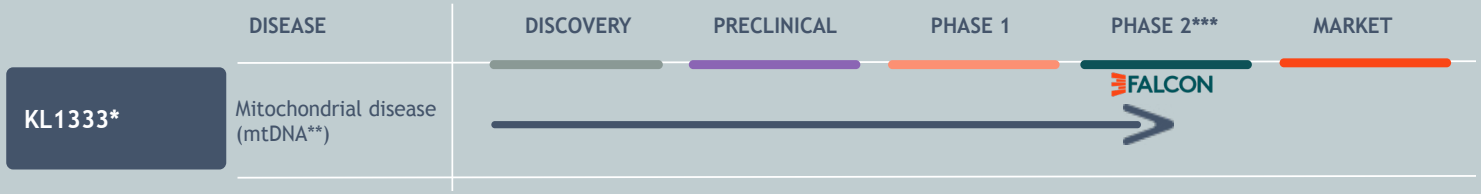
Building a World Class Organization
The key to the success of any company is the people who work there, and we are committed to attracting and retaining bright and innovative scientists, clinicians, and drug development experts. We will continue to support development opportunities for our colleagues 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 continue to attract new specialist and institutional investors as we grow the company and commercialize our portfolio.

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

KL1333 Innovative therapy in late-stage development

FALCON Positioned for Success Following Analysis by Independent Committee



*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 since the start of the second quarter

- In July, Abliva announced a positive outcome of the interim analysis of the 24-week data in Wave 1 of the FALCON study, increasing the probability of a positive readout upon completion of the full study. The analysis confirmed the strong safety profile of KL1333, both primary endpoints passed futility, and the company was recommended to include a total of 180 patients.

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

Abliva's lead candidate, KL1333, has been designed to treat debilitating fatigue and myopathy (muscle weakness) in genetically confirmed adult patients with primary mitochondrial disease. 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.

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.

THE FALCON STUDY

FALCON is a Phase 2, global, randomized, placebo-controlled, potentially registrational study evaluating the safety and efficacy of KL1333 in adult patients with primary mitochondrial disease who experience consistent, debilitating fatigue and myopathy (muscle weakness), the most common and impairing symptoms.

A total of 180 patients with mitochondrial DNA mutations who meet the eligibility criteria are randomized 3:2 to receive KL1333 (50mg-100mg) or placebo twice daily for 48 weeks. The two alternative primary endpoints assess consistent fatigue (using the PROMIS Fatigue Mitochondrial Disease Short Form) and myopathy (using the 30 second Sit-to-Stand test), one of which is sufficient for registration.

An interim analysis evaluating 24-week data from the first wave of patients confirmed the strong safety profile of KL1333, and both primary endpoints passed futility.

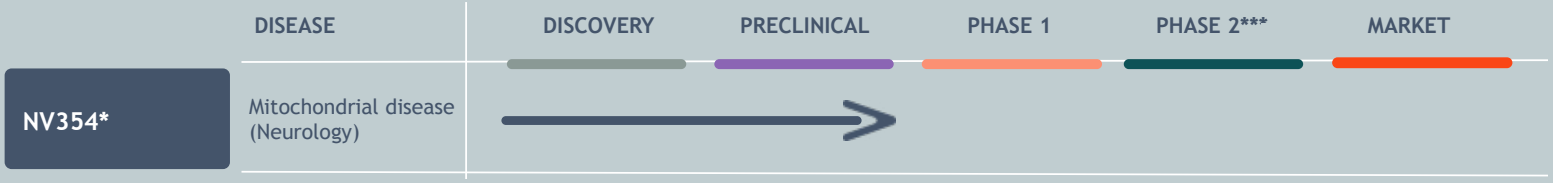
PATH TO MARKET

KL1333 has received Orphan Drug Designation in both the US and EU and Fast Track Designation in the US. Upon approval, the drug is expected to see significant uptake with an estimated patient population of up to 1:5,000 people[1]. Considering typical orphan drug pricing, this translates into a blockbuster opportunity of over USD 1 billion in peak sales.

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

NV354 First-in-class therapeutic 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 that mitochondrial disease is an orphan disease, a Phase 2 study in these patients, if successful, can have the potential for market approval.

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

INITIAL FINDINGS

The drug candidate was discovered due to its ability to increase mitochondrial function in cells from mitochondrial Leigh syndrome patients. Leigh syndrome usually debuts at one to two years of age and includes psychomotor regression, low muscle tone, and developmental delays. The disease is fatal, and children with early-onset Leigh syndrome usually die before adulthood.

TREATMENT OBJECTIVE

NV354 is being developed for mitochondrial disease with neu-rologic complications, in particular at insufficient activity in the mitochondrial protein complex I. The resulting deficiency in energy conversion contributes to clinical signs and symptoms in many types of mitochondrial disease, including neurologic complications seen in Leigh syndrome, MELAS, and LHON. There are also expansion opportunities outside of mitochondrial disease, including neurologic conditions where mitochondrial dysfunction has been confirmed.

HIGH UNMET MEDICAL NEED

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.

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 to the cell.

Consolidated Statement of

Comprehensive Income

Revenues

The consolidated turnover during the second quarter of 2024 was SEK 0 (0). Other operating revenues for the second quarter were SEK 0 (2,711,000) and pertain to exchange-rate gains. During the first six months of 2024 the consolidated turnover was KSEK 0 (0). Other operating revenues for the first six months amounted SEK 513,000 (3,766,000) and pertain to exchange-rate gains.

Results of operations

The operating loss for the second quarter was SEK 25,738,000 (21 289,000) and for the first six months the operating loss amounted SEK 43,907,000 (37,505,000). The net loss before tax for the second quarter amounted to SEK 25,750,000 (21,226,000). For the first six months the loss before tax was SEK 43,933,000 (37,318,000).

The operating loss was affected by other external expenses, which for the first six months were SEK 34,038,000 (30,040,000). Expenses related to development projects, as a part of external expenses, have affected the result with SEK 25,354,000 (21,610,000) whereof SEK 28,345,000 (21,178,000) relates to project in clinical phase. The cost for Projects in the clinical phase are higher, compared to the same period last year, due to predetermined payment schedules to suppliers. Personnel expenses during the first six months amounts to SEK 9,407,000 (9,805,000) and are less compared to last year due to less employees. Other operating expenses during the first six months amounts to, SEK -325 (0) and pertaines to exchange-rate losses.

Profit/loss from financial items

Financial items for the six months amounted to SEK -25,000 (186,000) and refers mainly to accrued interest for rental contracts.

(SEK 000)	Note	1 Apr, 2024 30 Jun, 2024	1 Apr, 2023 30 Jun, 2023	1 Jan, 2024 30 Jun, 2024	1 Jan, 2023 30 Jun, 2023	1 Jan, 2023 31 Dec, 2023
Net sales		-	-	-	-	137
Other operating income		-325	2,711	513	3,766	1,345
		-325	**2,711**	**513**	**3,766**	**1,482**
Operating expenses						
Other external expenses		-19,820	-18,200	-34,038	-30,040	-68,819
Personnel cost		-5,102	-5,086	-9,407	-9,805	-18,785
Depreciation and write-down of tangible and intangible assets		-490	-714	-975	-1,425	-10,426
Other operating expenses		-	-	-	-	-
		-25,413	**-23,999**	**-44,421**	**-41,270**	**-98,030**
Operating income		**-25,738**	**-21,289**	**-43,907**	**-37,505**	**-96,548**
Profit/loss from financial items						
Result from other securities and receivables related to non current assets		-	-	-	-	34
Financial income		1	87	2	231	1,072
Financial costs		-13	-25	-27	-44	-76
		-12	**63**	**-25**	**186**	**1,030**
Profit/loss before tax		**-25,750**	**-21,226**	**-43,933**	**-37,318**	**-95,518**
Income tax	2	-	-	1	-	9
Profit/loss for the period		**-25,750**	**-21,226**	**-43,932**	**-37,318**	**-95,509**
Other comprehensive income						
Items that may be reclassified to profit or loss						
Translation differences on foreign subsidiaries		-3	32	49	26	-30
Total comprehensive income for the period		**-25,753**	**-21,193**	**-43,883**	**-37,292**	**-95,539**
Loss for the period attributable to:						
Parent company shareholders		-25,750	-21,226	-43,932	-37,318	-95,509
Non-controlling interests		-	-	-	-	-
		-25,750	**-21,226**	**-43,932**	**-37,318**	**-95,509**
Total comprehensive income for the period						
Parent company shareholders		-25,753	-21,193	-43,883	-37,292	-95,539
Non-controlling interests		-	-	-	-	-
		-25,753	**-21,193**	**-43,883**	**-37,292**	**-95,539**
Earnings per share before and after dilution(SEK) based on average number of shares		-0.02	-0.02	-0.04	-0.04	-0.09
Average number of shares before and after dilution		1,259,418,711	1,056,299,165	1,157,858,938	1,056,299,165	1,056,299,165

Consolidated Statement of

Financial Position

Financial position

The equity/assets ratio was 89 (90) percent as of 30 June 2024, and equity was SEK 67,420,000 (128,386,000). Cash and cash equivalents amounted to SEK 45,253,000 (63,770,000) as of 30 June 2024, a decrease of SEK 12,411,000 from the beginning of the year.Total assets as of 30 June 2024 were SEK 75,695,000 (142,021,000). Long term liabilities refers to long term part of the rigth of use asset leases and amount to 216,000 (617,000). Current liabilities amounted to SEK 8 059,000 (13,018,000) as of June 30, 2024, and mainly refers to activities realted to the FALCON study.

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

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

(SEK 000)	Note	30 Jun, 2024	30 Jun, 2023	31 Dec, 2023
ASSETS				
Non-current assets				
Intangible assets	1			
Patents		10,264	17,990	10,505
Other Intangible assets		874	1,008	941
		11,138	**18,998**	**11,446**
Tangible assets				
Equipment		7	35	20
Right of use asset leases		571	951	761
		578	**986**	**781**
Financial assets				
Other long-term securities		13,101	13,101	13,101
Deferred tax		10	-	9
		13,111	**13,101**	**13,110**
Total non-current assets		**24,827**	**33,085**	**25,337**
Current assets				
Other receivables		1,858	1,266	1,051
Prepaid expenses and accrued income		3,758	2,629	3,447
Other short term recivables		-	41,271	-
Cash and cash equivalents		45,253	63,770	57,664
		50,869	**108,936**	**62,162**
TOTAL ASSETS		**75,695**	**142,021**	**87,499**

Consolidated Statement of

Financial Position

(SEK 000)	Note	30 Jun, 2024	30 Jun, 2023	31 Dec, 2023
EQUITY AND LIABILITIES				
Equity attributable to the shareholders of the parent company				
Share capital		67,469	52,815	52,815
Additional paid in capital		931,529	906,048	905,972
Translation reserve		852	859	803
Retained earnings*		-932,430	-831,336	-888,872
Total equity attributable to the shareholders of the parent		**67,420**	**128,386**	**70,718**
Total equity		**67,420**	**128,386**	**70,718**
Long-term liabilities				
Other longtrem liabilities		216	617	424
		216	**617**	**424**
Short-term liabilities				
Accounts payable		1,707	5,440	9,348
Other liabilities		750	824	699
Accrued expenses and deferred income		5,602	6,754	6,310
		8,059	**13,635**	**16,357**
Total liabilities		**8,275**	**13,635**	**16,781**
TOTAL EQUITY AND LIABILITIES		**75,695**	**142,021**	**87,499**

Consolidated Statement of

Changes in Equity

	Equity attributable to the shareholders of the parent company						
(SEK 000)	Share-capital	Additional paid in capital	Translation reserve	Retained earnings	Total	Non-controlling interests	Total equity
Opening balance, 1 January 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	-	-	-	1,218	1,218	-	1,218
Change of ownership in share issue	-	752	-	-	752	-	752
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**
Opening balance, 1 January 2023	**52,815**	**905,221**	**833**	**-794,581**	**164,287**	**0**	**164,287**
Comprehensive profit/loss for the period							
Profit/loss for the period	-	-	-	-37,318	-37,318	-	-37,318
Other comprehensive income							
Translation differences	-	-	26	-	26	-	26
Other comprehensive profit/loss for the period, net after tax	**-**	**-**	**26**	**-**	**26**	**-**	**26**
Total comprehensive profit/loss	**-**	**-**	**26**	**-37,318**	**-37,292**	**-**	**-37,292**
Transactions with shareholders							
Share-based payment	-	-	-	564	564	-	564
Change of ownership in share issue	-	827	-	-	827	-	827
Total transactions with shareholders	**-**	**827**	**-**	**564**	**1,391**	**-**	**1,391**
Closing balance, 30 June 2023	**52,815**	**906,048**	**859**	**-831,336**	**128,386**	**0**	**128,386**
Opening balance, 1 January 2024	**52,815**	**905,972**	**803**	**-888,872**	**70,718**	**0**	**70,718**
Comprehensive profit/loss for the period							
Profit/loss for the period	-	-	-	-43,932	-43,932	-	-43,932
Other comprehensive income							
Translation differences	-	-	49	-	49	-	49
Other comprehensive profit/loss for the period, net after tax	**-**	**-**	**49**	**-**	**49**	**-**	**49**
Total comprehensive profit/loss	**-**	**-**	**49**	**-43,932**	**-43,883**	**-**	**-43,883**
Transactions with shareholders							
Rights Issue	14,654	25,186	-	-	39,840	-	39,840
Share-based payment	-	-	-	375	375	-	375
New share Issue, Employee stock options	-	371	-	-	371	-	371
Total transactions with shareholders	**14,654**	**25,557**	**-**	**375**	**40,585**	**-**	**40,585**
Closing balance, 30 June 2024	**67,470**	**931,529**	**852**	**-932,430**	**67,420**	**0**	**67,420**

Total equity includes funds from the April 19th completed preferential rights issue with net SEK 39,840,000 less expenses SEK 6,163,000 wherof SEK 2,136,000 constituted compensation to the guarantors.

Consolidated Statement of

Cash Flows

Cash flow and investments

Operating cash flow for the second quarter was SEK - 25,651,000 (4 222,000). For the first six months the operating cash flow amounted SEK -52,040,000 (-3,109,000). The cash flow effect related to investments in intangibles equals SEK -464,000 (-214,000) for the first six months. The cash flow effect related to investments in financing activities equals SEK 40,025,000 (661,000) and refers mainly to the preferential rights issue that affected cash flow positively by SEK 39,840,000 and the warrant programs for management and board that affected cash flow positively by SEK 371,000.Cashflow for the first six months equals SEK -12,480 (-2,663,000).

(SEK 000)	1 Apr, 2024 30 Jun, 2024	1 Apr, 2023 30 Jun, 2023	1 Jan, 2024 30 Jun, 2024	1 Jan, 2023 30 Jun, 2023	1 Jan, 2023 31 Dec, 2023
Cash flow from operating activities					
Operating income	-25,738	-21,289	-43,908	-37,505	-96,547
Adjustments for non-cash items:					
Depreciation	490	714	975	1,425	10,426
Currency differences on intercompany items	7	60	91	56	-58
Impaired Value	9	1	-	-10	-7
Share-based payments	91	346	375	564	1,218
Result from other securities and receivables related to non current assets	-	-	-	-	34
Interest received	1	87	2	231	1,072
Interest paid	-13	-25	-27	-44	-76
Paid taxes	-	-	-	-	-
Net cash from operating activities before changes in working capital	**-25,153**	**-20,104**	**-42,492**	**-35,283**	**-83,938**
Changes in working capital					
Increase/decrease of other current assets	1,226	18,268	-1,115	38,258	78,923
Increase/decrease of other short-term liabilities	-1,724	6,058	-8,433	-6,084	-2,787
Changes in working capital	**-498**	**24,326**	**-9,548**	**32,174**	**76,136**
Cash flow from operating activities	**-25,651**	**4,222**	**-52,040**	**-3,109**	**-7,802**
Investing activities					
Acquisition of intangible assets	-382	-150	-464	-214	-1,290
Acquisition of tangible assets	-	-0	-	-	-
Cash flow from investing activities	**-382**	**-150**	**-464**	**-214**	**-1,290**
Financing activities					
New share issue	40,211	225	40,211	827	752
Amoritization lease	-94	-84	-186	-166	-338
Cash flow from financing activities	**40,117**	**141**	**40,025**	**661**	**414**
Cash flow for the period	14,084	4,213	-12,480	-2,663	-8,678
Cash and cash equivalents at the beginning of the period	31,156	59,518	57,664	66,392	66,392
Effect of exchange rate changes on cash	13	39	69	41	-50
Cash and cash equivalents at end of period	**45,253**	**63,770**	**45,253**	**63,770**	**57,664**

Parent Company

Income Statement

Parental company

Company earnings after tax for the second quarter amount to SEK -25,684,000 (-21,359,000). Loss after tax for the first six months amount to SEK 43,540,000 (36,987,000). Most of the Group's operations are conducted within the parent company. Accordingly, no further specific information regarding the parent company is presented.

(SEK 000)	Note	1 Apr, 2024 30 Jun, 2024	1 Apr, 2023 30 Jun, 2023	1 Jan, 2024 30 Jun, 2024	1 Jan, 2023 30 Jun, 2023	1 Jan, 2023 31 Dec, 2023
Net sales		-	-	-	-	137
Other operating income		-340	2,664	523	3,709	1,508
		-340	**2,664**	**523**	**3,709**	**1,645**
Operating expenses						
Other external expenses		-21,810	-20,430	-37,550	-33,522	-75,410
Personnel cost		-3,139	-3,056	-5,729	-6,165	-11,803
Depreciation and write-down of tangible and intangible assets		-395	-618	-785	-1,235	-10,046
Other operating expenses		-	-	-	-	-
		-25,344	**-24,105**	**-44,064**	**-40,921**	**-97,259**
Operating income		**-25,684**	**-21,440**	**-43,541**	**-37,212**	**-95,614**
Profit/loss from financial items						
Result from other securities and receivables related to non current assets		-	-	-	-	-23,691
Interest income and other similar profit items		1	87	2	231	1,072
Interest expenses and other similar loss items		-1	-6	-1	-6	-5
		-	**81**	**1**	**225**	**-22,624**
Profit/loss before tax		**-25,684**	**-21,359**	**-43,540**	**-36,987**	**-118,238**
Income tax	2	-	-	-	-	-
Profit/loss for the period		**-25,684**	**-21,359**	**-43,540**	**-36,987**	**-118,238**

Parent Company

Statement of Comprehensive Income

(SEK 000)	Note	1 Apr, 2024 30 Jun, 2024	1 Apr, 2023 30 Jun, 2023	1 Jan, 2024 30 Jun, 2024	1 Jan, 2023 30 Jun, 2023	1 Jan, 2023 31 Dec, 2023
Profit/loss for the period		-25,684	-21,359	-43,540	-36,987	-118,238
Other comprehensive income		-	-	-	-	-
Total comprehensive profit/loss for the period		**-25,684**	**-21,359**	**-43,540**	**-36,987**	**-118,238**

Parent Company

Balance Sheet

(SEK 000)	Note	30 Jun, 2024	30 Jun, 2023	31 Dec, 2023
ASSETS				
Non-current assets				
Intangible assets	1			
Patents		10,264	17,990	10,505
Other intangible assets		874	1,008	941
		11,138	**18,998**	**11,446**
Tangible assets				
Equipment		7	35	20
		7	**35**	**20**
Financial assets				
Shares in subsidiaries	3	1,465	13,100	1,465
Other long-term placement		13,100	25,160	13,101
		14,565	**38,260**	**14,566**
Total non-current assets		**25,710**	**57,293**	**26,032**
Current assets				
Short term receivables				
Receivables from group companies		-	-	-
Other receivables		1,837	1,241	1,031
Prepaid expenses and accrued income		3,748	2,602	3,425
		5,585	**3,842**	**4,456**
Other short term recievables		-	41,271	-
Cash and bank balances		43,778	62,961	55,826
Total current assets		**49,363**	**108,074**	**60,282**
TOTAL ASSETS		**75,073**	**165,367**	**86,314**

Parent Company

Balance Sheet

(SEK 000)	Note	30 Jun, 2024	30 Jun, 2023	31 Dec, 2023
EQUITY AND LIABILITIES				
Equity				
Restricted equity				
Share capital		67,469	52,815	52,815
Statutory reserve		1,856	1,856	1,856
Development expenditure reserve**		-	309	-
		69,325	**54,980**	**54,671**
Unrestricted equity				
Share premium reserve		200,763	175,488	225
Retained earnings		-159,343	-41,414	134,159
Profit/loss for the period		-43,540	-36,987	-118,238
		-2,120	**97,087**	**16,145**
Total equity		**67,205**	**152,067**	**70,816**
Short-term liabilities				
Accounts payable		1,703	5,423	9,345
Liabilities subsidiary		1,565	1,968	1,620
Other liabilities		349	466	319
Accrued expenses and deferred income		4,251	5,444	4,213
		7,868	**13,300**	**15,498**
TOTAL EQUITY AND LIABILITIES		**75,073**	**165,367**	**86,314**

Notes

Note 1 — Intangible assets

(SEK 000)	Patents	Other	Total
ACCUMULATED COST			
Opening balance 1 Jan. 2024	**21,612**	**2,864**	**24,476**
Additions	464	-	464
Impaired value	-5	-	-5
Closing balance 30 Jun. 2024	**22,071**	**2,864**	**24,935**
ACCUMULATED DEPRECIATION			
Opening balance 1 Jan. 2024	**-11,107**	**-1,923**	**-13,030**
Depreciation for the period	-416	-351	-767
Impaired value	-284	284	0
Closing balance 30 Jun. 2024	**-11,807**	**-1,990**	**-13,797**
Residual value 30 Jun. 2024	**10,264**	**874**	**11,138**

(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**

Note 2 – Tax

The group's total loss carry-forward amount to SEK996,310,000 as of 30 June 2024 (889,255,000). The parent company's total loss carry-forwards amounts to SEK 970,123,000 as of 30 June 2023 (863,106,000). 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.

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®.

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.

Apart from remuneration to senior executives no transactions with related parties have occured.

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

Human resources
The average number of employees of the group for the period January to June 2024 was 6 (8), of which 4 (6) are women.

Important events during the second quarter (Apr-Jun 2024)
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 four warrant programs.

Stock Option Programs
The general meeting on 8 March, 2023, decided on a 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.

The general meeting on 23 May, 2024, decided on a four-year incentive stock option program 2024/2030 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 25,000,000 ordinary shares. The redemption price amounts to SEK 0.19. The program is vested at 25% per year on 1 June, 2025, 1 June, 2026, 1 June, 2027 and 1 June, 2028. Latest redemption date is 1 June, 2030.

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 for management and other and key employees. One warrant entitles the holder to one new share in Abliva AB. Unsubscribed options have been cancelled. 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.

At the general meeting on 23 May, 2024, it was decided on a warrant program 2024/2028 to management and other and key employees of a maximum of 15.0 million warrants at a price of SEK 0.03 per warrant, corresponding to a subscription price of SEK 0.48 per share. In total, approx. 9.4 million options have been subscribed in the warrant program for management and other and key employees. One warrant entitles the holder to one new share in Abliva AB. Redemption date is 1 June - 31 December 2028.

On 23 May the AGM resolved on a warrant program 2024/2028 for certain board members of a maximum of 4.0 million warrants at a price of SEK 0.03 per warrant and a subscription price of SEK 0.48 per share. In total, 3 million options have been subscribed in the warrant program for certain board members. One warrant entitles the holder to one new share in Abliva AB. Redemption date is June 1 - December 31, 2028.

In case of full utilization of all incentive programs the maximum dilution amounts to 5.27 per cent on a fully diluted basis. The dilution effects have been calculated as the number of additional shares and votes in relation to the number of existing shares and votes plus the number of additional shares and votes. The dilution is only expected to have a marginal effect on the Company's key performance indicator "Earnings (loss) per share".

For further information please see www.abliva.com and the Annual report 2023 note 11.

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

Upcoming financial statements

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 www.abliva.com

Risks and uncertainty factors

A research company such as Abliva AB (publ) is subject to high operational and financial risks because the projects the company conducts are in different developmental phases, where a number of parameters influence the likelihood of commercial success. Briefly, operations are associated with risks relating to factors including drug development, competition, technological progress, patents, regulatory requirements, capital requirements, currencies and interest rates. The Board of Directors works continuously to secure the business operation's need for financing. For a more detailed description of the risks and uncertainty factors that Abliva is facing, please refer to the risk analysis on pages 16-19 in the Annual Report for 2023.

Financing
The Board continuously monitors and evaluates the company's funding need and financial position given ongoing development. The company announced the outcome from a prefertial rights issue in April 2024 of approximately SEK 39.8 million after transaction costs. In July, the conversion of a convertible loan of approximately SEK 39.1 million after transaction costs was announced. 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 funds from the financing round of approximately SEK 80 million after transaction costs, 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.

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 Reportin..

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 2023 on pages 43-55.

Definitions alternative performance measures

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

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

The declaration of the Board of Directors and the CEO

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

Lund, Sweden, August 22, 2024

David Laskow-Pooley
Chair of the Board

David Bejker
Board member

Roger Franklin
Board member

Denise Goode
Board member

Jan Törnell
Board member

Ellen Donnelly
Chief Executive Officer


David Laskow-Pooley


David Bejker


Roger Franklin


Denise Goode


Jan Törnell


Ellen Donnelly

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

The information was submitted for publication, through the agency of the contact person set out above, at 8:30 a.m. CEST on August 22, 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.
Hypotonia. An abnormally low level of tension, important for posture, in the resting muscle
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 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 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.
Psychomotor regression. When the development of the ability to perform will-driven movements is initially normal but deteriorates during infancy or early childhood.
Succinate. Endogenous substance that plays an important role in mitochondrial energy production. Succinate is used by mitochondrial protein complex II.
TBI. Traumatic Brain Injury. An injury to the brain where some nerve cells are subjected to immediate damage. The injury then continues to exacerbate several days after the incident, which significantly impacts the final extent of damage.

About Abliva

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

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

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

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

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