

# ABLIVA

## Interim Report

January - December 2024



# 2024

Delivering mitochondrial health

# 2024 Summary

## Positive Interim Analysis of the FALCON Study

### Important events during 2024

#### KL1333

- 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.

#### Financial

- In February, the Board of Directors resolved on a capital raise totaling app. SEK 88 million through a fully guaranteed rights issue and a directed issue of convertible bonds.
- The new share issue with preferential rights for existing shareholders, announced in February and carried out in April, was subscribed to 100 percent. Abliva raised approximately SEK 46 million before deduction for transactions costs.
- Following the positive outcome of the interim analysis, Abliva was in August provided with additional proceeds of SEK 42 million before transaction costs through the conversion of the convertible bonds pledged in the capital raise in February.

### Public cash offer from Pharming Technologies B.V.

- As per 20 February 2025, Pharming Technologies B.V. controls in total 1,494,181,625 shares and votes in Abliva, corresponding to approximately 92.7 percent of the total number of shares and votes in Abliva.
- On 7 February 2025, Pharming declared unconditional, with approximately 87.7 percent of the total number of shares and votes in Abliva, and completed the recommended cash offer to the shareholders of Abliva and extended the acceptance period until February 20, 2025.
- Following an announcement of Pharming Technologies B.V. on December 15, 2024, on a public cash offer to acquire all shares in Abliva for SEK 0.45 per share, the Board of Directors of Abliva unanimously recommended the shareholders of Abliva to accept the offer. The acceptance period for the offer commenced on 16 January 2025.

### Financial information

#### October-December 2024\*

- Net revenues: SEK 0 (137,000)
- Other operating income: SEK 207,000 (0)
- Loss before tax: SEK 26,478,000 (25,258,000)
- Loss per share before dilution: SEK 0.02 (0.02)
- Diluted loss per share: SEK 0.02 (0.02)

#### January-December 2024\*

- Net revenues: SEK 0 (137,000)
- Other operating income: SEK 497,000 (1,345,000)
- Loss before tax: SEK 89,954,000 (95,518,000)
- Loss per share before dilution: SEK 0.07 (0.09)
- Diluted loss per share: SEK 0.07 (0.09)

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



# Pharming's Cash Offer for Abliva Reaches 92.7% Acceptance Rate

**The fourth quarter culminated in a public cash offer by Pharming Group N.V. to the shareholders of Abliva to acquire all issued and outstanding shares in the company. The offer, motivated by the successful interim analysis, was accepted by over 90% of our shareholders on February 20.**

## **Our Positive Interim Analysis is a First in Adult Mitochondrial Disease**

The FALCON study made significant progress throughout 2024, achieving several important milestones. As of January 2024, the company had achieved full enrollment of patients into Wave 1. Participants were administered with KL1333 or placebo twice daily for a duration of 48 weeks. The initial 24 weeks of treatment for this cohort contributed valuable data for an interim analysis in July. The interim analysis, conducted by an independent external group of experts, confirmed the strong safety profile of KL1333. The analysis further indicated that both primary endpoints—fatigue and myopathy—showed potential for success upon completion of the full study and validated the final study size to 180 participants. The interim readout was notable as it represented the first positive findings in a well-controlled clinical study of adult mitochondrial disease, marking a significant milestone for both Abliva and the broader mitochondrial disease community.

By the end of November, the last patient in Wave 1 received their final dose. With this phase complete, the team is now finalizing the site footprint for Wave 2 to ensure an expedited start to the final stage of the study.

In December, Abliva announced the publication of Phase 1a/1b study data evaluating KL1333 in healthy volunteers and patients. This research was published in the esteemed journal *Brain* under the title “Optimising rare disorder trials:

a phase 1a/1b randomized study of KL1333 in adults with mitochondrial disease,” authored by Dr. Pizzamilglio and colleagues. The article can be accessed here: <https://academic.oup.com/brain/article/148/1/39/7911991>.

## **Interim Analysis Triggers Strategic Discussions**

The field of primary mitochondrial disease has attracted attention from investors and pharmaceutical companies for several years. This interest stems from the relatively high number of patients affected and the potential for significant revenue, as therapeutics for rare diseases often command premium pricing. However, potential partners had been hesitant to commit for several reasons including limited understanding of mitochondrial biology, challenges targeting mitochondrial disease, and a history of clinical failures.

The positive interim analysis has changed the landscape. As the furthest advanced program focused on primary mitochondrial disease associated with mtDNA mutations, our study has sparked renewed interest from potential partners. In order to evaluate this interest while considering all options to maximize shareholder value and ensure an efficient path to market, the company engaged strategic advisors. The team evaluated a number of options including a large financing, partnership (development and commercial) as well as mergers and acquisitions (M&A). By pursuing these strategies, we aimed to capitalize on the positive momentum generated by the interim analysis and position ourselves for success in the evolving landscape of mitochondrial disease therapeutics.

## **Pharming Announces Public Cash Offer**

On December 15, Pharming announced a public cash offer to acquire all shares in Abliva AB at a price per share of SEK 0.45, valuing the transaction at approximately SEK 725.3 million. The offer price represented a 227% premium com-

pared to the closing price of the Abliva share the trading day prior to the announcement of the offer, which is one of the highest bid premiums in a public offer seen in Sweden since 2017.

Abliva's Board of Directors recommended that shareholders accept the offer. The Board's decision followed a comprehensive evaluation of the company's financial position, future funding needs, and the opportunities and risks presented by current market conditions. The Board emphasized that Pharming as the new strategic owner could provide greater financial stability, immediate access to necessary capital, and the resources of a larger organization, significantly strengthening the company's ability to develop and commercialize its programs successfully.

The offer was declared unconditional on February 7 and Pharming announced that they would complete the recommended cash offer on the tendered shares (87.7% of the total number of shares in Abliva) and extend the acceptance period until February 20. Pharming announced control of over 90% of the shares on February 20.

Overall, 2024 has been a breakthrough year for Abliva and KL1333, with the FALCON study showing promising results and the Pharming offer paving the way for the next phase of mitochondrial disease development.

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.



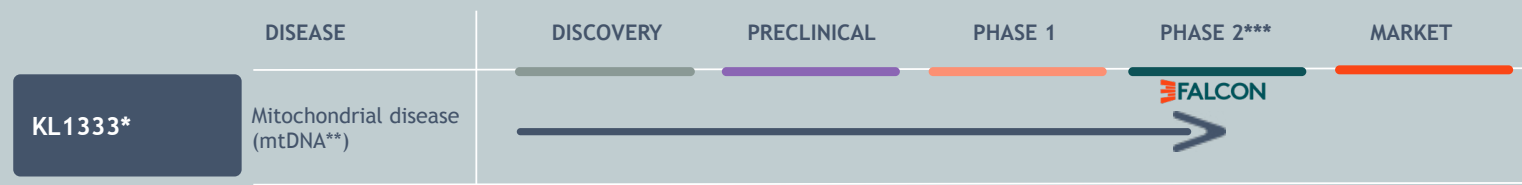
\*KL1333 and NV354 have Orphan Drug Designation (ODD) in the U.S. and Europe, and KL1333 has Fast Track designation in the U.S.

\*\*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.

# 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 fourth quarter

- By the end of the fourth quarter, all patients in Wave 1 of the FALCON study had completed all visits of the study.
- The European Medicines Agency (EMA) agreed to Abliva's proposed stepwise Pediatric Investigation Plan (PIP) for KL1333.

### Objectives for 2024

- Interim readout of the KL1333 FALCON study. ✓
- Progression of commercial production of KL1333. ✓

### Objectives for 2025

- Commencement of Wave 2 of the KL1333 FALCON study.



### 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<sup>+</sup> 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), only one of which must be positive to file for marketing approval.

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 feasibility, meaning that both have the potential to demonstrate benefit in the final analysis of the study.

### PATH TO MARKET

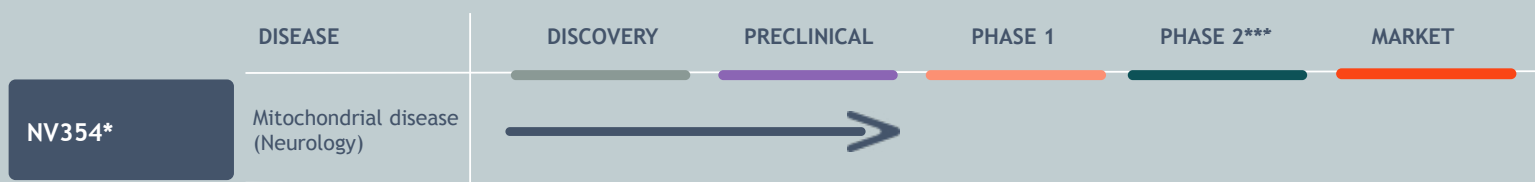
KL1333 has received Orphan Drug Designation in both the US and EU and Fast Track Designation in the US. Upon approval, the drug is expected to see significant uptake with an estimated patient population of up to 1:5,000 people<sup>1</sup>. Considering typical orphan drug pricing, this translates into 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 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.

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.

## TREATMENT OBJECTIVE

NV354 is being developed for mitochondrial disease with neurologic 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.



# Consolidated Statement of Comprehensive Income

## Revenues

The consolidated turnover during the fourth quarter of 2024 was SEK 0 (137,000). Other operating revenues for the fourth quarter were SEK 207,000 (0) and pertain to exchange-rate gains. During the full year of 2024 the consolidated turnover was SEK 0 (137,000). Other operating revenues for the full year amounted to SEK 497,000 (1,345,000) and pertain to exchange-rate gains.

## Results of operations

The operating loss for the fourth quarter was SEK 27,243,000 (26,106,000) and for the full year the operating loss amounted SEK 91,014,000 (96,548,000). The net loss before tax for the fourth quarter amounted to SEK 26,478,000 (25,258,000). For the full year the loss before tax was SEK 89,954,000 (95,518,000).

The operating loss was affected by other external expenses, which for the full year were SEK 70,628,000 (68,819,000). Expenses related to development projects, as a part of external expenses, have affected the result with SEK 56,561,000 (53,638,000) whereof SEK 56,717,000 (53,215,000) 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 for the full year 2024 amounts to SEK 18,964,000 (18,785,000) and are higher compared to last year due to bonus reservations and exchange rate differences. Depreciation and impairment of intangible and tangible assets for the full year amount to SEK 1,919,000 (10,426,000). Comparative figures from 2023 includes impairment of patents of in total SEK 7,797,000. For further information see Note 1 Intangible assets.

## Profit/loss from financial items

Financial items for the full year 2024 amounted to SEK 1,060,000 (1,030,000) and refers mainly to accrued interest for short term placements.

(SEK 000)	Note	1 Oct, 2024 31 Dec, 2024	1 Oct, 2023 31 Dec, 2023	1 Jan, 2024 31 Dec, 2024	1 Jan, 2023 31 Dec, 2023
Net sales		-	137	-	137
Other operating income		207	-	497	1,345
		<b>207</b>	<b>137</b>	<b>497</b>	<b>1,482</b>
<b>Operating expenses</b>					
Other external expenses		-22,330	-19,990	-70,628	-68,819
Personnel cost		-4,650	-4,334	-18,964	-18,785
Depreciation and write-down of tangible and intangible assets		-470	-481	-1,919	-10,426
Other operating expenses		-	-1,438	-	-
		<b>-27,450</b>	<b>-26,243</b>	<b>-91,511</b>	<b>-98,030</b>
<b>Operating income</b>		<b>-27,243</b>	<b>-26,106</b>	<b>-91,014</b>	<b>-96,548</b>
<b>Profit/loss from financial items</b>					
Result from other securities and receivables related to non current assets		192	34	192	34
Financial income		583	828	917	1,072
Financial costs		-10	-14	-49	-76
		<b>765</b>	<b>848</b>	<b>1,060</b>	<b>1,030</b>
<b>Profit/loss before tax</b>		<b>-26,478</b>	<b>-25,258</b>	<b>-89,954</b>	<b>-95,518</b>
Income tax	2	-	21	-	9
<b>Profit/loss for the period</b>		<b>-26,478</b>	<b>-25,237</b>	<b>-89,954</b>	<b>-95,509</b>
<b>Other comprehensive income</b>					
<i>Items that may be reclassified to profit or loss</i>					
Translation differences on foreign subsidiaries		80	-47	84	-30
<b>Total comprehensive income for the period</b>		<b>-26,398</b>	<b>-25,284</b>	<b>-89,870</b>	<b>-95,539</b>
<b>Loss for the period attributable to:</b>					
Parent company shareholders		-26,478	-25,237	-89,954	-95,509
Non-controlling interests		-	-	-	-
		<b>-26,478</b>	<b>-25,237</b>	<b>-89,954</b>	<b>-95,509</b>
<b>Total comprehensive income for the period</b>					
Parent company shareholders		-26,398	-25,284	-89,871	-95,539
Non-controlling interests		-	-	-	-
		<b>-26,398</b>	<b>-25,284</b>	<b>-89,870</b>	<b>-95,539</b>
Earnings per share before and after dilution(SEK) based on average number of shares		-0.02	-0.02	-0.07	-0.09
Average number of shares before and after dilution		1,544,801,203	1,056,299,165	1,351,330,070	1,056,299,165

# Consolidated Statement of Financial Position

## Financial position

The equity/assets ratio was 84 (81) percent as of 31 December 2024, and equity was SEK 61,688,000 (70,718,000). Long term liabilities refers to long term part and tax liability of the right of use asset leases and amount to SEK 0 (424,000). Short term Liabilities amounted SEK 11,863,000 (16,357,000) as of 31 December 2024, and mainly refers to activities related to the FALCON study. Other short-term receivables amounts to SEK 11,487,000 (0) and referred to the investment of surplus liquidity. Cash and cash equivalents amounted to SEK 32,670,000 (57,664,000) as of 31 December 2024. In total, short term receivables and cash and cash equivalents amount to SEK 44,157,000, a decrease of SEK 13,507,000 compared to the beginning of the year when short term receivables and cash and cash equivalents amounted to SEK 57,664,000. Total assets as of 31 December 2024 were SEK 73,551,000 (87,499,000).

## 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, 2024	31 Dec, 2023
<b>ASSETS</b>			
<b>Non-current assets</b>			
Intangible assets	1		
Patents		10,304	10,505
Other Intangible assets		807	941
		<b>11,111</b>	<b>11,446</b>
<b>Tangible assets</b>			
Equipment		4	20
Right of use asset leases		380	761
		<b>384</b>	<b>781</b>
<b>Financial assets</b>			
Other long-term securities		13,101	13,101
Deferred tax		9	9
		<b>13,110</b>	<b>13,110</b>
<b>Total non-current assets</b>		<b>24,605</b>	<b>25,337</b>
<b>Current assets</b>			
Other receivables		1,117	1,051
Prepaid expenses and accrued income		3,672	3,447
Other short term receivables		11,487	-
Cash and cash equivalents		32,670	57,664
		<b>48,946</b>	<b>62,162</b>
<b>TOTAL ASSETS</b>		<b>73,551</b>	<b>87,499</b>



# Consolidated Statement of Financial Position

(SEK 000)	Note	31 Dec, 2024	31 Dec, 2023
<b>EQUITY AND LIABILITIES</b>			
<b>Equity attributable to the shareholders of the parent company</b>			
Share capital		80,594	52,815
Additional paid in capital		957,613	905,972
Translation reserve		887	803
Retained earnings*		-977,406	-888,872
<b>Total equity attributable to the shareholders of the parent</b>		<b>61,688</b>	<b>70,718</b>
<b>Total equity</b>		<b>61,688</b>	<b>70,718</b>
<b>Long-term liabilities</b>			
Other longterm liabilities		-	424
		-	<b>424</b>
<b>Short-term liabilities</b>			
Accounts payable		3,336	9,348
Other liabilities		713	699
Accrued expenses and deferred income		7,814	6,310
		<b>11,863</b>	<b>16,357</b>
<b>Total liabilities</b>		<b>11,863</b>	<b>16,781</b>
<b>TOTAL EQUITY AND LIABILITIES</b>		<b>73,551</b>	<b>87,499</b>

## 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		
<b>Opening balance, 1 January 2023</b>	<b>52,815</b>	<b>905,221</b>	<b>833</b>	<b>-794,581</b>	<b>164,287</b>	<b>0</b>	<b>164,287</b>
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
<b>Other comprehensive profit/loss for the period, net after tax</b>	<b>-</b>	<b>-</b>	<b>-30</b>	<b>-</b>	<b>-30</b>	<b>-</b>	<b>-30</b>
<b>Total comprehensive profit/loss</b>	<b>-</b>	<b>-</b>	<b>-30</b>	<b>-95,509</b>	<b>-95,539</b>	<b>-</b>	<b>-95,539</b>
Transactions with shareholders	-	-	-	-	-	-	-
Share-based payment	-	-	-	1,218	1,218	-	1,218
New share Issue, Employee stock options	-	752	-	-	752	-	752
<b>Total transactions with shareholders</b>	<b>-</b>	<b>752</b>	<b>-</b>	<b>1,218</b>	<b>1,970</b>	<b>-</b>	<b>1,970</b>
<b>Closing balance, 31 December 2023</b>	<b>52,815</b>	<b>905,972</b>	<b>803</b>	<b>-888,872</b>	<b>70,718</b>	<b>0</b>	<b>70,718</b>
<b>Opening balance, 1 January 2024</b>	<b>52,815</b>	<b>905,972</b>	<b>803</b>	<b>-888,872</b>	<b>70,718</b>	<b>0</b>	<b>70,718</b>
<b>Comprehensive profit/loss for the period</b>							
Profit/loss for the period	-	-	-	-89,954	-89,954	-	-89,954
Other comprehensive income	-	-	-	-	-	-	-
Translation differences	-	-	84	-	84	-	84
<b>Other comprehensive profit/loss for the period, net after tax</b>	<b>-</b>	<b>-</b>	<b>84</b>	<b>-</b>	<b>84</b>	<b>-</b>	<b>84</b>
<b>Total comprehensive profit/loss</b>	<b>-</b>	<b>-</b>	<b>84</b>	<b>-89,954</b>	<b>-89,870</b>	<b>-</b>	<b>-89,870</b>
<b>Transactions with shareholders</b>							
Rights Issue	14,654	25,186	-	-	39,840	-	39,840
Convertible loans	13,125	26,084	-	-	39,209	-	39,209
Share-based payment	-	-	-	1,420	1,420	-	1,420
New share Issue, Employee stock options	-	371	-	-	371	-	371
<b>Total transactions with shareholders</b>	<b>27,779</b>	<b>51,641</b>	<b>-</b>	<b>1,420</b>	<b>80,840</b>	<b>-</b>	<b>80,840</b>
<b>Closing balance, 31 December 2024</b>	<b>80,594</b>	<b>957,613</b>	<b>887</b>	<b>-977,406</b>	<b>61,688</b>	<b>0</b>	<b>61,688</b>

# Consolidated Statement of Cash Flows

## Cash flow and investments

Operating cash flow for the fourth quarter was SEK -13,659,000 (252,000). For the full year the operating cash flow amounted SEK -102,840,000 (-7,802,000). The cash flow effect related to investments in intangibles equals SEK -1,187,000 (-1,290,000) for the full year. The cash flow effect related to investments in financing activities equals SEK 78,932,000 (414,000) for the full year and refers mainly to the preferential rights issue that affected cash flow positively by SEK 39,840,000, the warrant programs for management and board that affected cash flow positively by SEK 371,000 and the conversion of the convertible that effected the cash flow positively by SEK 39,209,000. Cash flow for the fourth quarter equals negative SEK -14,216,000 (-867,000). Cashflow for the full year equals negative SEK -25,095,000 (-8,678,000).

(SEK 000)	1 Oct, 2024 31 Dec, 2024	1 Oct, 2023 31 Dec, 2023	1 Jan, 2024 31 Dec, 2024	1 Jan, 2023 31 Dec, 2023
<b>Cash flow from operating activities</b>				
Operating income	-27,243	-26,105	-91,014	-96,547
<b>Adjustments for non-cash items:</b>				
Depreciation	470	481	1,919	10,426
Currency differences on intercompany items	190	-101	188	-58
Impaired Value	96	3	63	-7
Share-based payments	381	327	1,420	1,218
Result from other securities and receivables related to non current assets	192	34	192	34
Interest received	583	828	917	1,072
Interest paid	-10	-15	-49	-76
<b>Net cash from operating activities before changes in working capital</b>	<b>-25,341</b>	<b>-24,547</b>	<b>-86,364</b>	<b>-83,938</b>
<b>Changes in working capital</b>				
Increase/decrease of other current assets	9,033	20,882	-11,774	78,923
Increase/decrease of other short-term liabilities	2,649	3,917	-4,702	-2,787
<b>Changes in working capital</b>	<b>11,682</b>	<b>24,799</b>	<b>-16,476</b>	<b>76,136</b>
<b>Cash flow from operating activities</b>	<b>-13,659</b>	<b>252</b>	<b>-102,840</b>	<b>-7,802</b>
<b>Investing activities</b>				
Acquisition of intangible assets	-351	-957	-1,187	-1,290
<b>Cash flow from investing activities</b>	<b>-351</b>	<b>-957</b>	<b>-1,187</b>	<b>-1,290</b>
<b>Financing activities</b>				
New share issue	-	-75	79,420	752
Amoritzation lease	-97	-87	-379	-338
Increase/decrease of long-term liabilities	-109	-	-109	-
<b>Cash flow from financing activities</b>	<b>-206</b>	<b>-162</b>	<b>78,932</b>	<b>414</b>
Cash flow for the period	-14,216	-867	-25,095	-8,678
Cash and cash equivalents at the beginning of the period	46,812	58,637	57,664	66,392
Effect of exchange rate changes on cash	74	-106	101	-50
<b>Cash and cash equivalents at end of period</b>	<b>32,670</b>	<b>57,664</b>	<b>32,670</b>	<b>57,664</b>

## Parent Company

# Income Statement

### Parental company

Earnings after tax for the fourth quarter amounts to SEK -26,126,000 (-24,929,000). Earnings after tax for the full year amount to SEK -88,574,000 (-118,238,000). 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 Oct, 2024 31 Dec, 2024	1 Oct, 2023 31 Dec, 2023	1 Jan, 2024 31 Dec, 2024	1 Jan, 2023 31 Dec, 2023
Net sales		-	137	-	137
Other operating income		278	-	515	1,508
		<b>278</b>	<b>137</b>	<b>515</b>	<b>1,645</b>
<b>Operating expenses</b>					
Other external expenses		-24,084	-21,561	-77,648	-75,410
Personnel cost		-2,719	-2,915	-11,009	-11,803
Depreciation and write-down of tangible and intangible assets		-375	-386	-1,538	-10,046
Other operating expenses		-	-1,068	-	-
		<b>-27,178</b>	<b>-25,930</b>	<b>-90,195</b>	<b>-97,259</b>
<b>Operating income</b>		<b>-26,900</b>	<b>-25,793</b>	<b>-89,680</b>	<b>-95,614</b>
<b>Profit/loss from financial items</b>					
Result from other securities and receivables related to non current assets		192	34	192	-23,691
Interest income and other similar profit items		583	828	916	1,072
Interest expenses and other similar loss items		-1	1	-2	-5
		<b>774</b>	<b>863</b>	<b>1,106</b>	<b>-22,624</b>
<b>Profit/loss before tax</b>		<b>-26,126</b>	<b>-24,929</b>	<b>-88,574</b>	<b>-118,238</b>
<b>Profit/loss for the period</b>		<b>-26,126</b>	<b>-24,929</b>	<b>-88,574</b>	<b>-118,238</b>

## Parent Company

# Statement of Comprehensive Income

(SEK 000)	Note	1 Oct, 2024 31 Dec, 2024	1 Oct, 2023 31 Dec, 2023	1 Jan, 2024 31 Dec, 2024	1 Jan, 2023 31 Dec, 2023
Profit/loss for the period		-26,126	-24,929	-88,574	-118,238
<b>Total comprehensive profit/loss for the period</b>		<b>-26,126</b>	<b>-24,929</b>	<b>-88,574</b>	<b>-118,238</b>

Parent Company  
**Balance Sheet**

(SEK 000)	Note	31 Dec, 2024	31 Dec, 2023
<b>ASSETS</b>			
<b>Non-current assets</b>			
<i>Intangible assets</i>			
	1		
Patents		10,304	10,505
Other intangible assets		807	941
		<b>11,111</b>	<b>11,446</b>
<i>Tangible assets</i>			
Equipment		4	20
		<b>4</b>	<b>20</b>
<i>Financial assets</i>			
Shares in subsidiaries	3	1,670	1,465
Other long-term placement		13,101	13,101
		<b>14,771</b>	<b>14,566</b>
<b>Total non-current assets</b>		<b>25,886</b>	<b>26,032</b>
<b>Current assets</b>			
<i>Short term receivables</i>			
Other receivables		1,094	1,031
Prepaid expenses and accrued income		3,668	3,425
		<b>4,762</b>	<b>4,456</b>
<i>Other short term receivables</i>			
		11,487	-
Cash and bank balances		31,002	55,826
<b>Total current assets</b>		<b>47,251</b>	<b>60,282</b>
<b>TOTAL ASSETS</b>		<b>73,137</b>	<b>86,314</b>

Parent Company  
**Balance Sheet**

(SEK 000)	Note	31 Dec, 2024	31 Dec, 2023
<b>EQUITY AND LIABILITIES</b>			
<b>Equity</b>			
<i>Restricted equity</i>			
Share capital		80,594	52,815
Statutory reserve		1,856	1,856
		<b>82,450</b>	<b>54,671</b>
<i>Unrestricted equity</i>			
Share premium reserve		51,360	225
Retained earnings		16,351	134,159
Profit/loss for the period		-88,574	-118,238
		<b>-20,863</b>	<b>16,145</b>
<b>Total equity</b>		<b>61,587</b>	<b>70,816</b>
<b>Short-term liabilities</b>			
Accounts payable		3,333	9,345
Liabilities subsidiary		2,614	1,620
Other liabilities		288	319
Accrued expenses and deferred income		5,315	4,213
		<b>11,550</b>	<b>15,498</b>
<b>TOTAL EQUITY AND LIABILITIES</b>		<b>73,137</b>	<b>86,314</b>

# Notes

## Note 1 — Intangible assets

(SEK 000)	Patents	Other	Total
<b>ACCUMULATED COST</b>			
Opening balance 1 Jan. 2024	21,612	2,864	24,476
Additions	1,187	-	1,187
Impaired value	-5	-	-5
<b>Closing balance 31 Dec. 2024</b>	<b>22,794</b>	<b>2,864</b>	<b>25,658</b>
<b>ACCUMULATED DEPRECIATION</b>			
Opening balance 1 Jan. 2024	-11,107	-1,923	-13,030
Depreciation for the period	-1,383	-134	-1,517
<b>Closing balance 31 Dec. 2024</b>	<b>-12,490</b>	<b>-2,057</b>	<b>-14,547</b>
<b>Residual value 31 Dec. 2024</b>	<b>10,304</b>	<b>807</b>	<b>11,111</b>

(SEK 000)	Patents	Other	Total
<b>ACCUMULATED COST</b>			
Opening balance 1 Jan. 2023	36,086	2,864	38,950
Additions	1,459	-	1,459
Impaired value	-15,933	-	-15,933
<b>Closing balance 31 Dec. 2023</b>	<b>21,612</b>	<b>2,864</b>	<b>24,476</b>
<b>ACCUMULATED DEPRECIATION</b>			
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
<b>Closing balance 31 Dec. 2023</b>	<b>-11,107</b>	<b>-1,923</b>	<b>-13,030</b>
<b>Residual value 31 Dec. 2023</b>	<b>10,505</b>	<b>941</b>	<b>11,446</b>

## Note 2 – Tax

The group's total loss carry-forwards amounts to SEK 1,043,950,000 as of 31 December 2024 (946,666,000). The parent company's total loss carry-forwards amounts to SEK 1,017,820,000 as of 31 December 2024 (920,497,000). 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 relate to the wholly owned American subsidiary Abliva Inc., Boston and the Swedish subsidiary Abliva Incentive AB, holding option programs for the CEO and warrant programs for management 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 subsidiaries, 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 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 2024 was 6 (8), of which 4 (6) are women.

### Important events during the fourth quarter (Oct-Dec 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 4.06 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](http://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.



## Other disclosures cont.

---

### Upcoming financial statements

Interim Report January-March 2025	May 22, 2025
Interim Report January-June 2025	August 22, 2025
Interim Report January-September 2025	November 21, 2025
Year-End Report 2025	February 20, 2026

The interim reports and the Annual Year Report are available [www.abliva.com](http://www.abliva.com)

### Annual General Meeting 2025

Annual General Meeting of Abliva AB (publ) will be held on June 12, 2025, at 10 a.m. at Medicon Village, Scheeletorget 1, in Lund, Sweden.

### Proposed appropriation of profits

The Board of Directors proposes that Abliva does not pay dividends for the financial year 2024.

## 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 Board acknowledges that there is

a need for capital for the next 12 months and a significant uncertainty for continued operations. On December 15, 2024, Pharming Technologies B.V. ("Pharming") announced a public cash offer. Further, on February 7, 2025, it was announced that Pharming had unconditionally completed the cash offer. The interim report is 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 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 2023. New or amended standards or interpretations of standards effective as of January 1, 2024 have not had any significant impact on Abliva's financial statements.

## 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 21, 2025

**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. CET on February 21, 2025.

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<sup>+</sup>/NADH.** A coenzyme involved in metabolism. NAD<sup>+</sup> 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<sup>+</sup> 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).

## Abliva AB (publ)

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

[ir@abliva.com](mailto:ir@abliva.com)

[www.abliva.com](http://www.abliva.com)

