# ABLIVA Interim Report

January - March 2024



# First Quarter Summary

SEK 46 million raised through preferential rights issue Preparations for the interim analysis ongoing

#### Important events January - March 2024

- The Board of Directors of Abliva AB on 22 February resolved on a capital raise totalling app. SEK 88 million through a fully guaranteed rights issue of app. SEK 46 million, and a directed issue of convertible bonds of app. SEK 42 million. The convertible loan amount shall be paid and immediately converted into shares in the Company after the announcement of the interim data from the KL 1333 Phase 2 study provided the results from the study is positive, i.e. non futile.
- Abliva held an Extraordinary General Meeting on March 26, 2024, where the capital raise was approved.

# Important events after the reporting period

 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 means that Abliva raises approximately SEK 46 million before deduction for transactions costs.

#### **Financial information**

#### January-March 2024\*

- Net revenues: SEK 0 (0)
- Other operating income: SEK 838,000 (1,055,000)
- Loss before tax: SEK 18,183,000 (16,092,000)
- Loss per share before dilution: SEK 0.02 (0.02)
- Diluted loss per share: SEK 0.02 (0.02)

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



# Countdown to Interim Analysis

The first quarter of 2024 had the team working across three axes, progressing FALCON towards interim analysis, financing, and increasing Abliva's visibility. Financing secured we are now looking forward to the interim analysis, ensuring everything is in place for the mid-year readout.

#### **FALCON Interim Analysis is On Track**

With Wave 1 fully enrolled in December, the team continues to work closely with the FALCON clinical sites, ensuring that operational questions are answered, and data collection is timely and accurate. The team is working to 'clean' the data (or confirm the recorded data is correct and entered in the systems in the appropriate manner) to enable a short timeline to interim analysis. The interim analysis will include the data for the first 24 weeks of dosing (KL1333 or placebo) for the Wave 1 patients. Once the last patient has had their 24-week visit, the final data will be cleaned and sent to the Independent Data Monitoring Committee (DMC) for their review. In their analysis the DMC will review the safety profile of KL1333 and the potential to achieve statistical significance after 48 weeks of dosing. After reviewing the data, the DMC will make a recommendation as to whether the study should continue, and, if so, the final size of the study. If the recommendation is to stop the study, we will review the broader set of clinical data and return with a recommendation for the program based on that secondary analysis.

# **Keeping Connected With the Mitochondrial Disease Community**

The quarter started with an opportunity to meet with French physicians and FALCON investigators during a national mitochondrial disease meeting in Strasbourg, France in early February. In March the Abliva team traveled to Hinxton, UK, for the Mitochondrial Medicine – Therapeutic Development meeting where we had the chance to learn about recent advances in mitochondrial research and connect with some of our fellow drug developers. We are now looking forward to the Mitochondrial Medicine Conference, sponsored by

the United Mitochondrial Disease Foundation (UMDF), a prominent patient advocacy foundation in the US. Being the premier annual meeting in our space, this event brings together physicians, researchers, patients, and companies focused on developing therapies for mitochondrial disease. We are looking forward to meeting with the other companies developing medicines, connecting with the physicians participating in Wave 1 and Wave 2 of our study, and talking with patients about their experiences living with mitochondrial disease.



"In their analysis the DMC will review the safety profile of KL1333 and the potential to achieve statistical significance after 48 weeks of dosing"

# Investor Outreach Increases As We Approach Interim Analysis

This week we were honored to host a virtual KOL event for investors, shareholders, and potential partners, featuring Amel Karaa MD, a mitochondrial disease expert, internist and clinical geneticist who treats patients at Massachusetts General Hospital in Boston. During the event, Amel educated the group on primary mitochondrial disease, the patient condition and the challenges and opportunities for developing medicines for these patients. Our CMO, Magnus Hansson, then introduced the group to KL1333 – the mechanism of action, data to date and the ongoing clinical study. The event ended with a stimulating question and answer session. Attendance at the event was fantastic, and I'd like

to thank everyone who joined us for your engagement and continued interest in the program.

We have also been meeting investors and continue to hear positive feedback on the program. We started the season at the Kempen Life Science event in April, and then Magnus and I attended BioEquity in mid-May. Coming up, Magnus will be speaking at the BioStock Global Forum on May 30 at 13:45 CET in Lund, and I will be attending BioInternational in San Diego in early June.

#### **Successful Financing Round Announced**

In February, we announced a two-part financing round comprised of a preferential rights issue (with a subscription period in April) and a convertible loan that would convert with a positive (i.e. non-futile) readout of the interim analysis. The company announced a successful completion of the issue in mid-April, raising SEK 46 million in the rights issue for the company (before transaction costs). Later in the month we announced that several of the guarantors had elected to take their underwriting fee in shares, a strong signal of their commitment and belief in the company.

As you may have heard at our KOL event this week, living with a chronic disease is difficult for everyone, and those that lack a supportive network of friends and family often deal with the suffering alone. In rare diseases this is even more often the case, as many rare disease patients have never met someone else with the disease. Imagine being diagnosed with primary mitochondrial disease and then being told that there is nothing you can do. We bring hope. Here's to a successful interim analysis this summer that takes us one step forward to a treatment for these patients.

Best wishes,

#### **Ellen Donnelly**

CEO

# Innovative Portfolio in Rare and Severe Mitochondrial Disease



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

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

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

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

<sup>\*\*</sup>mtDNA-related mitochondrial disorders caused by mutation(s) in mitochondrial DNA (as opposed to nuclear DNA).

<sup>\*\*\*</sup>Given that mitochondrial disease is an orphan disease, a Phase 2 study in these patients, if successful, can have the potential for market approval.

# Strategic focus: Mitochondrial Disease

At Abliva, we are focused on becoming the leading company in mitochondrial medicine, developing therapeutics for mitochondrial disease, orphan indications of high unmet medical need. We intend to build a fully integrated research, development, and commercial organization, developing innovative therapeutics and taking them directly to the patients.

#### **Building the Premier Mitochondrial Medicine Company**

Abliva's long-term goal is to become the leading global company focused on the discovery of therapeutics for mitochondrial disease. We will do this with our clear strategy, strong portfolio of assets, research and development organization, and team with decades of experience in mitochondrial medicine and drug development.

Over the next few years, we will focus on the delivery of our portfolio to the market. We aim to:

- Augment our strong research and development capabilities and build a commercial organization.
- Bring new innovative therapeutics to the patients and fuel our pipeline with new candidates from discovery.
- Attract and retain talented colleagues with a passion for drug development.
- Build a strong network of experts that will complement, enhance, and support our efforts across development that will include patients, physicians, researchers, regulators, payers, and technical experts.
- Generate future revenues through two paths: sales revenue for the drugs we intend to bring to market, and revenue from out-licensing assets (through milestone payments and royalties).

#### **Addressing Primary Mitochondrial Disease**

Primary mitochondrial disease is a rare orphan disease where the energy metabolism in the cells, by the power-houses of our cells – the mitochondria – is impaired. This causes deterioration that leads to multifaceted disorders and great suffering for patients. Mitochondrial medicine has

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

#### Delivering a Portfolio of First-in-Class Therapies

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

KL1333 is being developed as a treatment for primary mitochondrial disease patients suffering from multiple debilitating symptoms, including chronic fatigue and myopathy. KL1333 has completed several key Phase 1 studies that enabled the start of a potentially registrational Phase 2 study in 2022. KL1333 is protected by a composition of matter patent and Orphan Drug Designation (ODD) in the US and in Europe. It has also received Fast Track Designation in the US. The commercial opportunity is significant with even conservative estimates exceeding USD 1 billion per year in annual sales<sup>1)</sup>.

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<sup>2,3)</sup>. 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**

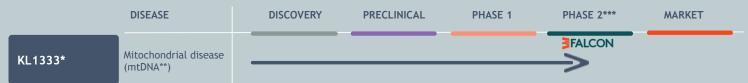
Abliva is a public company traded on NASDAQ Stockholm (ABLI, Small cap). We appreciate the continued commitment of our shareholders and look to attract new investors as we advance our portfolio and build the company. The investment of Hadean Ventures in 2020 was the first step to bringing specialist 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.

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



# KL1333 Innovative therapy in late-stage development

# Patient recruitment to Wave 1 of the FALCON study completed Interim analysis planned for mid-2024



- \*KL1333 has Orphan Drug Designation (ODD) in the U.S. and Europe and Fast Track designation in the U.S.
- \*\*mtDNA-related mitochondrial disorders caused by mutation(s) in mitochondrial DNA (as opposed to nuclear DNA).
- \*\*\*Given that mitochondrial disease is an orphan disease, a Phase 2 study in these patients, if successful, can have the potential for market approval.

#### **Events during the first quarter**

Dosing is ongoing at all Wave 1 sites in the FALCON study.
 The interim analysis remains on track for mid-2024.

#### 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 chronic 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

The FALCON study is a global, randomized, placebo-controlled, potentially registrational, Phase 2 study testing KL1333 in adult patients with primary mitochondrial disease with mitochondrial DNA mutations who experience chronic fatigue and myopathy.

Efficacy will be evaluated with two alternate primary endpoints, a mitochondrial disease-specific fatigue scale and a functional test of myopathy, the 30 second Sit-to-Stand test. The study is designed so that the result at study completion has the potential to be positive both if only one or both of the primary endpoints show clinical benefit. All patients will take KL1333 or placebo twice daily for 48 weeks. The study has an adaptive design and will be run in two waves with 120 – 180 total patients participating.



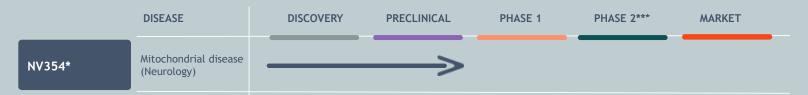
#### PATH TO MARKET

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



<sup>\*</sup>NV354 has Orphan Drug Designation (ODD) in the U.S. and Europe.

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

#### **INITIAL FINDINGS**

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.

<sup>\*\*</sup>Given that mitochondrial disease is an orphan disease, a Phase 2 study in these patients, if successful, can have the potential for market approval.

# Comprehensive Income

#### Revenues

The consolidated turnover during the first quarter of 2024 was SEK 0 (0). Other operating revenues for the first quarter were SEK 838,000 (1,055,000) and pertain to net exchange rate gains.

#### **Results of operations**

The operating loss for the first quarter was SEK 18,170,000 (16,216,000). The net loss before tax for the first quarter amounted to SEK 18,183,000 (16,092,000).

The operating loss was affected by other external expenses, which for the full were SEK 14,218,000 (11,840,000). During the first quarter, expenses related to development projects, as a part of external expenses, have affected the result with SEK 11,598,000 (8,307,000) whereof SEK 11,589,000 (8 038,000) 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 quarter amount to SEK 4,305,000 (4,720,000) and are less compared to last year due to less employees .

#### **Profit/loss from financial items**

Financial items for the first quarter amount to SEK -13,000 (123,000) and refers mainly to accrued interests.

		1 Jan, 2024	1 Jan, 2023	1 Jan, 2023
(SEK 000)	Note	31 Mar, 2024	31 Mar, 2023	31 Dec, 2023
Net sales		-	-	137
Other operating income		838	1,055	1,345
		838	1,055	1,482
Operating expenses				
Other external expenses		-14,218	-11,840	-68,819
Personnel cost		-4,305	-4,720	-18,785
Depreciation and write-down of tangible and intangible assets		-485	-711	-10,426
Other operating expenses		-	-	-
		-19,008	-17,271	-98,030
Operating income		-18,170	-16,216	-96,548
Profit/loss from financial items				
Result from other securities and receivables related to non current assets		-	-	34
Financial income		1	143	1,072
Financial costs		-14	-20	-76
		-13	123	1,030
Profit/loss before tax		-18,183	-16,092	-95,518
Income tax	2	1	-	9
Profit/loss for the period		-18,182	-16,092	-95,509
Other comprehensive income				
Items that may be reclassified to profit or loss				
Translation differences on foreign subsidiaries		52	-6	-30
Total comprehensive income for the period		-18,130	-16,098	-95,539
Loss for the period attributable to:			40.000	
Parent company shareholders		-18,182	-16,092	-95,509
Non-controlling interests		-	-	-
		-18,182	-16,092	-95,509
Total comprehensive income for the period				
Parent company shareholders		-18,130	-16,098	-95,539
Non-controlling interests		-	-	-
		-18,130	-16,098	-95,539
Earnings per share before and after dilution(SEK) based on average number of shares		-0.02	-0.02	-0.09
Average number of shares before and after dilution		1,056,299,165	1,056,299,165	1,056,299,165

# Financial Position

#### **Financial position**

The equity/assets ratio was 84 (95) percent as of 31 March 2024, and equity was SEK 52,871,000 (70,718,000) compared to beginning of the year. Long term liabilities SEK 321,000 (711,000) refers to long term part of the rigth of use asset leases. Current liabilities amounted to SEK 9,978,000 (6,932,000) as of March 31, 2024, and mainly refers to activities realted to the FALCON study. Other short-term recivables amounts to 0 (59,466) and refered to the investment of surplus liquidity. Cash and cash equivalents amounted to SEK 31,156,000 (59,518,000) as of 31 March 2024, a decrease of SEK 26,508,000 from the beginning of the year. Total assets as of 31 March 2024 were SEK 63,170,000 (156,650,000).

#### **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 Mar, 2024	31 Mar, 2023	31 Dec, 2023
ASSETS				
Non-current assets				
Intangible assets	1			
Patents		10,477	18,468	10,505
Other Intangible assets		907	1,042	941
		11,384	19,510	11,446
Tangible assets				
Equipment		13	42	20
Right of use asset leases		666	1,046	761
		679	1,088	781
Financial assets				
Other long-term securities		13,101	13,101	13,101
		13,110	13,101	13,110
Total non-current assets		25,173	33,700	25,337
Current assets				
Other receivables		789	1,265	1,051
Prepaid expenses and accrued income		6,052	2,701	3,447
Other short term recivables		-	59,466	-
Cash and cash equivalents		31,156	59,518	57,664
		37,997	122,950	62,162
TOTAL ASSETS		63,170	156,650	87,499

# Financial Position

(SEK 000) Note	31 Mar, 2024	31 Mar, 2023	31 Dec, 2023
EQUITY AND LIABILITIES			
Equity attributable to the shareholders of the parent company			
Share capital	52,815	52,815	52,815
Additional paid in capital	905,972	905,823	905,972
Translation reserve	855	827	803
Retained earnings*	-906,772	-810,458	-888,872
Total equity attributable to the shareholders of the parent	52,871	149,007	70,718
Total equity	52,871	149,007	70,718
Long-term liabilities			
Other longtrem liabilities	321	711	424
	321	711	424
Short-term liabilities			
Accounts payable	4,996	2,922	9,348
Other liabilities	1,187	674	699
Accrued expenses and deferred income	3,795	3,337	6,310
	9,978	6,932	16,357
Total liabilities	10,299	8,354	17,205
TOTAL EQUITY AND LIABILITIES	63,170	156,650	87,499

# Changes in Equity

	Equity at	ttributable to	the sharehold	ers of the pare	nt company		
		Additional				Non-	
	Share-	paid in	Translation	Retained		controlling	Total
(SEK 000)	capital	capital	reserve	earnings	Total	interests	equity
Opening balance, 1 January 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	-	-	-	-	-	-	-
Rights Issue	-	-	-	-	-	-	-
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	-794,582	164,287	0	164,287
Comprehensive profit/loss for the period							
Profit/loss for the period	-	-	_	-16,092	-16,092	-	-16,092
Other comprehensive income							
Translation differences	-	-	-6	-	-6	-	-6
Other comprehensive profit/loss for the period, net after tax	-	-	-6	-	-6	-	-6
Total comprehensive profit/loss	-	-	-6	-16,092	-16,098	-	-16,098
Transactions with shareholders							
Rights Issue*	-	-		_	-	-	
Share-based payment	-	602	_	-	602	-	602
Shareholder contribution	-	-	_	217	217	-	217
Total transactions with shareholders	-	602	-	217	819	-	819
Closing balance, 31 March 2023	52,815	905,823	827	-810,457	149,008	0	149,008
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	-	-	_	-18,182	-18,182	-	-18,182
Other comprehensive income							
Translation differences	-	-	52	_	52	-	52
Other comprehensive profit/loss for the period, net after tax	-	-	52	-	52	-	52
Total comprehensive profit/loss	-	-	52	-18,182	-18,130	-	-18,130
Transactions with shareholders							
Share-based payment	-	-	-	-	-	-	-
Change of ownership in share issue	-	-	-	283	283	-	283
Total transactions with shareholders	-	-	-	283	283	-	283
Closing balance, 31 March 2024	52,815	905,972	855	-906,771	52,871	0	52,871

# Consolidated Statement of Cash Flows

#### **Cash flow and investments**

Operating cash flow for the first quarter was SEK -26,389,000 (-7,330,000). The cash flow effect related to investments in intangibles equals SEK -82,000 (-65,000) for the first quarter. Cash flow for the first quarter equals SEK -26,563,000 (-6,875,000).

(SEK 000)	1 Jan, 2024	1 Jan, 2023	1 Jan, 2023
Cash flow from operating activities	31 Mar, 2024	31 Mar, 2023	31 Dec, 2023
Operating income	-18,170	-16,216	-96,547
	· ·		,
Adjustments for non-cash items:			
Depreciation	485	711	10,426
Currency differences on intercompany items	84	-4	-58
Impaired Value	-8	-11	-7
Share-based payments	283	217	1,218
Result from other securities and receivables related to non current assets	-	-	34
Interest received	1	143	1,072
Interest paid	-14	-20	-76
Paid taxes	-	-	-
Net cash from operating activities before changes in working capital	-17,339	-15,179	-83,938
Changes in working capital	2.241	10.001	79.022
Increase/decrease of other current assets	-2,341	19,991	78,923
Increase/decrease of other short-term liabilities	-6,709	-12,142	-2,787
Changes in working capital	-9,050	7,849	76,136
Cash flow from operating activities	-26,389	-7,330	-7,802
Investing activities			
Acquisition of intangible assets	-82	-65	-1,290
Acquisition of tangible assets	-	-	-
Cash flow from investing activities	-82	-65	-1,290
Physical Control of the Control of t			
Financing activities			
New share issue	-	602	752
Amoritization lease	-92	-82	-338
Increase/decrease of long-term liabilities	-	-	-
Cash flow from financing activities	-92	520	414
Cash flow for the period	-26,563	-6,875	-8,678
Cash and cash equivalents at the beginning of the period	57,664	66,392	66,392
Effect of exchange rate changes on cash	55	1	-50
Cash and cash equivalents at end of period	31,156	59,518	57,664

## Parent Company

# **Income Statement**

#### **Parental company**

Company earnings after tax for the first quarter amounts to SEK -17,856,000 (-15,628,000). Accordingly, no further specific information regarding the parent company is presented.

## Parent Company

# Statement of Comprehensive Income

(SEK 000)		1 Jan, 2024	1 Jan, 2023	1 Jan, 2023
	Note	31 Mar, 2024	31 Mar, 2023	31 Dec, 2023
Net sales		-	-	137
Other operating income		862	1,045	1,508
		862	1,045	1,645
Operating expenses				
Other external expenses		-15,740	-13,091	-75,410
Personnel cost		-2,590	-3,109	-11,803
Depreciation and write-down of tangible and intangible assets		-389	-616	-10,046
Other operating expenses		-	-	-
		-18,719	-16,816	-97,259
Operating income		-17,857	-15,772	-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	143	1,072
Interest expenses and other similar loss items		-	-	-5
		1	143	-22,624
Profit/loss before tax		-17,856	-15,628	-118,238
Income tax	2	-	-	-
Profit/loss for the period		-17,856	-15,628	-118,238

(SEK 000)		1 Jan, 2024	1 Jan, 2023	1 Jan, 2023
	Note	31 Mar, 2024	31 Mar, 2023	31 Dec, 2023
Profit/loss for the period		-17,856	-15,628	-118,238
Other comprehensive income  Total comprehensive profit/loss for the period		-17.856	-15.628	-118.238

## Parent Company

# **Balance Sheet**

(SEK 000)	Note	31 Mar, 2024	31 Mar, 2023	31 Dec, 2023
ASSETS				
Non-current assets				
Intangible assets	1			
Patents		10,477	18,469	10,505
Other intangible assets		907	1,042	941
		11,384	19,511	11,446
Tangible assets				
Equipment		13	42	20
		13	42	20
Financial assets				
Shares in subsidiaries	3	1,465	24,557	1,465
Other long-term placement		13,100	13,101	13,101
		14,565	37,658	14,566
Total non-current assets		25,962	57,211	26,032
Current assets				
Short term receivables				
Receivables from group companies		-	602	-
Other receivables		1,301	1,241	1,031
Prepaid expenses and accrued income		6,052	2,646	3,425
		7,353	4,488	4,456
Other short term recievables		-	59,466	-
Cash and bank balances		30,186	58,614	55,826
Total current assets		37,539	122,568	60,282
TOTAL ASSETS		63,501	179,779	86,314

## Parent Company

# **Balance Sheet**

(SEK 000) Note	31 Mar, 2024	31 Mar, 2023	31 Dec, 2023
EQUITY AND LIABILITIES			
Equity			
Restricted equity			
Share capital	52,815	52,815	52,815
Statutory reserve	1,856	1,856	1,856
Development expenditure reserve**	-	788	-
	54,671	55,459	54,671
Unrestricted equity			
Share premium reserve	175,488	175,263	225
Retained earnings	-159,343	-41,892	134,159
Profit/loss for the period	-17,856	-15,628	-118,238
	-1,711	117,742	16,145
Total equity	52,960	173,201	70,816
Short-term liabilities			
Accounts payable	4,898	2,891	9,345
Liabilities subsidiary	1,620	749	1,620
Other liabilities	796	326	319
Accrued expenses and deferred income	3,227	2,612	4,213
	10,541	6,578	15,498
TOTAL EQUITY AND LIABILITIES	63,501	179,779	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	320	-	320
Impaired value	-5	-	-5
Closing balance 31 Mar. 2024	21,927	2,864	24,791
ACCUMULATED DEPRECIATION			
Opening balance 1 Jan. 2024	-11,107	-1,923	-13,030
Depreciation for the period	-60	-318	-378
Impaired value	-283	284	1
Closing balance 31 Mar. 2024	-11,450	-1,957	-13,407
Residual value 31 Mar. 2024	10,477	907	11,384

(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-forwards amounts to SEK 964,457,000 as of 31 March 2024 (825,819,000). The parent company's total loss carry-forwards amounts to SEK 938,246,000 as of 31 March 2024 (799,190,000). 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 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 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 March 2024 was 6 (8), of which 4 (6) are women.

## Important events during the first quarter (Jan-Mar 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 two warrant programs

The annual general meeting on 20 May, 2021, decided on a four-year incentive stock option program 2021/2025 for the Company's CEO. The incentive stock option program entitles the holder to a new share in Abliva AB up to a maximum of 4,600,000 ordinary shares. The redemption price amounts to SEK 0.725. The program is vested at 25% per year on 1 June, 2022, 1 June, 2023, 1 June, 2024 and 1 June, 2025. Latest redemption date is 31 December, 2025. The Board has decided to termintate the program.

The general meeting on 8 March, 2023, decided on a second four-year incentive stock option program 2023/2027 for the Company's CEO. The incentive stock option program entitles the holder to a new share in Abliva AB up to a maximum of 17,500,000 ordinary shares. The redemption price amounts to SEK 0.27. The program is vested at 25% per year on 1 April, 2024, 1 April, 2025, 1 April, 2026 and 1 April, 2027. Latest redemption date is 31 December, 2027.

#### **Warrant Program**

At the general meeting on 8 March, 2023, it was decided on a warrant program 2023/2027 to management and other key employees of a maximum of 23.5 million warrants at a price of SEK 0.06 per warrant, corresponding to a subscription price of SEK 0.67 per share. In total, approx. 10 million options have been subscribed in the warrant program for management and other key employees. Redemption date is 1 June - 31 December 2027.

On 5 May, 2023, the AGM resolved on a warrant program 2023/2027 for certain board members of a maximum of 4.5 million warrants at a price of SEK 0.05 per warrant and a subscription price of SEK 0.5767 per share. One warrant entitles the holder to one new share in Abliva AB Redemption date is June 1 - December 31, 2027.

In case of full utilization of all incentive programs, excluding Employee option program 2021/2025 which is being wound up, the maximum dilution amounts to 2.24 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 Annula report 2023 note 11.

#### **Audit review**

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

#### **Upcoming financial statements**

Q2 Report January-June 2024 August 22, 2024
Q3 Report January-September 2024 November 21, 2024
Year-End Report 2024 February 21, 2025

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

#### **Annual General Meeting 2024**

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

#### Proposed appropriation of profits

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



## Risks and uncertainty factors

A research company such as Abliva AB (publ) is subject to high operational and financial risks because the projects the company conducts are in different developmental phases, where a number of parameters influence the likelihood of commercial success. Briefly, operations are associated with risks relating to factors including drug development, competition, technological progress, patents, regulatory requirements, capital requirements, currencies and interest 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

preferential rights issue in April 2024 of approximately SEK 39.5 million after transaction costs. The Board acknowledges that further funding (equity, loan, grants and/or partnerships) will be required to recruit patients into 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 preferential rights issue of approximately SEK 39.5 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, May 23, 2024

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

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

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

The information was submitted for publication, through the agency of the contact person set out above, at 8:30 a.m. CEST on May 23, 2024.

This Interim Report is published in Swedish and English. In the event of any difference between the English version and the Swedish original, the Swedish version shall prevail.













#### Glossary

**Candidate drug.** A particular compound which is selected during the preclinical phase. The candidate drug is subsequently tested in humans in clinical studies.

Clinical study. The examination of healthy or unhealthy humans to study the safety and efficacy of a pharmaceutical or treatment method. Clinical trials are divided into different phases, termed Phase 1, Phase 2, Phase 3. Phase 2 is usually divided into an early phase (Phase 2a) and a later phase (Phase 2b). See also "phase (1,2 and 3)".

(The) FALCON study. Abliva's global potentially registrational Phase 2 clinical trial with the drug candidate KL1333. The study will evaluate the efficacy of KL1333 on fatigue and muscle weakness in adult patients with primary mitochondrial diseases caused by inherited mutations in the mitochondrial DNA.

**Fatigue.** Extreme tiredness. Often includes muscle fatigue with exercise intolerance.

**FDA.** The United States Federal Food and Drug Administration. **Indication.** A disease condition requiring treatment, such as traumatic brain injury or fatty liver, NASH.

**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 Ophthalmople-gia/Chronic Progressive External Ophthalmoplegia.

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

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

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

**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 mito-chondrial 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 www.abliva.com

