

A person is running away from the camera on a dirt path in a forest. The trees have yellow and orange autumn leaves. The sun is shining from the right, creating a warm glow. The person is wearing a grey hoodie, black leggings, and blue running shoes. The path is covered with fallen leaves.

ABLIVA

Interim Report

January - September 2023

2023

Delivering mitochondrial health

Third Quarter Summary

KL1333 Received FDA Fast Track Designation | The FALCON Study Reached an Important Milestone

Important events July – September 2023

- Fast Track designation was received for Abliva's lead drug candidate KL1333 from the U.S. Food and Drug Administration (FDA), facilitating its clinical development and path forward to market.
- World Mitochondrial Disease Week was recognized by Abliva by the release of videos highlighting the ongoing activities at the company. The videos can be found at Abliva's website www.abliva.com.

Important events after the reporting period

- The target number of patients required for screening was reached in Wave 1 of the FALCON study with lead candidate KL1333. The study continues as planned and the interim analysis is expected towards the middle of 2024.
- A licensing and collaboration agreement for Abliva's NeuroSTAT®, for the treatment of moderate to severe traumatic brain injury (TBI), was signed by Abliva and Owl Therapeutics of San Antonio, Texas (US).

Financial information

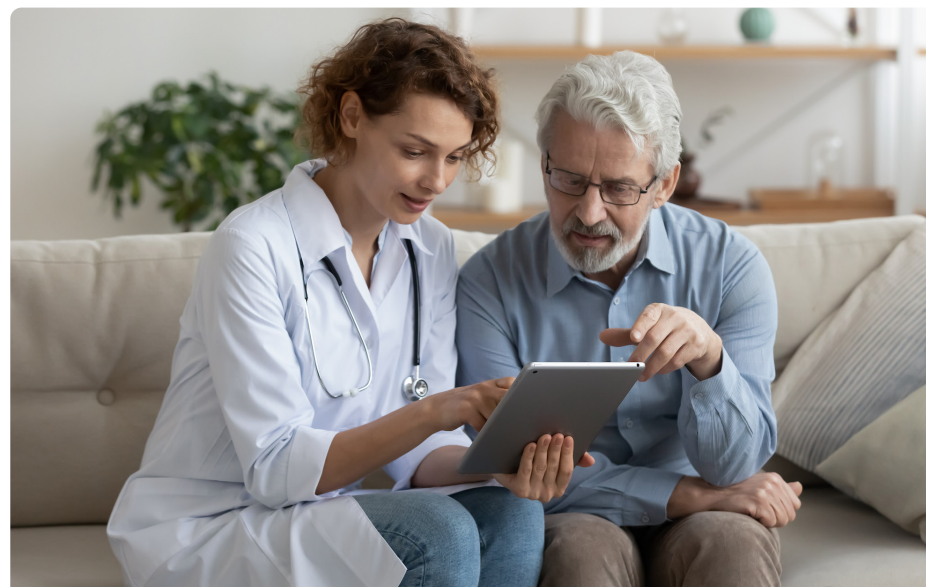
July-September 2023*

- Net revenues: SEK 0 (31,000)
- Other operating income: SEK 0 (651,000)
- Loss before tax: SEK 32,942,000 (25,124,000)
- Loss per share before dilution: SEK 0.03 (0.04)
- Diluted loss per share: SEK 0.03 (0.04)

January-September 2023*

- Net revenues: SEK 0 (31,000)
- Other operating income: SEK 2,783,000 (212,000)
- Loss before tax: SEK 70,260,000 (67,688,000)
- Loss per share before dilution: SEK 0.07 (0.11)
- Diluted loss per share: SEK 0.07 (0.11)

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



Patients Flock to FALCON

The execution of the FALCON study exceeded expectations in Q3 with over 90 patients screened in Wave 1 of the study. The study remains on track to have all eligible Wave 1 patients initiate dosing by the end of 2023 with the interim analysis towards the middle of 2024.

Patients Eager to Participate in FALCON Study

Having achieved first patient dosed in the FALCON study at the end of June, the Abliva team spent the third quarter activating the remaining sites in the study and identifying patients for Wave 1 of the study. We were thrilled to find that all the sites were engaged and active and all 18 of the planned sites had commenced screening patients. It is unusual to have 100% participation from sites in clinical studies and this impressive response speaks to the high unmet need and commitment of the physicians to finding a treatment for these patients as well as an excitement from the investigators in the mechanism of action.

The patients are also clearly interested in new therapies as the response to our study has been outstanding. We were quickly able to identify over 90 patients for evaluation during the screening period of Wave 1 of the study. This number is very encouraging as it suggests that we should be able to quickly identify the remaining patients for Wave 2. It is also supportive of the unmet need in this space, further giving us comfort on our commercial projections suggesting that KL1333 could be a blockbuster therapy with potential revenue of over US \$1billion per annum.

We are now looking forward to initiating dosing in all eligible patients by the end of the year with a goal to dose around 40 patients. The criteria a patient must meet to be dosed and

included in the study are intentionally stringent and will ensure that we include a population of patients with the optimal genotype and phenotype to show improvement when dosed with KL1333.



"We are now looking forward to initiating dosing in all eligible patients by the end of the year"

KL1333 Path to Market Enabled with Fast Track Designation

The Abliva team continues to work to ensure KL1333 is well-positioned for approval upon readout of the FALCON study, and the team was delighted to receive Fast Track Designation for KL1333 by the U.S. Food and Drug Administration (FDA) on September 4. This important designation gives Abliva the opportunity to meet more frequently with the FDA and allows for expedited review of the NDA (New Drug Application), potentially shortening the time to market for KL1333.

NeuroSTAT® Licensing and Collaboration Agreement Provides New Life to the TBI Program

Earlier this week we announced a licensing and collaboration agreement for NeuroSTAT with Owl Therapeutics, a biotech company from San Antonio, Texas (US), focused on the development of diagnostic-enabled therapies for traumatic brain

injury ("TBI") and brain health. Under the terms of the agreement, Abliva is eligible to receive over US\$43 million in clinical and commercial milestones together with royalties in the mid-single digits.

NeuroSTAT has a long and rich history at Abliva with strong data out of experiments done in collaboration with the University of Pennsylvania and favorable results in a Phase 1b/2a clinical study. Although the unmet needs for therapies for both mitochondrial diseases and TBI are substantial, the path to market is quite different from that of our mitochondrial disease portfolio, so we are thrilled that Owl Therapeutics, with their team of TBI experts with backgrounds spanning from academia and large biotech to the US Department of Defense, will provide the focus and expertise necessary to further develop the NeuroSTAT program. Owl Therapeutics will continue to progress the ongoing activities initiated by Abliva, and Abliva will remain involved in the program on a limited basis to ensure the transition is successful and the asset is well positioned for success.

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

PROGRAM	DISEASE	DISCOVERY	PRECLINICAL	PHASE 1	PHASE 2***	MARKET
KL1333*	Mitochondrial disease (mtDNA**)					
NV354*	Mitochondrial disease (Neurology)					
Early programs	Mitochondrial disease					

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

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

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

Strategic focus: Mitochondrial Disease

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

Building the Premier Mitochondrial Medicine Company

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

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

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

Addressing Primary Mitochondrial Disease

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

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

Delivering a Portfolio of First-in-Class Therapies

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

KL1333 is being developed as a treatment for primary mitochondrial disease patients suffering from multiple debilitating symptoms, including chronic fatigue and myopathy. KL1333 has completed several key Phase 1 studies that enabled the start of a potentially registrational Phase 2 study in 2022. KL1333 is protected by a composition of matter patent and Orphan Drug Designation (ODD) in the US and in Europe. It has also received Fast Track Designation in the US. The commercial opportunity is significant with even conservative estimates exceeding USD 1 billion per year in annual sales¹⁾.

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

Further, Abliva has efforts ongoing to identify additional portfolio opportunities focused on the regulation and stabilization of cellular energy production.

Leveraging Opportunities in Rare Diseases

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

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

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

Building a World Class Organization

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

Accessing Capital to Finance the Vision

Abliva is a public company traded on NASDAQ Stockholm (ABLI, Small cap). We appreciate the continued commitment of our shareholders and look to attract new investors as we advance our portfolio and build the company. The investment of Hadean Ventures in 2020 was the first step to bringing specialist investors into the company. 2022 brought investment from life science specialist IP Group plc and Norwegian institutional investor Oslo Pensjonsforsikring AS. We aim to continue to attract new specialist and institutional investors.

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

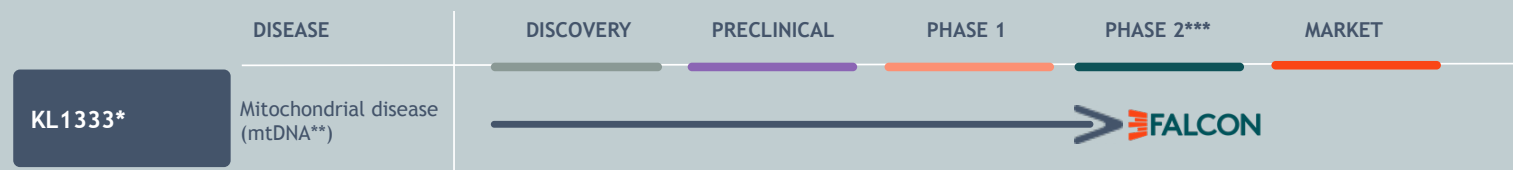
2) Jayasundra et al. Orphanet J of Rare Dis. Estimating the clinical cost of drug development for orphan versus non-orphan drugs. 2019.3) EvaluatePharma, Orphan Drug Report 2019.

KL1333 Innovative therapy in late-stage development

Dosing in patients is ongoing in the FALCON study

Fast Track Designation from FDA

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



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

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

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

Events during the third quarter

- KL1333 received Fast Track designation from the U.S. Food and Drug Administration (FDA), facilitating its clinical development and path forward to market.

Events after the reporting period

- The target number of patients required for screening in Wave 1 of the FALCON study was reached.

Objectives for 2023

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

DISEASE AREA

KL1333 is being developed as a treatment for a subset of adult primary mitochondrial disease patients suffering from multiple debilitating symptoms, including chronic fatigue and myopathy. Diagnoses can include MELAS-MIDD and KSS-CPEO spectrum disorders as well as MERRF syndrome. The drug candidate is intended for long-term oral treatment.

THE FALCON STUDY

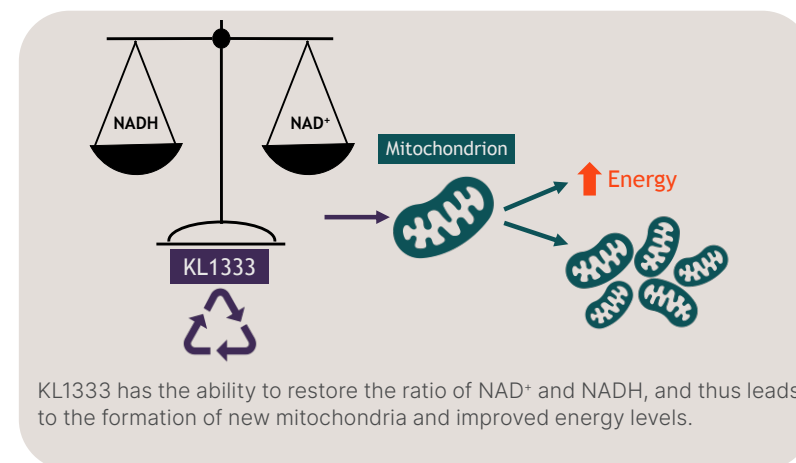
The FALCON study is a global, randomized, placebo-controlled, potentially registrational, clinical Phase 2 study with KL1333. Through the study, the company evaluates the safety and efficacy of KL1333 on primary mitochondrial disease in adult patients with mitochondrial DNA mutations, with a focus on chronic fatigue and muscle weakness which are the most common and debilitating

disease expressions in these patients. The company will recruit 120 – 180 patients, in two waves, who will be given KL1333 or placebo twice daily for 48 weeks. An interim analysis will take place after the completion of Wave 1 and will give important statistical information on safety and powering in Wave 2.

PATH TO MARKET

KL1333's Orphan Drug- and Fast Track designations and the possibility to make a coherent, potentially registrational, study bring significant benefits, and Abliva's intention is to apply for market approval at the conclusion of the study. The number of patients in the target group for treatment with KL1333 is approximately 40,000¹⁾ in Europe and the US. At typical orphan drug pricing, this translates into a blockbuster opportunity.

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



NV354

First-in-class therapeutic targeting high unmet need

Increased patent protection and granted orphan drug designation in the U.S.



*NV354 has Orphan Drug Designation (ODD) in the U.S.

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

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

INITIAL FINDINGS

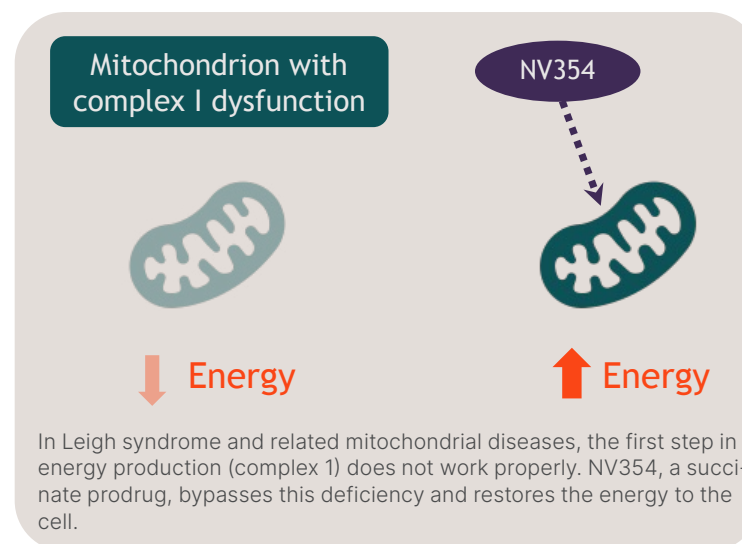
NV354 was discovered due to its ability to increase mitochondrial activity in cells from Leigh syndrome patients. Leigh syndrome is a severe mitochondrial disease that usually debuts at one to two years of age. The disease is fatal, and children usually die before age 5.

TREATMENT OBJECTIVE

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

PATH TO MARKET

Given the orphan drug designation and the high unmet medical need, NV354 is expected to have an expedited path to market and the potential for significant commercial sales.



Out-licensed asset: NeuroSTAT® - For treatment of Traumatic Brain Injury

Traumatic brain injury (TBI) is caused by external force to the head resulting in immediate damage to nerve cells. The damage continues to worsen for several days after the acute trauma. In November 2023, Abliva and US-based Owl Therapeutics signed a licensing and collaboration agreement for NeuroSTAT® for the prevention and treatment of moderate to severe TBI.

Treatment objective

The aim for NeuroSTAT, targeting the mitochondria, is to counteract the emergence of neurological and functional secondary brain damage after a traumatic injury, and thereby establish a therapy that will lead to increased survival, improved quality of life and preserved neurological function.

Project status

NeuroSTAT has shown favorable properties in a Phase 1b/2a clinical study and in advanced experimental TBI models at the

University of Pennsylvania (Penn). NeuroSTAT has orphan drug designation in Europe and the US as well as an IND approval and Fast Track designation for clinical development in the US.

Licensing and collaboration agreement with Owl Therapeutics

In November 2023, Abliva and Owl Therapeutics of San Antonio, Texas, a clinical-stage biopharmaceutical company focused on the development of diagnostic-powered therapeutics for traumatic brain injury (TBI) and brain health, signed a licensing and collaboration agreement for Abliva's NeuroSTAT for the prevention and treatment of moderate to severe TBI.

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

The Abliva team will remain involved in the program and will contribute to the operational and strategic elements of the program. Abliva will contribute by way of an agreed and time-limited commitment with respect to certain Abliva team members.

Owl Therapeutics will continue to progress the ongoing activities initiated by Abliva, and Abliva will remain involved in the program on a limited basis (at no cost to Abliva) to ensure the transition is successful and the asset is well positioned for success.

Consolidated Statement of Comprehensive Income

Revenues

The consolidated turnover during the third quarter of 2023 was SEK 0 (31,000). Other operating revenues for the third quarter were SEK 0 (651,000). During the first nine months of 2023 the consolidated turnover was SEK 0 (31,000). Other operating revenues for the first nine months amounted to SEK 2,783,000 (212,000) and pertain to exchange-rate gains.

Results of operations

The operating loss for the third quarter was SEK 32,938,000 (25,540,000) and for the first nine months the operating loss amounted SEK 70,442,000 (65,365,000). The net loss before tax for the third quarter amounted to SEK 32,942,000 (25,124,000). For the first nine months the loss before tax was 70,260,000 (67,688,000).

The operating loss was affected by other external expenses, which for the first nine months were SEK 48,829,000 (52,414,000). Expenses related to development projects, as a part of external expenses, have affected the result with SEK 37,198,000 (46,319,000) whereof SEK 36,983,000 (45,497,000) relates to project in clinical phase. Expenses during 2023 compared to 2022 is less due to decreased development rate during first part of 2023 pending funding. Personnel expenses during the first nine months amounts to KSEK 14,451,000 (11,283,000) and are higher compared to last year due to bonus reservations. Depreciation and impairment of intangible and tangible assets for the first nine months amount to SEK 9,945,000 (-1,911,000) whereof SEK 7,797,000 refers to impairment of patents. For further information see Note 1 Intangible assets. Other operating expenses amount to SEK 0 (0).

Profit/loss from financial items

Financial items for the nine months amounted to SEK 182,000 (-2,323,000) and refers mainly to accrued interest for short term placements. Comparative figures (2022) refer to 10% interest and set-up costs related to convertible loan from Hadean Ventures.

(SEK 000)	Note	1 Jul, 2023 30 Sep, 2023	1 Jul, 2022 30 Sep, 2022	1 Jan, 2023 30 Sep, 2023	1 Jan, 2022 30 Sep, 2022	1 Jan, 2022 31 Dec, 2022
Net sales		-	31	-	31	31
Other operating income		-	651	2,783	212	1,716
		0	681	2,783	243	1,746
Operating expenses						
Other external expenses		-18,789	-22,178	-48,829	-52,414	-68,298
Personnel cost		-4646	-3,347	-14,451	-11,283	-14,028
Depreciation and write-down of tangible and intangible assets		-8,520	-696	-9,945	-1,911	-2,610
Other operating expenses		-983	-	-	-	-
		-32,938	-26,221	-73,226	-65,608	-84,937
Operating income		-32,938	-25,540	-70,442	-65,365	-83,190
Profit/loss from financial items						
Result from other securities and receivables related to non current assets		-	238	-	238	298
Financial income		13	191	243	191	392
Financial costs		-17	-13	-62	-2,752	-2,764
		-4	416	182	-2,323	-2,073
Profit/loss before tax		-32,942	-25,124	-70,260	-67,688	-85,264
Income tax	2	-13	-	-13	-	-
Profit/loss for the period		-32,954	-25,124	-70,273	-67,688	-85,264
Other comprehensive income						
<i>Items that may be reclassified to profit or loss</i>						
Translation differences on foreign subsidiaries		-8	36	18	213	147
Total comprehensive income for the period		-32,954	-25,088	-70,255	-67,475	-85,117
Loss for the period attributable to:						
Parent company shareholders		-32,954	-25,123	-70,273	-67,686	-85,262
Non-controlling interests		-	-1	-	-2	-2
		-32,954	-25,124	-70,273	-67,688	-85,264
Total comprehensive income for the period						
Parent company shareholders		-32,963	-25,088	-70,255	-67,475	-85,117
Non-controlling interests		-	-	-	-	-
		-32,963	-25,088	-70,255	-67,475	-85,117
Earnings per share before and after dilution(SEK) based on average number of shares		-0.03	-0.04	-0.07	-0.11	-0.12
Average number of shares before and after dilution		1,056,299,165	633,882,892	1,056,299,165	633,882,892	739,486,960

Consolidated Statement of Financial Position

Financial position

Other short-term receivables amounts to 22,985 (93,212) and refer to the investment of surplus liquidity. Cash and cash equivalents amounted to SEK 58,673,000 (73,444,000) as of 30 September 2023. In total, short-term receivables and cash and cash equivalents amount to 81,621,000 a decrease of SEK 63,720,000 compared to the beginning of the year. Total assets as of 30 September 2023 were SEK 109,003,000 (203,674,000).

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	30 Sep, 2023	30 Sep, 2022	31 Dec, 2022
ASSETS				
Non-current assets				
Intangible assets	1			
Patents		10,026	19,310	18,928
Other Intangible assets		975	1,108	1,075
		11,000	20,418	20,004
Tangible assets				
Equipment		27	57	49
Right of use asset leases		856	944	859
		883	1,001	908
Financial assets				
Other long-term securities		13,101	13,101	13,101
		13,101	13,101	13,101
Total non-current assets		24,984	34,520	34,013
Current assets				
Other receivables		1,032	1,371	849
Prepaid expenses and accrued income		1,365	1,127	3,626
Other short term receivables		22,985	93,212	78,949
Cash and cash equivalents		58,637	73,444	66,392
		84,019	169,154	149,816
TOTAL ASSETS		109,003	203,674	183,829

Consolidated Statement of Financial Position

Financial position

The equity/assets ratio was 88 (89) percent as of 30 September 2023, and equity was SEK 95,749,000 (181,829,000). Long term liabilities refers to long term part and tax liability of the right of use asset leases and amount to 534,000 (624,000). Short term Liabilities amounted SEK 12,719,000 (21,221,000) as of 30 September 2023, and mainly refers to activities related to the FALCON study.

(SEK 000)	Note	30 Sep, 2023	30 Sep, 2022	31 Dec, 2022
EQUITY AND LIABILITIES				
Equity attributable to the shareholders of the parent company				
Share capital		52,815	52,815	52,815
Additional paid in capital		906,047	905,221	905,221
Translation reserve		224	899	833
Retained earnings*		-863,336	-777,115	-794,582
Total equity attributable to the shareholders of the parent		95,749	181,820	164,287
Non-controlling interests		-	9	-
Total equity		95,749	181,829	164,287
Long-term liabilities				
Deferred tax liabilities		13	-	-
Other longterm liabilities		521	624	534
		534	624	534
Short-term liabilities				
Accounts payable		6,044	15,524	4,860
Other liabilities		717	533	548
Accrued expenses and deferred income		5,958	5,164	13,599
		12,719	21,221	19,007
Total liabilities		13,253	21,845	19,541
TOTAL EQUITY AND LIABILITIES		109,003	203,674	183,828

Consolidated Statement of Changes in Equity

(SEK 000)	Equity attributable to the shareholders of the parent company					Non- controlling interests	Total equity
	Share- capital	Additional paid in capital	Translation reserve	Retained earnings	Total		
Opening balance, 1 January 2022	20,150	730,560	688	-709,879	41,519	9	41,528
Comprehensive profit/loss for the period	-	-	-	-	-	-	-
Profit/loss for the period	-	-	-	-85,262	-85,262	-2	-85,264
Other comprehensive income	-	-	-	-	-	-	-
Translation differences	-	-	145	-	145	2	147
Other comprehensive profit/loss for the period, net after tax	-	-	145	-	145	2	147
Total comprehensive profit/loss	-	-	145	-85,262	-85,117	-	-85,117
Transactions with shareholders	-	-	-	-	-	-	-
Rights Issue	32,665	174,661	-	-	207,326	-	207,326
Share-based payment	-	-	-	551	551	-	551
Change of ownership in share issue	-	-	-	9	9	-9	-
Total transactions with shareholders	32,665	174,661	-	560	207,886	-9	207,877
Closing balance, 31 December 2022	52,815	905,221	833	-794,581	164,288	0	164,287
Opening balance, 1 January 2022	20,150	730,560	688	-709,879	41,519	9	41,528
Comprehensive profit/loss for the period	-	-	-	-	-	-	-
Profit/loss for the period	-	-	-	-67,686	-67,686	-2	-67,688
Other comprehensive income	-	-	-	-	-	-	-
Translation differences	-	-	211	-	211	2	213
Other comprehensive profit/loss for the period, net after tax	-	-	211	-	211	2	213
Total comprehensive profit/loss	-	-	211	-67,686	-67,475	-	-67,475
Transactions with shareholders	-	-	-	-	-	-	-
Rights Issue*	32,665	174,661	-	-	207,326	-	207,326
Share-based payment	-	-	-	450	450	-	450
Total transactions with shareholders	32,665	174,661	-	450	207,776	-	207,776
Closing balance, 30 September 2022	52,815	905,221	899	-777,115	181,820	9	181,829
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	-	-	-627	-69,646	-70,273	-	-70,273
Other comprehensive income	-	-	-	-	-	-	-
Translation differences	-	-	18	-	18	-	18
Other comprehensive profit/loss for the period, net after tax	-	-	18	-	18	-	18
Total comprehensive profit/loss	-	-	-609	-69,646	-70,255	-	-70,255
Transactions with shareholders	-	-	-	-	-	-	-
Share-based payment	-	827	-	-	827	-	827
Change of ownership in share issue	-	-	-	891	891	-	891
Total transactions with shareholders	-	827	-	891	1,718	-	1,718
Closing balance, 30 September 2023	52,815	906,047	224	-863,336	95,750	0	95,749

Consolidated Statement of Cash Flows

Cash flow and investments

Operating cash flow for the third quarter was SEK 4,945,000 (-104,383,000) whereof SEK 93,212,000 relates to investment of surplus liquidity. For the first nine months the operating cash flow amounted SEK -8,054,000 (152,966,000) (the comparative figure for 2022 includes SEK 93,212,000, which referred to short-term investment of surplus liquidity). The cash flow effect related to investments in intangibles equals SEK -332,000 (-645,000) for the first nine months. The cash flow effect related to investments in financing activities equals SEK 576 (204,506,000) for the first nine months. Cash flow for the third quarter equals SEK -5,148 (-61,792,000). Cashflow for the first nine months equals SEK -7,810,000 (50,953,000).

(SEK 000)	1 Jul, 2023 30 Sep, 2023	1 Jul, 2022 30 Sep, 2022	1 Jan, 2023 30 Sep, 2023	1 Jan, 2022 30 Sep, 2022	1 Jan, 2022 31 Dec, 2022
Cash flow from operating activities					
Operating income	-32,938	-25,540	-70,442	-65,365	-83,190
Adjustments for non-cash items:					
Depreciation	8,520	696	9,945	1,911	2,610
Currency differences on intercompany items	-13	113	43	284	192
Impaired Value	-	-	-10	-	-
Share-based payments	327	100	891	451	551
Result from other securities and receivables related to non current assets	-	238	-	238	298
Interest received	13	191	243	191	392
Interest paid	-17	-13	-62	-13	-25
Paid taxes	-	-	-	-	-
Net cash from operating activities before changes in working capital	-24,108	-24,215	-59,391	-62,303	-79,172
Changes in working capital					
Increase/decrease of other current assets	19,784	-83,265	58,042	-93,791	-81,506
Increase/decrease of other short-term liabilities	-621	3,097	-6,705	3,208	1,118
Changes in working capital	19,163	-80,168	51,337	-90,583	-80,388
Cash flow from operating activities	-4,945	-104,383	-8,054	-152,886	-159,560
Investing activities					
Acquisition of intangible assets	-118	-309	-332	-645	-882
Acquisition of tangible assets	-	-22	-	-23	-23
Cash flow from investing activities	-118	-331	-332	-667	-905
Financing activities					
New share issue	-	18,780	827	180,364	180,364
Amoritzation lease	-85	-	-251	-	-170
Increase/decrease of long-term liabilities	-	24,143	-	24,143	24,223
Cash flow from financing activities	-85	42,922	576	204,506	204,417
Cash flow for the period	-5,148	-61,792	-7,810	50,953	43,952
Cash and cash equivalents at the beginning of the period	63,770	135,159	66,392	22,339	22,339
Effect of exchange rate changes on cash	14	77	55	152	101
Cash and cash equivalents at end of period	58,637	73,444	58,637	73,444	66,392

Parent Company

Income Statement

Parental company

Company earnings after tax for the third quarter amounts to SEK - 56,322,000 (-24,472,000). Earnings after tax for the first nine months amount to SEK -93,309,000 (-66,731,000). As of 31 August 2023, the subsidiary in Hong Kong, NeuroVive Pharmaceutical Ltd ("NVP Asia") was deregistered as Abliva no longer conducts any business in Asia. As a consequence of the closure of the subsidiary, the value of these shares has been written down in the parent company by a total of SEK 23,694,000. Most of the Group's operations are conducted within the parent company. Accordingly, no further specific information regarding the parent company is presented.

Parent Company

Statement of Comprehensive Income

(SEK 000)		1 Jul, 2023	1 Jul, 2022	1 Jan, 2023	1 Jan, 2022	1 Jan, 2022
	Note	30 Sep, 2023	30 Sep, 2022	30 Sep, 2023	30 Sep, 2022	31 Dec, 2022
Net sales		-	31	-	31	31
Other operating income		-	651	2,575	212	1,716
		-	681	2,575	243	1,746
Operating expenses						
Other external expenses		-20,327	-23,111	-53,849	-55,985	-72,875
Personnel cost		-2,723	-1,862	-8,888	-6,854	-8,580
Depreciation and write-down of tangible and intangible assets		-8,425	-610	-9,660	-1,825	-2,439
Other operating expenses		-1,133	-	-	-	-
		-32,609	-25,583	-72,396	-64,664	-83,894
Operating income		-32,609	-24,901	-69,821	-64,422	-82,148
Profit/loss from financial items						
Result from other securities and receivables related to non current assets		-23,725	238	-23,725	238	298
Interest income and other similar profit items		13	191	243	191	392
Interest expenses and other similar loss items		-	-	-6	-2,738	-2,738
		-23,713	429	-23,488	-2,309	-2,048
Profit/loss before tax		-56,322	-24,472	-93,309	-66,731	-84,196
Income tax	2	-	-	-	-	-
Profit/loss for the period		-56,322	-24,472	-93,309	-66,731	-84,196

(SEK 000)		1 Jul, 2023	1 Jul, 2022	1 Jan, 2023	1 Jan, 2022	1 Jan, 2022
	Note	30 Sep, 2023	30 Sep, 2022	30 Sep, 2023	30 Sep, 2022	31 Dec, 2022
Profit/loss for the period		-56,322	-24,472	-93,309	-66,731	-84,196
Other comprehensive income		-	-	-	-	-
Total comprehensive profit/loss for the period		-56,322	-24,472	-93,309	-66,731	-84,196

Parent Company

Balance Sheet

(SEK 000)	Note	30 Sep, 2023	30 Sep, 2022	31 Dec, 2022
ASSETS				
Non-current assets				
<i>Intangible assets</i>	1			
Patents		10,026	19,310	18,928
Other intangible assets		975	1,109	1,075
		11,000	20,418	20,004
<i>Tangible assets</i>				
Equipment		27	57	49
		27	57	49
<i>Financial assets</i>				
Other long-term placement		13,100	13,100	13,101
Shares in subsidiaries	3	1,465	24,558	24,557
		14,565	37,658	37,658
Total non-current assets		25,593	58,133	57,711
Current assets				
<i>Short term receivables</i>				
Receivables from group companies		-	-	-
Other receivables		1,010	1,345	825
Prepaid expenses and accrued income		1,311	1,118	3,626
		2,321	2,463	4,451
Other short term recievables		22,985	93,212	78,949
Cash and bank balances		57,053	72,375	65,123
Total current assets		82,359	168,050	148,522
TOTAL ASSETS		107,952	226,183	206,234

Parent Company

Balance Sheet

(SEK 000)	Note	30 Sep, 2023	30 Sep, 2022	31 Dec, 2022
EQUITY AND LIABILITIES				
Equity				
<i>Restricted equity</i>				
Share capital		52,815	52,815	52,815
Statutory reserve		1,856	1,856	1,856
Development expenditure reserve**		-	1,629	1,247
		54,671	56,300	55,919
<i>Unrestricted equity</i>				
Share premium reserve		175,488	245,195	174,661
Retained earnings		-41,104	-29,072	41,844
Profit/loss for the period		-93,309	-66,731	-84,196
		41,074	149,393	132,309
Total equity		95,745	205,692	188,228
Short-term liabilities				
Accounts payable		6,021	15,211	4,602
Liabilities subsidiary		1,649	1,346	1,290
Other liabilities		349	206	213
Accrued expenses and deferred income		4,188	3,728	11,901
		12,206	20,491	18,006
TOTAL EQUITY AND LIABILITIES		107,952	226,183	206,234

Notes

Note 1 — Intangible assets

(SEK 000)	Patents	Other	Total
ACCUMULATED COST			
Opening balance 1 Jan. 2023	36,086	2,864	38,950
Additions	635	-	635
Impaired value	-14,949	-	-14,949
Closing balance 30 Sep. 2023	21,771	2,864	24,635
ACCUMULATED DEPRECIATION			
Opening balance 1 Jan. 2023	-17,158	-1,789	-18,947
Depreciation for the period	-1,739	-100	-1,840
Impaired value	7,152	-	7,152
Closing balance 30 Sep. 2023	-11,746	-1,889	-13,635
Residual value 30 Sep. 2023	10,026	975	11,000

*During the third quarter, the company has carried out a strategic review of the patent portfolio. Lower value patents (due to focus, age, location) were impaired at a book value of SEK 7,797,000.

(SEK 000)	Patents	Other	Total
ACCUMULATED COST			
Opening balance 1 Jan. 2022	35,180	2,864	38,044
Additions	906	-	906
Impaired value	-	-	-
Closing balance 31 Dec. 2022	36,086	2,864	38,950
ACCUMULATED DEPRECIATION			
Opening balance 1 Jan. 2022	-14,887	-1,654	-16,541
Depreciation for the period	-2,271	-134	-2,406
Impaired value	-	-	-
Closing balance 31 Dec. 2022	-17,158	-1,789	-18,947
Residual value 31 Dec. 2022	18,928	1,075	20,004

Note 2 – Tax

The group's total loss carry-forwards amounts to SEK 921,771,000 as of 30 September 2023 (792,023,000). The parent company's total loss carry-forwards amounts to SEK 919,328,000 as of 30 September 2023 (765,652,000). Because the company is loss making, management cannot judge when deductible loss carry-forwards will be utilized.

Note 3 – Shares and participations in group companies

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

Other disclosures

Transactions with related parties

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

No compensation based on sales has been paid during the period under the agreement, in relation to mitochondrial energy regulation projects, with the Research Group at Lund University, which includes CSO Eskil Elmér and CMO Magnus Hansson.

At the EGM on 8 March, 2023, the meeting resolved on a bonus, amounting to to SEK 340,000, to Board Member Edwin Moses to subsidize the participant's tax costs for participation in Warrant program for the board member 2023/2027 through a bonus payment in cash.

The AGM on 5 May, 2023 resolved on a bonus payment in cash to David Laskow-Pooley of SEK 937,500. David Laskow-Pooley is required to use the full amount of the Bonus, net after income tax to acquire Abliva shares on the stock market. The company will pay the social security costs. The shares acquired for the Bonus will be locked in for a period of three (3) years after the acquisition.

Segment information

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

Human resources

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

Important events during the third quarter (Jul-Sep 2023)

For further information, see page 2.

Important events after the reporting period

For further information, see page 2.

Incentive programs/share warrants

The Company has two option programs and two warrant programs

Option Program

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 0.27. The program is vested at 25% per year on 1 June, 2022, 1 June, 2023, 1 June, 2024 and 1 June, 2025. Latest redemption date is 31 December, 2025.

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

Warrant Program

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 23.75 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 and key employees. 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. The warrant program is fully subscribed. One warrant entitles the holder to one new share in Abliva AB. Redemption date is June 1 - December 31, 2027.

In case of full utilization of all incentive programs the maximum dilution amounts to 4.55 per cent. 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 note 12.

Audit review

This Interim Report has been subject to review by the company's auditors in accordance with the Standard on Review Engagements (ISRE) 2410, Review of Interim Financial Information Performed by the Independent Auditor of the Entity.

Upcoming financial statements

Year-End Report 2023	February 23, 2024
Q1 Report January-March 2024	May 23, 2024
Q2 Report January-June 2024	August 22, 2024
Q3 Report January-September 2024	November 21, 2024
Year-End Report 2024	February 21, 2025

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

Risks and uncertainty factors

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

Financing

The Board continuously monitors and evaluates the company's funding need and financial position. The company announced a financing of SEK 200 million in June 2022 and acknowledges that further funding (equity, grants and/or partnerships) will be required prior to the start of Wave 2 of the FALCON study. If

the company is not successful in securing financing, there is a risk that Wave 2 of the program will be delayed. By adapting the pace of ongoing activities, regardless of the status regarding additional funding, there are conditions for continuing the business for the next twelve-month period. The interim report is thus prepared on the basis of a going concern assumption.

Macroeconomic and geopolitical factors

The Russian invasion of Ukraine in February 2022 has worsened the political security situation in the rest of the world and created significant uncertainty in the financial markets, which may affect the company. The company has no direct business in, nor does it conduct any preclinical or clinical studies in Ukraine or Russia, but sees a risk that the company eventually will suffer from increased raw material and energy prices, which are likely

to translate into both increased prices for goods and services as well as a change in strategy by investors and potential partners.

Disputes

Abliva is not involved in any disputes.

For more details on risks and uncertainty factors, refer to the Statutory Administration Report in the Annual Report for 2022 and the prospectus published on June 8, 2022.

Principles of preparation of the Interim Report

Abliva prepares its consolidated accounts in accordance with International Financial Reporting Standards (IFRS) issued by the International Accounting Standards Board (IASB) and interpretation statements from the IFRS Interpretations Committee, as endorsed by the EU for application within the EU. This Interim Report has been prepared in accordance with IAS 34 Interim Financial Reporting.

The parent company applies the Swedish Annual Accounts Act and RFR's (the Swedish Financial Reporting Board) recommendation RFR 2 Accounting for Legal Entities. Application of RFR 2 implies that, as far as possible, the parent company applies all IFRS endorsed by the EU within the limits of the Swedish Annual Accounts Act and the Swedish Pension Obligations Vesting Act,

and considering the relationship between accounting and taxation.

The group and parent company have applied the accounting principles described in the Annual Report for 2022 on pages 41-56.

Definitions alternative performance measures

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

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

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

The following key figures are used:	Definition	Reason for use
Net revenues	Revenue from goods and services sold that are part of the company's normal operations	
Other operating income	Income from secondary activities in ordinary activities such as grants received	
Operating income	Net sales and other revenues minus expenses for other external costs, personnel costs, depreciation and impairment and other expenses	Measures the result in the operations
Profit/loss before tax	Operating income after profit/loss from 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, November 17, 2023

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



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 November 17, 2023.

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

Auditor's review report

**TO THE BOARD OF DIRECTORS OF ABLIVA AB (PUBL),
CORP.ID.NO 556595-6538**

Introduction

We have reviewed the condensed interim report for Abliva AB (publ) as at September 30, 2023 and for the nine months period then ended. The Board of Directors and the Managing Director are responsible for the preparation and presentation of this interim report in accordance with IAS 34 and the Swedish Annual Accounts Act. Our responsibility is to express a conclusion on this interim report based on our review.

Scope of review

We conducted our review in accordance with the International Standard on Review Engagements, ISRE 2410 Review of Interim

Financial Statements Performed by the Independent Auditor of the Entity. A review consists of making inquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with International Standards on Auditing and other generally accepted auditing standards in Sweden. The procedures performed in a review do not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion.

Conclusion

Based on our review, nothing has come to our attention that causes us to believe that the interim report is not prepared, in

all material aspects, in accordance with IAS 34 and the Swedish Annual Accounts Act regarding the Group, and in accordance with the Swedish Annual Accounts Act regarding the Parent Company.

Uppsala, November 17, 2023.

Ernst & Young AB

Oskar Wall

Authorized Public Accountant

Glossary

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

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

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

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

FDA. The United States Federal Food and Drug Administration.

Hypotonia. An abnormally low level of tension, important for posture, in the resting muscle.

Indication. A disease condition requiring treatment, such as traumatic brain injury or fatty liver, NASH.

Interim analysis. The analysis of data in a clinical trial comparing intervention groups before the formal completion of the trial, typically before patient recruitment is complete. Can be used for various purposes, such as assessing the statistical strength of the study to meet the predetermined endpoints.

KSS. Mitochondrial disease, Kearns-Sayre’s syndrome. The disease debuts before the age of 20 and is characterized by eye related symptoms with pigment retention in the retina and paralysis of the outer eye muscles, as well as the effects on the cardiac retinal system and the cerebellum with disorders in the coordination of muscle movements (ataxia).

Leigh syndrome. Leigh syndrome is a serious condition with characteristic changes to the brain that usually affects small children. This disease is caused by faults in energy-producing mitochondria and is also known as subacute (fast onset) necrotizing (tissue destroying) encephalomyopathy (a disease of the brain and muscles).

LHON. Mitochondrial disease, Leber Hereditary Optic Neuropathy.

Affects the retina and the optic nerve, but in rare cases symptoms can be found in other parts of the central nervous system. There is no cure, but treatments are focused primarily on compensating for the visual impairment.

MELAS. MELAS is an acronym of mitochondrial encephalomyopathy (brain and muscle disease) with lactic acidosis (increased lactic acid levels in the blood) and 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.

MHRA. The UK Medicines and Healthcare products Regulatory Agency.

MIDD. Maternally Inherited Diabetes and Deafness

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

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

Mitochondrial myopathy. Primary mitochondrial disease which affects the muscles.

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

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

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

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

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

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

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

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

Succinate. Endogenous substance that plays an important role in mitochondrial energy production. Succinate is used by mitochondrial protein complex II.

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

About Abliva

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

What is primary mitochondrial disease?

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

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

Stock exchange

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

Abliva AB (publ)

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