


ABLIVA

Interim Report
January - September 2022



The activities required to start the KL1333 study ramped up over the last three months.

Ellen Donnelly, CEO

Delivering mitochondrial health

Third quarter summary

Additional regulatory approvals to start the FALCON study with KL1333

World Mitochondrial Disease Week raised awareness of mitochondrial diseases



Important events third quarter (Jul - Sep 2022)

- Abliva received additional regulatory approvals to start the FALCON study with KL1333.
- Abliva participated in World Mitochondrial Disease Week 2022 through videos focused on increasing the understanding of the community to rare disease development, and more specifically to the development of new therapies for primary mitochondrial diseases. The videos are available on Abliva's website.

Financial information

July-September 2022*

- Net revenues: SEK 31,000 (85,000)
- Other operating income: SEK 651,000 (0,000)
- Loss before tax: SEK 25,124,000 (34,854,000)
- Loss per share before dilution: SEK 0.04 (0.09)
- Diluted loss per share: SEK 0.04 (0.09)

January-September 2022*

- Net revenues: SEK 31,000 (103,000)
- Other operating income: SEK 212,000 (0,000)
- Loss before tax: SEK 67,688,000 (86,624,000)
- Loss per share before dilution: SEK 0.11 (0.24)
- Diluted loss per share: SEK 0.11 (0.24)

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

Building the Foundation (in Q3) to Deliver in Q4 and beyond

The third quarter marked a new phase for the company as we started utilizing our recent SEK 200 million raise by shifting into high gear in preparation for the KL1333 FALCON study. The raise did not change our direction or behaviors, with fiscal conservatism and a focus on delivery and prioritization remaining core. We are keeping a careful eye on the macroenvironment as inflation, interest rates, energy prices, elections and the war in Ukraine all bring continued risk to our industry.

KL1333 Clinical Study Remains on Track for 2022 Start

The activities required to start the KL1333 study ramped up over the last three months as we worked with our global contract research organization, ICON, to finalize translations of study documentation, build databases, program the assessments on tablets, contract with sites, and file regulatory and ethics documents in each country. We continue to receive beneficial feedback from regulatory authorities and have now added Denmark to our list of approved countries. We remain on track to achieve FALCON study start by the end of the year, and we had a productive Investigator Meeting with our committed site teams in mid-November.

Prioritization on Delivery and High Value Activities

Unlike many foreign (U.S. in particular) biotech companies where infrastructure costs are high and the number of full-time staff often number in the several tens of individuals, we intentionally keep our internal footprint and operational costs low while continuously reviewing our priorities to ensure our money is being spent efficiently on the highest value activities while optimizing the pace. The use of proceeds from the recent financing was focused on KL1333 and thus our activities have followed suit as we keep laser focused on delivering interim data from the FALCON study. For this reason, we have intentionally pushed some

goals for the NV354 program into 2023 to ensure KL1333 has our full attention during this critical stage of the study.

Telling Our Story to Impact Patient Recruitment

While study start is our next goal, our attention is also focused on increasing the awareness of the mitochondrial community, physicians, and patients to the FALCON study, to ensure efficient patient recruitment. The team spent a great deal of time this quarter engaging with the mitochondrial community with visits across Europe to present the FALCON study and meet with physicians and sites. We also engaged with patients during Mitochondrial Disease Awareness Week where we joined forces with the global mitochondria community to bring resources and learnings to patients suffering from mitochondrial diseases. I would encourage you to listen to our interview with Daniela Gallo, mitochondrial disease patient and clinical trial coordinator, which can be found on our YouTube site (<https://www.youtube.com/channel/UChqP7Ky5caXtp72CELhD6Mg>).

This is a challenging time for our industry. We must remain aware of the external dynamics but keep focused on our key priorities as well as on improving the quality of life for severely ill patients. The large financing round we completed in June provided the essential cash runway which we believe should enable delivery on our key priority of achieving interim data from the FALCON study, but we will not rest. We move forward evaluating all potential strategic opportunities and partnerships as we assess ways to increase the value from other parts of our of our business to maximize the opportunities across our pipeline.

Best wishes to all of you as we approach the end of another exciting year for Abliva.

Ellen Donnelly
CEO



"We remain on track to achieve FALCON study start by the end of the year, and we had a productive Investigator Meeting with our committed site teams in mid-November"



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

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

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

*Orphan drug designation in the US and Europe.

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

Strategic focus: Mitochondrial Diseases

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

Building the Premier Mitochondrial Medicine Company

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

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

Addressing Primary Mitochondrial Diseases

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

mature mortality. Mitochondrial medicine has become an area of 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 quality of life for these patients.

Delivering a Portfolio of First-in-Class Therapies

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

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

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

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

Leveraging Opportunities in Rare Diseases

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

ulatory designation that provides sponsors with a number of advantages including more regulatory assistance and scientific advice during the development process, lower development costs, attractive pricing, and market exclusivity (10 years in the EU and 7 years in the US). The outlook for reaching the market is also better than for traditional medicines^{2,3}.

In addition, we have sought scientific advice from pharmaceutical regulators in the US, UK and Europe. This advice has been extremely important to the company, as is clearly demonstrated with the advice from the FDA that led us to move to a single, potentially registrational Phase 2 study, allowing us to get to market more quickly.

Building a World Class Organization

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

Accessing Capital to Finance the Vision

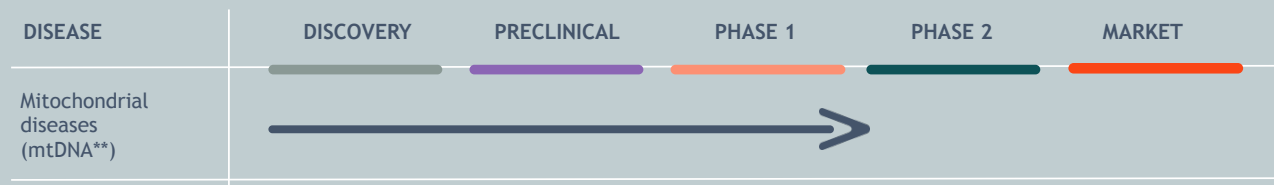
Abliva is a public company traded on NASDAQ Stockholm (ABLI, Small cap). The company appreciates the continued commitment of our shareholders and looks to attract new investors as we advance our portfolio and build the company. The investment of Hadean Ventures in 2020 was the first step to bringing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

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

2) 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 by the end of 2022

Financing enables start of the FALCON study in 2022
 Positive safety results and signs of efficacy from Phase 1a/b study
 Orphan drug designation in both the United States and Europe



Events since the start of the third quarter

- The company has received additional regulatory approvals (in Denmark and Belgium) to start the FALCON study, in addition to previously received approvals in the US and UK.
- The study vendors have been fully activated, and an investigator meeting has been held with the study personnel.

Objectives for 2022

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

DISEASE AREA

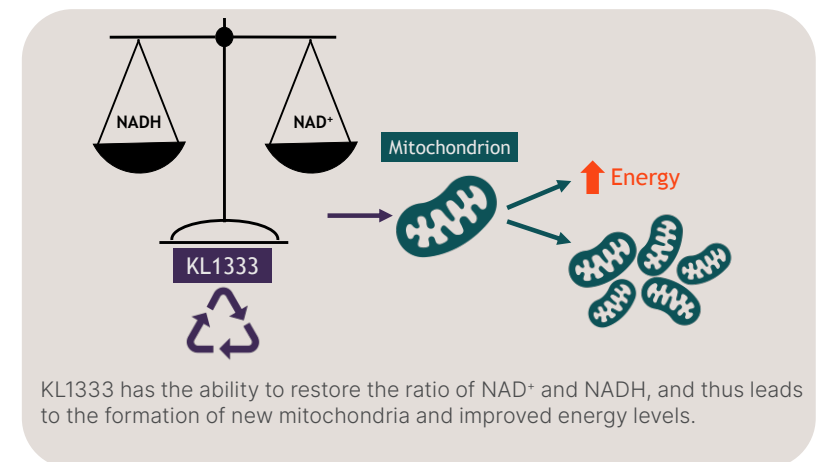
KL1333 is being developed as a treatment for a subset of adult primary mitochondrial disease patients suffering from multiple debilitating symptoms, including mitochondrial fatigue and myopathy. Diagnoses can include MELAS-MIDD and KSS-CPEO spectrum disorders as well as MERRF syndrome.

The drug candidate is intended for long-term oral treatment.

PATH TO MARKET

The recommendation from the FDA to make a coherent, potentially registrational study brings significant benefits to the KL1333 project, and Abliva's intention is to apply for market approval during 2026. The number of patients in the target group for treatment with KL1333 is approximately 40,000¹⁾ in Europe and the US. At typical orphan drug pricing, this translates into a blockbuster opportunity.

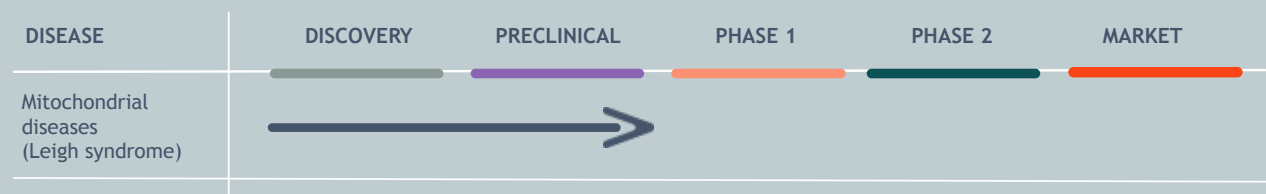
1) Gorman et al., Prevalence of Nuclear and Mitochondrial DNA Mutations Related to Adult Mitochondrial Disease, 2015



NV354

First-in-class therapeutic approaching clinical development

Positive feedback from UK MHRA scientific advice meeting



Events since the start of the third quarter

- Given the prioritization of KL1333, the progression of NV354 to Phase 1 continues at a reduced speed.
- The objectives for 2022 will carry over to 2023.

Objectives for 2022

- Produce NV354 clinical trial material for clinical Phase 1 study.
- Complete regulatory documentation to support clinical entrance.

PRIMARY INDICATION

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

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

EXPANSION OPPORTUNITY

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

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

PATH TO MARKET

Given the rarity of these conditions and the high unmet medical need, NV354 is expected to have an expedited path to market and a substantial commercial opportunity. Internal analyses suggest a launch in Leigh syndrome followed by expansion in LHON and MELAS could result in annual peak sales approaching USD 1 billion.

Mitochondrion with Leigh syndrome



↓ Energy

NV354



↑ Energy

In Leigh syndrome and related mitochondrial diseases, the first step in energy production (complex 1) does not work properly. NV354, a succinate prodrug, bypasses this deficiency and restores the energy needed.

Non-core asset: NeuroSTAT - For treatment of Traumatic Brain Injury

Traumatic brain injury (TBI) is caused by external force to the head resulting in immediate damage to nerve cells. The damage continues to worsen for several days after the acute trauma.

Treatment objective

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

Project status

NeuroSTAT has shown favorable properties in a Phase 1b/IIa clinical study and in advanced experimental TBI models at the University of Pennsylvania (Penn). NeuroSTAT has orphan drug designation in Europe and the US as well as an IND approval and Fast Track designation for clinical development in the US.

Abliva continues discussions with the TRACK-TBI network regarding a potential collaboration within the scope of the Precision Medicine project^{1) 2)} for a Phase 2 study of traumatic brain injury with NeuroSTAT. TRACK-TBI has updated its timelines, hence the study, if authorized by US Department of Defense (DOD), would commence in 2023 at the earliest, contingent upon DOD's approval of earlier steps of the project.

With a potential agreement with TRACK-TBI as a partner, the company will review possible options that may enable developing the NeuroSTAT program further.

1 Precision Medicine grant: TRACK-TBI Precision Medicine is a DOD-funded project run by the leading traumatic brain injury (TBI) clinical trial network TRACK-TBI in the US. The aim of the project is to validate novel imaging and blood -based biomarkers for moderate/severe TBI to enable precision medicine TBI clinical trials with a focus on specific disease pathologies and enriched study populations.

2 The views expressed regarding the Precision Medicine project are those of the company/authors and may not reflect the official policy or position of the Department of the Army, Department of Defense, or the U.S. Government.

Consolidated Statement of Comprehensive Income

Revenues

The consolidated turnover during the third quarter of 2022 was SEK 31,000 (85,000). Other operating revenues for the third quarter were SEK 651,000 (0,000) and pertain to exchange-rate gains. During the first nine months of 2022 the consolidated turnover was SEK 31,000 (103,000). Other operating revenues for the first nine months amounted to SEK 212,000 (0,000) and refers to net reported foreign exchange gains/losses of an operating nature.

Results of operations

The operating loss for the third quarter was SEK 25,540,000 (34,851,000) and for the first nine months the operating loss amounted SEK -65,365,000 (-86,613,000). The net loss before tax for the third quarter amounted to SEK 25,124,000 (34,854,000). For the first nine months the loss before tax was 67,688,000 (-86,624,000).

The operating loss was affected by other external expenses, which for the first nine months were SEK 52,414,000 (70,381,000). Expenses related to development projects, as a part of external expenses, have affected the result with SEK 45,497,000 (60,687,000) whereof SEK 45,908,000 (56,356,000) relates to project in clinical phase. Expenses during 2022 compared to 2021 is lower due to decreased development rate during first part of 2022 pending funding. Personnel expenses during the first nine months amounts to SEK 11,283,000 (13,899,000). Personnel expenses are lower compared to 2021 when salary during the notice period and severance pay to the former CEO were included. Other operating expenses amount to, SEK 0,000 (456,000) and pertained to exchange-rate losses in 2021.

(SEK 000)	Note	1 Jul, 2022 30 Sep, 2022	1 Jul, 2021 30 Sep, 2021	1 Jan, 2022 30 Sep, 2022	1 Jan, 2021 30 Sep, 2021	1 Jan, 2021 31 Dec, 2021
Net sales		31	85	31	103	151
Other operating income		651	-	212	-	-
		681	85	243	103	151
Operating expenses						
Other external expenses		-22,178	-30,688	-52,414	-70,381	-103,695
Personnel cost		-3,347	-3,400	-11,283	-13,899	-16,844
Depreciation and write-down of tangible and intangible assets		-696	-663	-1,911	-1,980	-2,764
Other operating expenses		-	-186	-	-456	-330
		-26,221	-34,936	-65,608	-86,716	-123,633
Operating income		-25,540	-34,851	-65,365	-86,613	-123,482
Profit/loss from financial items						
Result from other securities and receivables related to non current assets		238	-	238	-	-
Financial income		191	-	191	-	-
Financial costs		-13	-2	-2,752	-10	-12
		416	-2	-2,323	-10	-12
Profit/loss before tax		-25,124	-34,854	-67,688	-86,624	-123,494
Income tax	2	-	-	-	-	-4
Profit/loss for the period		-25,124	-34,854	-67,688	-86,624	-123,498
Other comprehensive income						
Items that may be reclassified to profit or loss						
<i>Translation differences on foreign subsidiaries</i>		36	13	213	11	71
Total comprehensive income for the period		-25,088	-34,841	-67,475	-86,613	-123,427
Loss for the period attributable to:						
Parent company shareholders		-25,123	-34,853	-67,686	-86,622	-123,492
Non-controlling interests		-1	-	-2	-2	-6
		-25,124	-34,853	-67,688	-86,624	-123,498
Total comprehensive income for the period						
Parent company shareholders		-25,088	-34,840	-67,475	-86,612	-123,420
Non-controlling interests		-	-	-	-2	-7
		-25,088	-34,841	-67,475	-86,613	-123,427
Earnings per share before and after dilution(SEK) based on average number of shares		-0.04	-0.09	-0.11	-0.24	-0.33
Average number of shares before and after dilution		633,882,892	395,895,687	633,882,892	359,221,764	370,168,023

Consolidated Statement of Financial Position

Financial position

The equity/assets ratio was 89 (78) percent as of 30 September 2022, and equity was SEK 181,829,000 (77,957,000). The equity includes funds from the in June completed directed share issue, which provided the company with net SEK 137,362,000 after deduction of issue costs of SEK 13,038,000 and the in July completed 100% guaranteed preferential rights issue, which provided the company with net SEK 43,003,000 after deduction of issue costs of SEK 8,289,000 wherof SEK 6,155,000 constituted compensation to the guarantors. In addition Equity includes the conversion of the convertible loan from Haeen Ventures amounting to 26,961,000 SEK. Short term Liabilities amounted SEK 21,221,000 (21,946,000) as of 30 September 2021, and mainly refers to preparatory activities before the start of the FALCON study with KL1333. Other short-term receivables amounts to 93,212 (0) and refer to the investment of surplus liquidity. Cash and cash equivalents amounted to SEK 73,444,000 (63,267,000) as of 30 September 2022, an increase of SEK 51,105,000 from the beginning of the year. Total assets as of 30 September 2022 were SEK 203,674,000 (99,903,000).

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, 2022	30 Sep, 2021	31 Dec, 2021
ASSETS				
Non-current assets				
Intangible assets	1			
Patents		19,310	20,303	20,293
Other Intangible assets		1,108	1,243	1,210
		20,418	21,546	21,503
Tangible assets				
Equipment		57	71	60
Righth of use asset leases		944	86	-
		1,001	157	60
Financial assets				
Other long-term securities		13,101	13,101	13,101
		13,101	13,101	13,101
Total non-current assets		34,520	34,804	34,664
Current assets				
Other receivables		1,371	1,088	912
Prepaid expenses and accrued income		1,127	743	1,003
Other short term recivables		93,212	-	-
Cash and cash equivalents		73,444	63,267	22,339
		169,154	65,099	24,254
TOTAL ASSETS		203,674	99,903	58,918

Consolidated Statement of Financial Position

(SEK 000)	Note	30 Sep, 2022	30 Sep, 2021	31 Dec, 2021
EQUITY AND LIABILITIES				
Equity attributable to the shareholders of the parent company				
Share capital		52,815	20,150	20,150
Additional paid in capital		905,221	730,592	730,560
Translation reserve		899	627	688
Retained earnings		-777,115	-673,424	-709,879
Total equity attributable to the shareholders of the parent		181,820	77,944	41,519
Non-controlling interests		9	13	9
Total equity		181,829	77,957	41,528
Long-term liabilities				
Other longterm liabilities		624	-	-
		624	-	-
Short-term liabilities				
Accounts payable		15,524	15,587	9,616
Other liabilities		533	359	277
Accrued expenses and deferred income		5,164	5,999	7,497
		21,221	21,946	17,390
Total liabilities		21,845	21,946	17,390
TOTAL EQUITY AND LIABILITIES		203,674	99,903	58,918

Consolidated Statement of Changes in Equity

(SEK 000)	Equity attributable to the shareholders of the parent company					Non-controlling interests	Total equity
	Share-capital	Additional paid in capital	Translation reserve	Retained earnings	Total		
Opening balance, 1 January 2021	14,817	660,025	616	-586,802	88,656	-0	88,656
Comprehensive profit/loss for the period	-	-	-	-	-	-	-
Profit/loss for the period	-	-	-	-86,622	-86,622	-2	-86,624
Other comprehensive income	-	-	-	-	-	-	-
Translation differences	-	-	11	-	11	-	11
Other comprehensive profit/loss for the period, net after tax	-	-	11	-	11	-	11
Total comprehensive profit/loss	-	-	11	-86,622	-86,612	-2	-86,613
Transactions with shareholders	-	-	-	-	-	-	-
Rights Issue	5,333	70,567	-	-	75,900	-	75,900
Change of ownership in share issue	-	-	-	-	-	14	14
Total transactions with shareholders	5,333	70,567	-	-	75,900	14	75,914
Closing balance, 30 September 2021	20,150	730,592	627	-673,424	77,944	13	77,957
Opening balance, 1 January 2021	14,817	660,025	616	-586,802	88,656	0	88,656
Comprehensive profit/loss for the period	-	-	-	-	-	-	-
Profit/loss for the period	-	-	-	-123,492	-123,492	-6	-123,498
Other comprehensive income	-	-	-	-	-	-	-
Translation differences	-	-	72	-	72	-1	71
Other comprehensive profit/loss for the period, net after tax	-	-	72	-	72	-1	71
Total comprehensive profit/loss	-	-	72	-123,492	-123,420	-7	-123,427
Transactions with shareholders	-	-	-	-	-	-	-
Rights Issue*	5,333	70,535	-	-	75,868	-	75,868
Share-based payment	-	-	-	415	415	-	415
Shareholder contribution	-	-	-	-	-	16	16
Total transactions with shareholders	5,333	70,535	-	415	76,283	16	76,299
Closing balance, 31 December 2021	20,150	730,560	688	-709,879	41,519	9	41,528
Opening balance, 1 January 2022	20,150	730,560	688	-709,879	41,519	9	41,528
Comprehensive profit/loss for the period	-	-	-	-	-	-	-
Profit/loss for the period	-	-	-	-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	0	-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

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

Consolidated Statement of Cash Flows

Cash flow and investments

Operating cash flow for the third quarter was SEK -104,463,000 (-30,307,000) whereof SEK 93,212,000 relates to investment of surplus liquidity. For the first nine months the operating cash flow amounted SEK 152,966,000 (-73,297,000). The cash flow effect related to investments in intangibles equals SEK -645,000 (-841,000) for the first nine months. The cash flow effect related to investments in financing activities equals SEK 204,506,000 (75,822,000) for the first nine months and refers to the directed share issue and the preferential rights issue that affected cash flow positively by SEK 180,364,000 and the conversion of the convertible loan that affected cash flow positively by SEK 24,223,000. Cash flow for the third quarter equals SEK -61,792,000 (-30,881,000). Cashflow for the first nine months equals SEK 50,593,000 (1,618,000).

(SEK 000)	1 Jul, 2022 30 Sep, 2022	1 Jul, 2021 30 Sep, 2021	1 Jan, 2022 30 Sep, 2022	1 Jan, 2021 30 Sep, 2021	1 Jan, 2021 31 Dec, 2021
Cash flow from operating activities					
Operating income	-25,540	-34,851	-65,365	-86,613	-123,482
Adjustments for non-cash items:					
Depreciation	696	663	1,911	1,980	2,660
Currency differences on intercompany items	113	13	284	6	-7
Impaired Value	-	-	-	-	104
Share-based payments	100	-	451	-	415
Result from other securities and receivables related to non current assets	238	-	238	-	-
Interest received	191	-	191	-	-
Interest paid	-13	-2	-13	-10	-12
Paid taxes	-	-	-	-	-4
Net cash from operating activities before changes in working capital	-24,215	-34,177	-62,303	-84,637	-120,326
Changes in working capital					
Increase/decrease of other current assets	-83,265	456	-93,791	-317	-400
Increase/decrease of other short-term liabilities	3,097	3,414	3,208	11,658	6,651
Changes in working capital	-80,168	3,870	-90,583	11,341	6,251
Cash flow from operating activities	-104,383	-30,307	-152,886	-73,297	-114,075
Investing activities					
Acquisition of intangible assets	-309	-573	-645	-841	-1,024
Acquisition of tangible assets	-22	-0	-23	-65	-65
Cash flow from investing activities	-331	-573	-667	-907	-1,089
Financing activities					
Shareholder contribution subsidiary	-	-	-	14	16
New share issue	18,780	-	180,364	75,900	75,868
Amorization lease	-	-	-	-92	-92
Increase/decrease of long-term liabilities	24,143	-	24,143	-	-
Cash flow from financing activities	42,922	-	204,506	75,822	75,792
Cash flow for the period	-61,792	-30,881	50,953	1,618	-39,372
Cash and cash equivalents at the beginning of the period	135,159	94,146	22,339	61,643	61,643
Effect of exchange rate changes on cash	77	2	152	7	68
Cash and cash equivalents at end of period	73,444	63,267	73,444	63,267	22,339

Parent Company

Income Statement

Parental company

Company earnings after tax for the third quarter amounts to SEK -24,472,000 (-32,808,000). Earnings after tax for the first nine months amount to KSEK -66,731,000 (-83,345,000). Most of the Group's operations are conducted within the parent company. Accordingly, no further specific information regarding the parent company is presented.

(SEK 000)	Note	1 Jul, 2022 30 Sep, 2022	1 Jul, 2021 30 Sep, 2021	1 Jan, 2022 30 Sep, 2022	1 Jan, 2021 30 Sep, 2021	1 Jan, 2021 31 Dec, 2021
Net sales		31	85	31	103	151
Other operating income		651	-	212	-	-
		681	85	243	103	151
Operating expenses						
Other external expenses		-23,111	-30,706	-55,985	-70,521	-107,521
Personnel cost		-1,862	-1,423	-6,854	-10,749	-12,952
Depreciation and write-down of tangible and intangible assets		-610	-577	-1,825	-1,722	-2,420
Other operating expenses		-	-186	-	-456	-330
		-25,583	-32,892	-64,664	-83,448	-123,223
Operating income		-24,901	-32,808	-64,422	-83,345	-123,072
Profit/loss from financial items						
Result from other securities and receivables related to non current assets		238	-	238	-	-
Interest income and other similar profit items		191	-	191	-	-
Interest expenses and other similar loss items		-	-	-2,738	-	-
		429	-	-2,309	-	-
Profit/loss before tax		-24,472	-32,808	-66,731	-83,345	-123,072
Income tax	2	-	-	-	-	-
Profit/loss for the period		-24,472	-32,808	-66,731	-83,345	-123,072

Parent Company

Statement of
Comprehensive
Income

(SEK 000)	Note	1 Jul, 2022 30 Sep, 2022	1 Jul, 2021 30 Sep, 2021	1 Jan, 2022 30 Sep, 2022	1 Jan, 2021 30 Sep, 2021	1 Jan, 2021 31 Dec, 2021
Profit/loss for the period		-24,472	-32,808	-66,731	-83,345	-123,072
Other comprehensive income		-	-	-	-	-
Total comprehensive profit/loss for the period		-24,472	-32,808	-66,731	-83,345	-123,072

Parent Company

Balance Sheet

(SEK 000)	Note	30 Sep, 2022	30 Sep, 2021	31 Dec, 2021
ASSETS				
Non-current assets				
Intangible assets	1			
Patents		19,310	20,303	20,293
Other intangible assets		1,109	1,243	1,210
		20,418	21,546	21,503
Tangible assets				
Equipment		57	71	60
		57	71	60
Financial assets				
Other long-term placement		13,100	13,101	24,557
Shares in subsidiaries	3	24,558	24,558	13,101
		37,658	37,659	37,658
Total non-current assets		58,133	59,276	59,221
Current assets				
<i>Short term receivables</i>				
Receivables from group companies		-	1,192	-
Other receivables		1,345	1,154	890
Prepaid expenses and accrued income		1,118	656	1,003
		2,463	3,002	1,893
Other short term receivables		93,212	-	-
Cash and bank balances		72,375	63,012	21,696
Total current assets		168,050	66,014	23,589
TOTAL ASSETS		226,183	125,290	82,810

Parent Company
Balance Sheet

(SEK 000)	Note	30 Sep, 2022	30 Sep, 2021	31 Dec, 2021
EQUITY AND LIABILITIES				
Equity				
<i>Restricted equity</i>				
Share capital		52,815	20,150	20,150
Statutory reserve		1,856	1,856	1,856
Development expenditure reserve**		1,629	3,153	2,613
		56,300	25,159	24,619
Unrestricted equity				
Share premium reserve		245,195	137,611	70,534
Retained earnings		-29,072	25,431	93,017
Profit/loss for the period		-66,731	-83,345	-123,072
		149,393	79,697	40,479
Total equity		205,692	104,857	65,098
Short-term liabilities				
Accounts payable		15,211	15,544	9,616
Liabilities subsidiary		1,346	-	1,253
Other liabilities		206	254	273
Accrued expenses and deferred income		3,728	4,635	6,570
		20,491	20,433	17,712
TOTAL EQUITY AND LIABILITIES		226,183	125,290	82,810

Notes

Note 1 — Intangible assets

(SEK 000)	Patents	Other	Total
ACCUMULATED COST			
Opening balance 1 Jan. 2022	35,180	2,864	38,044
Additions	715	-	715
Closing balance 31 Sep. 2022	35,895	2,864	38,759
ACCUMULATED DEPRECIATION			
Opening balance 1 Jan. 2021	-14,887	-1,654	-16,541
Depreciation for the period	-1,698	-102	-1,800
Impaired value	49	-	49
Closing balance 30 Sep. 2022	-16,536	-1,756	-18,292
Residual value 30 Sep. 2022	19,359	1,108	20,467

(SEK 000)	Patents	Other	Total
ACCUMULATED COST			
Opening balance 1 Jan. 2021	33,771	2,864	36,635
Additions	1,562	-	1,562
Impaired value	-153	-	-153
Closing balance 31 Dec. 2021	35,180	2,864	38,044
ACCUMULATED DEPRECIATION			
Opening balance 1 Jan. 2021	-12,800	-1,519	-14,319
Depreciation for the period	-2,136	-135	-2,271
Impaired value			
Closing balance 31 Dec. 2021	-14,887	-1,654	-16,541
Residual value 31 Dec. 2021	20,293	1,210	21,503

Note 2 – Tax

The group's total loss carry-forwards amounts to SEK 792,023,000 as of 30 September 2022 (761,613,000). The parent company's total loss carry-forwards amounts to SEK 765,652,000 as of 30 September 2022 (732,476,000). Because the company is loss making, management cannot judge when deductible loss carry-forwards will be utilized.

Note 3 – Shares and participations in group companies

These shares are the holding of 82.47% in the subsidiary NeuroVive Pharmaceutical Asia Ltd., domiciled in Hong Kong, the wholly owned American subsidiary Abliva Inc., Boston and the Swedish subsidiary Abliva Incentive AB, holding option program for the CEO.

Other disclosures

Transactions with related parties

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

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

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

Segment information

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

Human resources

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

Important events during the third quarter (Jul-Sep 2022)

For further information, see page 2.

Important events after the reporting period

For further information, see page 2.

Incentive programs/share warrants

The AGM on May 20, 2021, decided on a four-year incentive stock option program 2021/2025 for the Company's CEO. The incentive stock option program entitles the holder to a new ordinary share in Abliva AB up to a maximum of 4,600,000 ordinary shares. The redemption price amounts to 0.725 öre. The program is vested at 25% per year on June 1, 2022, June 1, 2023, June 1, 2024 and June 1, 2025. Latest redemption date is December 31, 2025. For further information, please see the 2021 Annual report on page 53.

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 2022	February 24, 2023
Q1 Report January-March 2023	May 23, 2023
Q2 Report January-June 2023	August 18, 2023
Q3 Report January-September 2023	November 17, 2023
Year-End Report 2023	February 23, 2024

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

Annual General Meeting 2023

Annual General Meeting of Abliva AB (publ) will be held on April 27, 2023, at 1 p.m. at Medicon Village, Scheeletorget 1, in Lund, Sweden.

The Nomination Committee for the 2023 AGM comprises:

- Ingrid Teigland Akay (chair) – for Hadean Ventures
- Sam Williams – for IP Group plc
- Ryan El Housseini – for OPF (Oslo Pensionsfond)

In total, the Nomination Committee represents some 45,4 percent of the votes in Abliva as of September 30, 2022.

The Nomination Committee's task ahead of the AGM 2023 is to prepare proposals on the following matters to present to the AGM for resolution

- Propose the Chairman of the AGM
- Propose the number of Board members
- Propose remuneration to Board members and remuneration to Committee members
- Propose remuneration to the Auditors
- Propose the Chairman of the Board and other Board members
- Propose Auditor
- Propose guidelines for appointing members of the Nomination Committee, and instructions for the Nomination Committee
- Propose remuneration to the members of the Nomination Committee

Shareholders wishing to make proposals on the above matters can contact the Committee by email to: valberedningen@abliva.com, or by post to: Abliva AB, FAO: Nomination Committee, Medicon Village, 223 81 Lund, Sweden. In order for the Nomination Committee to consider the proposals received with due care, proposals should be received by the Nomination Committee by no later than February 1, 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.

Financing

The Board continuously monitors and evaluates the company's funding need and financial position. The company announced a financing of SEK 200 million in June 2022. However, the company acknowledges the need for further financing in the future, including equity, grants, and partnering.

Impact of Covid-19 on the Company's operations

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

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

Macroeconomic and geopolitical factors

The Russian invasion of Ukraine 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 detail of risks and uncertainty factors, refer to the Statutory Administration Report in the 2021 Annual Report and the prospectus published on June 8, 2022.

Principles of preparation of the Interim Report

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

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

and considering the relationship between accounting and taxation.

The group and parent company have applied the accounting principles described in the Annual Report for 2021 on pages 43-58.

Definitions alternative performance measures

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

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

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

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

The declaration of the Board of Directors and the CEO

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

Lund, Sweden, November 22, 2022

David Laskow-Pooley

Chairman of the Board

David Bejker

Board member

Roger Franklin

Board member

Denise Goode

Board member

Jan Törnell

Board member

Ellen Donnelly

Chief Executive Officer



David Laskow-Pooley



David Bejker



Roger Franklin



Denise Goode



Jan Törnell



Ellen Donnelly

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

The information was submitted for publication, through the agency of the contact person set out above, at 8:30 a.m. CET on November 22, 2022.

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, 2022 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.

Malmö, November 22, 2022

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 stroke-like episodes.

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

MHRA. The UK Medicines and Healthcare products Regulatory Agency.

MIDD. Maternally Inherited Diabetes and Deafness

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

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

Mitochondrial myopathy. Primary mitochondrial disease which affects the muscles.

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

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

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

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

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

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

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

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

About Abliva

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

What is primary mitochondrial disease?

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

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

Stock exchange

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

Abliva AB (publ)

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