



NeuroVive Pharmaceutical AB (publ)

Interim Report January-March 2020

Important events, first quarter (Jan - Mar 2020)

- NeuroVive proposes a 90 percent guaranteed rights issue of MSEK 74 in order to ensure that the Company has financial resources for its prioritized primary mitochondrial disease programs.
- NeuroVive announces that it intends to initiate activities with the aim to transfer the rights to develop and commercialize its NeuroSTAT program into a new wholly-owned company based in the US.
- Extraordinary General Meeting is held in Lund on 17 March. The Board of Director's proposition on a preferential rights issue is approved.
- NeuroVive announces that the overall work on the company's study program is continuing and reports on the preparations being made to minimize delays in its various projects and other activities, in light of the impact of COVID-19.

Important events after the reporting period

- NeuroVive decides upon a directed issue of shares totaling around MSEK 20 to leading Nordic life science investor Hadean Ventures, for further information see page 9.
- NeuroVive raises approximately MSEK 67 before deduction of issue costs.

Financial information

First quarter (Jan-Mar 2020)*

- Net revenues: KSEK 8 (0)
- Other operating income: KSEK 0 (0)
- Loss before tax: KSEK 16,537 (13,822)
- Loss per share: SEK -0.10 (-0.12)
- Diluted loss per share: SEK -0.10 (-0.12)

* APM Alternative performance measures, see definition on page 17.

Two opportunities for developing treatments for primary mitochondrial diseases

There is no effective therapy for almost all primary mitochondrial diseases. This is the starting point for NeuroVive's operations and it is our ambition to develop drugs that improve the lives of patients with primary mitochondrial disease.



Erik Kinnman
CEO NeuroVive

If we succeed, it will have a very positive impact on the quality of life for both the patients affected and their family members. In concrete terms, this means that we are now focusing on two promising projects: KL1333 and NV354. KL1333 is being developed to increase the number of functional mitochondria whereas NV354 will provide patients with an alternative energy source.

KL1333 to patients for the first time

The KL1333 drug candidate is being developed for the treatment of genetic disorders that directly affect cellular energy conversion. KL1333 has received orphan drug designation in both the United States and Europe, and we have successfully completed the first two stages of the Phase Ia/b trial, where healthy volunteers were given doses of our drug candidate. The patients included in the third and final part of the Phase Ia/b trial suffer from a primary mitochondrial disease with such severe symptoms as pronounced fatigue, muscle function loss, intractable diabetes and reduced cardiac muscle function. This final part of the trial was planned to continue until summer 2020. Given the situation with the COVID-19 pandemic, there is uncertainty relating to patient recruitment.

NV354 – preparation for clinical phase

Leigh syndrome is a severe primary mitochondrial disease where the most serious symptoms are attributable to effects on the brain's functions, which leads, for example, to developmental delays and epilepsy. Other severe symptoms are muscle weakness, impairment of cardiac, kidney and lung function and vision. Very few children with Leigh syndrome live beyond five years of age. NV354 is being developed to provide these patients with an alternative energy source and thereby alleviate the symptoms, improve disease progression and prolong life. Preclinical safety studies are in progress, as well as design of pharmaceutical production, and we are planning to commence a Phase I trial in 2021.

Effects of the COVID-19 pandemic

The Company estimates that COVID-19 will delay NeuroVive's ongoing Phase Ia/b study with KL1333, since healthcare authorities and healthcare providers are prioritizing available resources, care locations and healthcare professionals to better meet the influx of COVID-19 patients. NeuroVive therefore is working with different alternatives by modifying the design of the upcoming Phase II study, which now is expected to begin in the first half of 2021. Our plans to bring NV354 into clinical phase in 2021 are currently not considered to be affected by the COVID-19 pandemic.

Focused strategy enabled by business development

In March this year, we started a process aimed at transferring the rights to develop and commercialize our NeuroSTAT program to a wholly-owned new company in the United States provided funding of the planned Phase II study. The decision is in line with NeuroVive's strategy to focus its resources on its primary mitochondrial dis-

ease projects and our ambition, subject to funding, is to establish the new company in the second half of 2020. The purpose of establishing a new company is to increase the possibilities to create value in the NeuroSTAT clinical program. NeuroSTAT is ready for Phase II in the United States. The FDA has approved the IND application and given the program a Fast Track designation.

Important and validating financing

The company's preferential rights issue of MSEK 74, guaranteed to 90%, and the recently announced directed issue of MSEK 20 to one of the leading Nordic life science investors, Hadean Ventures, create the prerequisites to deliver important near-term milestones. Further, the share issues are a clear sign of strength in the current volatile market situation. We are especially looking forward to adding Hadean's experiences and expertise, in the further development of NeuroVive and our projects.

Value creation in several dimensions

In 2020, we will, with the adjustments that are necessary to handle the COVID-19 pandemic, continue to work according to our updated strategy. Our ambition to in a decisive manner improve the quality of life for patients with mitochondrial diseases is motivating on a personal level for everybody at NeuroVive, at the same time as it also holds good opportunities to create medical as well as financial values.

Erik Kinnman, CEO

Strategic focus: primary mitochondrial diseases

NeuroVive's objective is to improve life for patients suffering from primary mitochondrial diseases, which means diseases caused by a genetic defect in mitochondrial function. These diseases often cause great suffering for both patients and family members. The symptoms worsen over time and many of the diseases lead to a far too early death. Today, a very limited number of treatment options are available, which means there are major unmet medical needs.

Focus on KL1333 and NV354

Strategically, NeuroVive's focus on mitochondrial diseases means that the company is allocating financial and personnel resources to the KL1333 and NV354 drug candidates, both of which are being developed to treat primary mitochondrial diseases. KL1333 is in Phase I and NV354 is being prepared for clinical trials. The aim is to use our internal resources to take these projects all the way to market authorization, either on our own or together with a partner.

Significant advantages with orphan drug designation

KL1333 has obtained orphan drug designation and NV354 also has potential to receive orphan drug designation. An orphan drug designation offers several positive benefits, including:

- regulatory assistance and scientific advice from pharmaceutical regulators
- shorter development time
- lower development costs
- greater chance of regulatory approval compared with drug candidates that lack orphan drug designation
- attractive pricing compared with drug candidates that lack orphan drug designation¹⁾²⁾

NeuroVive's experts collaborate continuously with world-class consultants in the field of orphan drugs, who also assist the company in its dialogue with regulators. NeuroVive has also established partnerships and a continuous dialogue with

some of the world's leading clinical centers for the treatment of primary mitochondrial diseases.

Focused strategy enabled by business development

NeuroVive's aim remains to find a partner for NeuroSTAT. NeuroSTAT was developed for the treatment of traumatic brain injury and the project has an approved IND application and Fast Track status from FDA and is ready to enter a Phase II efficacy trial.

Market

The main customers of NeuroVive's future products include specialist healthcare and institutions that pay for medicines. Primary prescribers of NeuroVive's future drugs include highly specialized physicians at national and regional centers of expertise for genetic metabolic disorders and cancer. In other words, the future customers are a relatively concentrated group of specialists, decision makers and patients.

Future revenue

NeuroVive works under two main scenarios for establishing future revenue: sales revenue for the drugs the company intends to bring all the way to market, and revenue from out-licensing, milestone payments and royalties from the drug candidates licensed out. NeuroVive has out-licensed parts of the NVP015 project to BridgeBio/Fortify that develops a local treatment for the mitochondrial eye disease LHON.

Projects within primary mitochondrial diseases (PMD) for development to the market with or without partner

Project (Partner)	Disease/symptom	Discovery	Preclinical	Phase I	Phase II	Phase III	Market
KL1333* (Yungjin)	PMD	<div></div>	<div></div>	<div></div>	<div></div>	<div></div>	<div></div>
NV354	Leigh syndrome	<div></div>	<div></div>	<div></div>	<div></div>	<div></div>	<div></div>
Other projects		<div></div>	<div></div>	<div></div>	<div></div>	<div></div>	<div></div>

* Orphan drug designation in the US and Europe.

1) Jayasundra et al. Orphanet J of Rare Dis. Estimating the clinical cost of drug development for orphan versus non-orphan drugs. 2019.

2) EvaluatePharma, Orphan Drug Report 2019.



Phase I

KL1333 - for treatment of primary mitochondrial diseases

Ongoing clinical Phase Ia/b study

Dosing in healthy volunteers concluded

Primary mitochondrial diseases are metabolic diseases that affect the ability of cells to convert energy. The disorders can manifest differently depending on the organs affected by the genetic defects and are viewed as clinical syndromes. An estimated 125 in every 1,000,000 people suffer from a primary mitochondrial disease.

Primary mitochondrial diseases often present in early childhood and lead to severe symptoms, such as mental retardation, myopathy, heart failure and rhythm disturbances, diabetes, movement disorders, stroke-like episodes, deafness, blindness, limited mobility of the eyes and seizures.

KL1333 is a potent modulator of the cellular levels of NAD⁺, a central co-enzyme in the cell's energy metabolism. The candidate drug is intended for chronic oral

treatment of primary genetic mitochondrial disorders, in particular MELAS-MIDD spectrum disorders mainly caused by the mutation m.3243A>G in the mitochondrial DNA (mtDNA) which affects about 35 in 1,000,000 people. An additional group is PEO-KSS spectrum disorders, caused by a deletion of a large part of mtDNA which affects 15 in 1,000,000.

KL1333 was in-licensed in 2017 from Yungjin Pharm, a Korean pharmaceutical company, and has been granted orphan drug designation in both the United States and Europe.

Events in the first quarter

KL1333 is currently being evaluated in a clinical Phase Ia/b study in the UK. The third and final part of the study, where KL1333 for the first time will be dosed in patients,

will be initiated as soon as it is safe for patients with regard to the COVID-19 pandemic. In preparation for a Phase II efficacy study, existing clinical patient data are analyzed to optimize the outcome measures and patient inclusion criteria.

Objectives for 2020/2021

- In the ongoing clinical study - start the Phase Ib part with patients (H1 2020)*
- Conclude the Phase Ia/b study and report results (H2 2020)
- Initiate clinical Phase II efficacy study (H1 2021)

* will be initiated as soon as it is safe for patients with regard to the COVID-19.



Preclinical

NV354 - alternative energy source in primary mitochondrial disease

The project is in preparation for clinical phase

Ongoing safety studies

One of the most common causes of mitochondrial diseases relates to Complex I dysfunction, i.e. when energy conversion in the first of the five protein complexes in the mitochondrion that are essential for effective energy conversion does not function normally. This is apparent in disorders including Leigh syndrome and MELAS, both of which are very serious diseases with symptoms such as muscle weakness, epileptic fits and other severe neurological manifestations.

This project is based on a NeuroVive innovation in which the body's own energy substrate, succinate, is made

available in the cell via a prodrug technology. A prodrug is an inactive drug that is activated first when it enters the body by the transformation of its chemical structure.

Within the project a lead compound, NV354, has been selected for further development in the program based on tolerability, oral bioavailability, plasma stability and organ delivery, specifically to the brain.

Events in the first quarter

NV354 preclinical safety studies have continued.

Objectives for 2020/2021

- Complete preclinical safety studies (H2 2020)
- Produce NV354 clinical trial material for clinical studies (H2 2020)
- Initiate Phase I study (H1 2021)
- Conclude the Phase I study and report results (H2 2021)

Out-licensed projects and commercial partnerships

NeuroVive has currently out-licensed compounds developed within NVP015 project to US company BridgeBio/Fortify. The compounds are being developed for the treatment of the eye disorder LHON. In addition, NeuroVive has a distribution agreement for research substances with the Austrian company Oroboros.

Project for local treatment of LHON

In 2018, NeuroVive out-licensed molecules from the NVP015 project to BridgeBio Pharma's new subsidiary Fortify Therapeutics. Fortify develops the in-licensed NVP015 chemistry further to a local therapy for the mitochondrial eye disorder Leber's Hereditary Optic Neuropathy (LHON).

Discovery



Commercial partnership with Oroboros

In 2019, NeuroVive announced that the company has entered into an exclusive agreement with Oroboros Instruments, a leading global supplier of mitochondrial research technologies. NeuroVive have agreed to provide, at scale, two research compounds, originating from its NVP015 program, on an exclusive basis to Oroboros. Oroboros has initiated commercialization and distributes the compounds under the product name MitoKit-CII.

Our discovery projects

NeuroVive's focus is developing drugs for patients with primary mitochondrial diseases. NVP025 is a discovery project where we evaluate compounds for the treatment of mitochondrial myopathy (muscle disease).

We constantly look at new possibilities to find additional molecules and variants of our drug candidates, having optimal properties, that could be included in new development programs.

NeuroVive works with a number of new molecules in the project portfolio, focused on regulation of mitochondrial energy production, especially for primary mitochondrial disorders. NeuroVive's project portfolio also includes cyclophilin inhibitors that serve as organ protection and have proven to be suitable for development of drug candidates for certain primary mitochondrial disorders and in other disease areas.

Non-core assets

The company is actively seeking strategic partnerships for NeuroSTAT. With regards to NV556, the company will not invest additional resources in this project and will have an opportunistic licensing approach going forward.

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: candidate drug in clinical Phase II

NeuroSTAT has shown favorable properties in a Phase II 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.

NeuroVive has initiated a process with the aim to transfer the rights to develop and commercialize the NeuroSTAT program into a new wholly owned company based in the US.

NV556 – for treatment of NASH

Non-alcoholic fatty liver disease (NAFLD) affects 20-25 percent of the global population, a condition that may lead to liver cirrhosis or hepatocellular carcinoma (liver cancer).



Treatment objective

NV556 is a candidate drug with a directly acting anti-fibrotic mechanism of action targeting patients with NASH (non-alcoholic steatohepatitis, a form of NAFLD) who have progressed from the initial metabolic stage. The anti-fibrotic effect can also be developed for other diseases involving liver fibrosis, such as Primary Biliary Cholangitis (PBC) and Primary Sclerosing Cholangitis (PSC).

Project status: no further investments

NeuroVive will not invest further in the NV556 project, and has adopted an opportunistic approach to continued licensing activities.

Consolidated Statement of Comprehensive Income

Revenues

The consolidated turnover during the first quarter of 2020 was KSEK 8 (0). Other operating revenues for the first quarter were KSEK 0 (0).

Results of operations

The operating loss for the first quarter was KSEK 16,528 (13,809). The net loss before tax for the first quarter amounted to KSEK 16,537 (13,822).

The operating loss was affected by other external expenses, which for the full were KSEK 11,957 (9,630). During the first quarter, expenses related to development projects, as a part of external expenses, have affected the result with KSEK 7,035 (6,128) whereof KSEK 3,845 (2,415) relates to project in clinical phase. Personnel expenses during the first quarter amount to KSEK 3,550 (3,480). Other operating expenses amount to, KSEK 403 (133) and pertains to exchange-rate losses.

(SEK 000)	Note	1 Jan, 2020 31 Mar, 2020	1 Jan, 2019 31 Mar, 2019	1 Jan, 2019 31 Dec, 2019
Net sales		8	-	134
Other operating income		-	-	3,500
		8	-	3,634
<i>Operating expenses</i>				
Other external expenses		-11,957	-9,630	-63,133
Personnel cost		-3,550	-3,480	-14,872
Depreciation and write-down of tangible and intangible assets		-626	-567	-2,379
Other operating expenses		-403	-133	-325
		-16,536	-13,809	-80,709
Operating income		-16,528	-13,809	-77,075
<i>Profit/loss from financial items</i>				
Result from other securities and receivables related to non current assets		-	-	121
Financial income		-	-	-
Financial costs		-9	-13	-46
		-9	-13	75
Profit/loss before tax		-16,537	-13,822	-77,000
Income tax	2	-	-	-
Profit/loss for the period		-16,537	-13,822	-77,000
<i>Other comprehensive income</i>				
Items that may be reclassified to profit or loss				
Translation differences on foreign subsidiaries		2	2	3
Total comprehensive income for the period		-16,535	-13,820	-76,997
<i>Loss for the period attributable to:</i>				
Parent company shareholders		-16,537	-13,822	-76,994
Non-controlling interests		0	-	-6
		-16,537	-13,822	-77,000
<i>Total comprehensive income for the period</i>				
Parent company shareholders		-16,535	-13,820	-76,991
Non-controlling interests		0	-	-6
		-16,535	-13,820	-76,997
Earnings per share before and after dilution(SEK) based on average number of shares		-0.10	-0.12	-0.45

Consolidated Statement of Financial Position

Financial position

The equity/assets ratio was 93 (93) percent as of 31 March 2020, and equity was KSEK 111,261 (127,795) compared to beginning of the year. Cash and cash equivalents amounted to KSEK 29,568 (113,339) as of 31 March 2020, a decrease of KSEK 28,751 from the beginning of the year. Total assets as of 31 March 2020 were KSEK 119,895 (204,646). During the period April 6 - April 29, 2020, the Company completed a rights issue of MSEK 54 after deductions for issue costs and compensation for guarantee commitments totaling MSEK 13.

The company decided on 22 April 2020, upon a directed issue of shares totaling around MSEK 20 to leading Nordic life science investor Hadean Ventures. The Issue is conditional upon on the VWAP not being less than SEK 0.70, unless the investors in their own discretion would agree to pay SEK 0.70 per share, and on the Company's rights issue in April, 2020, was subscribed and paid by no less than 90 percent of the total amount of the rights issue and that one person representing the investors is elected as member of the Board of Directors of the Company at an General Meeting held on or prior to June 15, 2020.

Financial instruments

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

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

(SEK 000)	Note	31 Mar, 2020	31 Mar, 2019	31 Dec, 2019
ASSETS				
Non-current assets				
<i>Intangible assets</i>	1			
Development costs		51,706	51,706	51,706
Patents		21,560	20,057	21,501
Other Intangible assets		1,445	1,579	1,479
		74,711	73,343	74,686
<i>Tangible assets</i>				
Equipment		83	113	99
Riqth of use asset leases		601	945	687
		684	1,057	786
<i>Financial assets</i>				
Other long-term securities		13,101	13,101	13,101
		13,101	13,101	13,101
Total non-current assets		88,496	87,501	88,573
Current assets				
Other receivables		1,211	3,080	1,141
Prepaid expenses and accrued income		620	726	459
Cash and cash equivalents		29,568	113,339	58,319
		31,399	117,145	59,919
TOTAL ASSETS		119,895	204,646	148,492
EQUITY AND LIABILITIES				
Equity attributable to the shareholders of the parent company				
Share capital		9,298	9,298	9,298
Additional paid in capital		592,980	593,207	592,980
Translation reserve		621	618	619
Retained earnings		-491,644	-411,935	-475,107
Total equity attributable to the shareholders of the parent		111,255	191,188	127,790
Non-controlling interests		6	11	5
Total equity		111,261	191,199	127,795
<i>Long-term liabilities</i>				
Other longterm liabilities		448	687	361
		448	687	361
<i>Short-term liabilities</i>				
Accounts payable		1,769	5,120	14,234
Other liabilities		615	703	811
Accrued expenses and deferred income		5,802	6,937	5,291
		8,187	12,760	20,336
Total liabilities		8,635	14,134	21,058
TOTAL EQUITY AND LIABILITIES		119,895	204,646	148,492

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 2020	9,298	592,980	619	-475,107	127,791	5	127,795
Comprehensive profit/loss for the period							
Profit/loss for the period	-	-	-	-16,537	-16,537	0	-16,536
Other comprehensive income							
Translation differences	-	-	2	-	2	-	2
Other comprehensive profit/loss for the period, net after tax	-	-	2	-	2	-	2
Total comprehensive profit/loss	-	-	2	-16,537	-16,535	0	-16,534
Transactions with shareholders							
Rights Issue*	-	-	-	-	-	-	-
Total transactions with shareholders	-	-	-	-	-	-	-
Closing balance, 31 March 2020	9,298	592,980	621	-491,643	111,255	6	111,261
Opening balance, 1 January 2019	4,585	489,913	616	-398,113	97,002	11	97,012
Comprehensive profit/loss for the period							
Profit/loss for the period	-	-	-	-76,994	-76,994	-6	-77,000
Other comprehensive income							
Translation differences	-	-	3	-	3	-	3
Other comprehensive profit/loss for the period, net after tax	-	-	3	-	3	-	3
Total comprehensive profit/loss	-	-	3	-76,994	-76,991	-6	-76,997
Transactions with shareholders							
Rights Issue	4,713	103,067	-	-	107,780	-	107,780
Total transactions with shareholders	4,713	103,067	-	-	107,780	-	107,780
Closing balance, 31 December 2019	9,298	592,980	619	-475,107	127,791	5	127,795

Consolidated Statement of Cash Flows

Cash flow and investments

Operating cash flow for the first quarter was KSEK -15 911 (-13,255). The cash flow effect related to investments in intangibles equals KSEK -525 (-260) for the first quarter. Cash flow for the first quarter equals KSEK -28,756 (87,385).

(SEK 000)	1 Jan, 2020 31 Mar, 2020	1 Jan, 2019 31 Mar, 2019	1 Jan, 2019 31 Dec, 2019
<i>Cash flow from operating activities</i>			
Operating income	-16,528	-13,809	-77,074
<i>Adjustments for non-cash items:</i>			
Depreciation	626	567	2,379
Impaired Value	-	-	-
Result from other securities and receivables related to non current assets	-	-	121
Interest received	-	-	-
Interest paid	-9	-13	-46
Net cash from operating activities before changes in working capital	-15,911	-13,255	-74,620
<i>Changes in working capital</i>			
Increase/decrease of other current assets	-230	-1,129	1,077
Increase/decrease of other short-term liabilities	-12,006	-5,978	1,131
Changes in working capital	-12,237	-7,107	2,208
Cash flow from operating activities	-28,147	-20,362	-72,412
<i>Investing activities</i>			
Acquisition of intangible assets	-525	-260	-2,626
Acquisition of tangible assets	-	-	-69
Increase in other financial assets	-	-	-
Cash flow from investing activities	-525	-260	-2,695
<i>Financing activities</i>			
New share issue	-	108,007	107,780
Amortization lease	-84	-	-309
Cash flow from financing activities	-84	108,007	107,471
Cash flow for the period	-28,756	87,385	32,364
Cash and cash equivalents at the beginning of the period	58,319	25,951	25,951
Effect of exchange rate changes on cash	5	3	4
Cash and cash equivalents at end of period	29,568	113,339	58,319

Parent Company Income Statement

Parental company

Company earnings after tax for the first quarter amounts to KSEK 16,533 (-13,814). 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 Jan, 2020 31 Mar, 2020	1 Jan, 2019 31 Mar, 2019	1 Jan, 2019 31 Dec, 2019
Net sales		8	-	134
Other operating income		-	-	3,500
		8	-	3,634
<i>Operating expenses</i>				
Other external expenses		-12,047	-9,721	-63,469
Personnel cost		-3,550	-3,480	-14,872
Depreciation and write-down of tangible and intangible assets		-540	-481	-2,036
Other operating expenses		-403	-133	-325
		-16,541	-13,814	-80,702
Operating income		-16,533	-13,814	-77,068
<i>Profit/loss from financial items</i>				
Result from other securities and receivables related to non current assets		-	-	122
Interest expenses and other similar loss items		-	-	-1
		-	-	121
Profit/loss before tax		-16,533	-13,814	-76,947
Income tax	2	-	-	-
Profit/loss for the period		-16,533	-13,814	-76,947

Statement of Comprehensive Income, Parent Company

(SEK 000)	Note	1 Jan, 2020 31 Mar, 2020	1 Jan, 2019 31 Mar, 2019	1 Jan, 2019 31 Dec, 2019
Profit/loss for the period		-16,533	-13,814	-76,947
Other comprehensive income		-	-	-
Total comprehensive profit/loss for the period		-16,533	-13,814	-76,947

Parent Company

Balance Sheet

(SEK 000)	Note	31 Mar, 2020	31 Mar, 2019	31 Dec, 2019
ASSETS				
Non-current assets				
<i>Intangible assets</i>	1			
Development costs		51,706	51,706	51,706
Patents		21,560	20,057	21,501
Other intangible assets		1,445	1,579	1,479
		74,711	73,343	74,686
<i>Tangible assets</i>				
Equipment		83	113	99
		83	113	99
<i>Financial assets</i>				
Other long-term placement		13,101	13,101	23,625
Shares in subsidiaries	3	23,625	23,625	13,101
		36,726	36,726	36,726
Total non-current assets		111,521	110,182	111,511
Current assets				
Short term receivables				
Receivables from group companies		-	-	-
Other receivables		1,207	3,077	1,138
Prepaid expenses and accrued income		620	726	459
		1,827	3,803	1,597
Cash and bank balances		29,517	113,277	58,272
Total current assets		31,344	117,081	59,869
TOTAL ASSETS		142,865	227,263	171,380
EQUITY AND LIABILITIES				
Equity				
<i>Restricted equity</i>				
Share capital		9,298	9,298	9,298
Statutory reserve		1,856	1,856	1,856
Development expenditure reserve		14,164	10,610	14,106
		25,319	21,764	25,260
<i>Unrestricted equity</i>				
Share premium reserve		103,067	103,294	103,067
Retained earnings		23,021	103,523	100,026
Profit/loss for the period		-16,533	-13,814	-76,947
		109,554	193,003	126,146
Total equity		134,873	214,767	151,406
Short-term liabilities				
Accounts payable		1,769	5,120	14,234
Other liabilities		444	439	467
Accrued expenses and deferred income		5,780	6,937	5,273
		7,992	12,496	19,974
TOTAL EQUITY AND LIABILITIES		142,865	227,263	171,380

Notes

Note 1 – Intangible assets

(SEK 000)	Development costs	Patents	Other	Total
ACCUMULATED COST				
Opening balance 1 Jan. 2020	51,706	32,279	2,864	86,849
Additions	-	550	-	550
Closing balance 31 Mar. 2020	51,706	32,829	2,864	87,399
ACCUMULATED DEPRECIATION				
Opening balance 1 Jan. 2020	-	-10,778	-1,385	-12,163
Depreciation for the period	-	-491	-34	-525
Closing balance 31 Mar. 2020	-	-11,269	-1,419	-12,688
Residual value 31 Mar. 2020	51,706	21,560	1,445	74,711

(SEK 000)	Development costs	Patents	Other	Total
ACCUMULATED COST				
Opening balance 1 Jan. 2019	51,706	29,107	2,864	83,677
Additions	-	3,172	-	3,172
Closing balance 31 Dec. 2019	51,706	32,279	2,864	86,849
ACCUMULATED DEPRECIATION				
Opening balance 1 Jan. 2019	-	-8,986	-1,251	-10,237
Depreciation for the period	-	-1,792	-134	-1,926
Closing balance 31 Dec. 2019	-	-10,778	-1,385	-12,163
Residual value 31 Dec. 2019	51,706	21,501	1,479	74,686

Note 2 – Tax

The group's total loss carry-forwards amounts to KSEK 561,101 as of 31 March 2020 (481,524). The parent company's total loss carry-forwards amounts to SEK 535,272 as of 31 March 2020 (455,749). 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.

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.

Transactions with related parties			
	1 Jan. 2020	1 Jan. 2019	
(SEK 000)	31 Mar. 2020	31 Dec. 2019	
Eskil Elmér, CSO	-	6	
Magnus Hansson, CMO	-	3	
Total	-	9	

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

Segment information

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

Human resources

The average number of employees of the group for the period January to March 2020 was 8 (8), of which 4 (4) are women.

Incentive programs/share warrants

Currently there is no incentive program.

Audit review

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

Upcoming financial statements

Interim Report January-June 2020	August 21, 2020
Interim Report January-September 2020	November, 2020
Year-End Report 2020	February 19, 2021

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

Annual General Meeting 2020

NeuroVives Annual General Meeting will be held at Medicon Village, Scheelevägen 2, in Lund on May 20th at 10.00 am.

As a precautionary measure to reduce the risk of spreading the coronavirus, the Board of Directors of NeuroVive Pharmaceutical AB has decided to keep planned speeches at the general meeting to a minimum. The CEO's speech will be recorded and posted on the website after the Annual General Meeting. Participation at the general meeting by members of the Board of Directors, management as well as non-shareholders staff will be limited. Due to the authorities' regulations, the Company would like to emphasize all shareholders to carefully consider, instead of physically attending the meeting, use the below described opportunity to vote by proxy. This is especially true for people who feel ill, who are part of a risk group, who have been in an area of spread of infection or have been in close contact with someone who is infected by the new corona virus. A proxy form for representatives to represent shareholders and exercise their voting rights is available on the Company's website (www.neurovive.com). No refreshments will be served at the Annual General Meeting.

Risks and uncertainty factors

A research company such as NeuroVive Pharmaceutical AB (publ) is subject to high operational and financial risks because the projects the company conducts are in different developmental phases, where a number of parameters influence the likelihood of commercial success. Briefly, operations are associated with risks relating to factors including drug development, competition, technological progress, patents, regulatory requirements, capital requirements, currencies and interest rates. The Board of Directors works continuously to secure the business operation's need for financing. A way to spread risks is through continuous development activities, to out-license projects or enter strategic partnerships.

Impact of COVID-19 on the Company's clinical trials

The Company estimates that COVID-19 will delay NeuroVive's ongoing Phase Ia/b study with KL1333, since health-

care authorities and healthcare providers will prioritize available resources, care locations and healthcare professionals to better meet the possible influx of COVID-19 patients. At present, the planned final part of the Phase I a/b study with KL1333 against PMD is ready to start recruiting patients. Trial centers in Newcastle and London, where the study is to be conducted, have announced that, due to the situation with the COVID-19 pandemic, there will be delays in recruitment to all clinical trials for some time to come. This will cause the timing of inclusion of the first patient in the final phase of the Phase I a/b study with KL1333 to be delayed and that there is a risk that final results from this part of the study will be announced later than planned. NeuroVive therefore is working with different alternatives to adapt the study program for KL1333 to take into account the risk of continued delays, by modifying the design of the upcoming Phase II study,

which therefore is expected to continue in the first half of 2021. NeuroVive's preparations in the form of preclinical safety studies to be able to take the drug candidate, NV354 for Leigh syndrome, into clinical phase in 2021 are currently not considered to be affected by the COVID-19 pandemic. In NeuroVive's assessment, it is currently difficult to assess the actual effects of COVID-19 over the longer term and the degree to which they will affect the Company's operations and clinical studies.

NeuroVive is not involved in any disputes.

For more detail of risks and uncertainty factors, refer to the Statutory Administration Report in the Annual Report 2019 and the prospectus published April 3, 2020 for the preferential rights issue carried out in April 2020.

Principles of preparation of the Interim Report

NeuroVive 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 2019 on pages 52-68.

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



David Laskow-Pooley

David Beijker

Denise Goode

Erik Kinnman

Magnus Persson

Jan Törnell

The declaration of the Board of Directors and the CEO

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

Lund, Sweden, May 20, 2020

David Laskow-Pooley
Chairman of the Board

David Beijker
Board member

Denise Goode
Board member

Magnus Persson
Board member

Jan Törnell
Board member

Erik Kinnman
Chief Executive Officer

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.

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

The information was submitted for publication, through the agency of the contact person set out above, at 08:30 a.m. CEST on May 20, 2020.

Glossary

Active compound. A pharmaceutical active ingredient in a pharmaceutical product.

Alpers Disease. Mitochondrial disease. Also known as Alpers-Huttenlocher's disease. Usually appear in children under four years of age, first as difficult-to-treat epilepsy followed by brain injury, and usually also affecting the liver, the gastrointestinal tract and the peripheral nerves. The disease is progressive and results in increasing dementia, visual impairments and paralysis. There is no cure, but treatment efforts are focused on relieving the symptoms, preventing medical complications and providing support.

Blood-brain barrier. The blood-brain barrier consists of very closely joined capillary walls in the blood vessels of the brain that reduce the availability of certain bloodborne substances to access brain tissue (nerve cells).

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

Cell proliferation. When cells grow, and divide, i.e the number of cells are increased keeping the size of the cell intact. This results in an expansion of the tissue and consequently an increase of the size of the organ/tumor.

CHIC. Copenhagen Head Injury Ciclosporin study, phase IIa study of NeuroSTAT.

CHOP. The Children's Hospital of Philadelphia.

Ciclosporin. A natural active compound produced by the fungus *Tolypocladium inflatum*. Ciclosporin is now produced by artificial or chemical methods. Ciclosporin is a well-known substance that has been demonstrated to potentially protect brain in animal models of brain injury, where ciclosporin has transited the blood-brain barrier and entered the brain.

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 I, phase II, phase III. Phase II is usually divided into an early phase (phase IIa) and a later phase (phase IIb). See also "phase (I, II and III)".

COMP. EMA's Committee for Orphan Medicinal Products.

CRO. Contract research organization.

Cyclophilin D. The mitochondria target of ciclosporin and other cyclophilin inhibitors present in virtually all cells of the body.

EMA. The European Medicines Agency.

Energy metabolites. Digestion products from foodstuffs which reflects cell energy status and function of the mitochondria.

Experimental model. A model of a disease or other injury to resemble a similar condition or disease in humans.

FDA. The United States Federal Food and Drug Administration.

HCC. Hepatocellular carcinoma, liver cancer.

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

In vivo/in vitro. In vivo are scientific studies in animal models. In vitro are scientific studies carried out outside of the living body, for example in cells in test tubes.

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.

Liver fibrosis/cirrhosis. Liver fibrosis is the formation of fibrous tissue (scar tissue) in the liver as a result of, for example, infection. May lead to liver cirrhosis.

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. Mitochondrial disease. The most prominent symptoms of MERRF (Myoclonic epilepsy with ragged-red fibers) are epilepsy, muscle twitches and difficulty coordinating muscle movements, but the disease affects many functions.

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.

NAFLD. Non-Alcoholic Fatty Liver Disease.

NASH. Non-alcoholic steatohepatitis, inflammatory fatty liver disease.

Natural history study. A study that follows a group of people over time who have, or are at risk of developing, a specific medical condition or

disease. A natural history study collects health information in order to better understand how the medical condition or disease develops and how to treat it.

NIH. The National Institutes of Health, the American equivalent of the Swedish Research Council.

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).

Pearson syndrome. Mitochondrial disease. Appears early, in infants, with symptoms from several different tissues, mainly from the bone marrow, resulting in severe blood deficiency, as well as from the pancreas. Children with Pearson's syndrome who survive past adolescence later in life develop Kearns-Sayre's syndrome or other types of mitochondrial diseases.

Penn. University of Pennsylvania.

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

Pharmacokinetics. Describes how the body affects a specific drug after administration.

Phase (I, II and III). The various stages of trials on the efficacy of a pharmaceutical in humans. See also "clinical trial." Phase I examines the safety on healthy human subjects, phase II examines efficacy in patients with the relevant disease and phase III 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 II is often divided between phase IIa and phase IIb.

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.

Protonophores. Substance which carries protons across the mitochondrial membrane leading to increased energy expenditure.

Sangamides. Compound class of cyclophilin-D inhibitors.

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 NeuroVive

NeuroVive Pharmaceutical AB is a leader in mitochondrial medicine, with one project in clinical phase I (KL1333) for chronic treatment of primary mitochondrial diseases and one project, in preparation for clinical trials (NV354), for treatment of primary mitochondrial diseases with Complex I deficiency. NeuroSTAT for traumatic brain injury (TBI) is ready to enter a clinical phase II efficacy study. The R&D portfolio also consists of early projects. NeuroVive's ambition is to take drugs for primary mitochondrial diseases through clinical development and all the way to market, with or without partners. For the TBI and NASH projects the goal is to enter strategic partnerships. A subset of compounds under NeuroVive's NVP015 program has been licenced to Fortify Therapeutics, a BridgeBio company, for local treatment development of Leber's Hereditary Optic Neuropathy (LHON).

What is mitochondrial medicine?

Mitochondrial medicine is an area spanning from cell protection in acute and chronic medical conditions to the regulation of energy production and cell proliferation. Mitochondria are found inside the cells and can be considered as the cells' power plants. They give us the amount of energy we need to move, grow and think.

NeuroVive's discovery projects focus on deeper understanding of the mechanisms for our unique chemistry platforms, and the development of next-generation compounds for primary mitochondrial diseases.

Stock exchange

NeuroVive is listed on Nasdaq Stockholm, Sweden (ticker: NVP). The share is also traded on the OTC Markets' Pink Open Market in the US (OTC: NEVPF).

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