

NeuroVive Pharmaceutical AB Year End Report January-December 2019



Important events in 2019

KL1333

- NeuroVive enrolls first subject in its European KL1333 phase Ia/b clinical study
- NeuroVive initiates second part of its ongoing KL1333 Phase Ia/b clinical study
- NeuroVive completes recruitment of healthy volunteers in the second part of its ongoing KL1333 clinical Phase Ia/b study

NV354

 NeuroVive initiates NV354 preclinical safety studies and scales up compound production

NeuroSTAT

- NeuroVive's IND for clinical development of NeuroSTAT approved by FDA
- NeuroSTAT receives Fast Track designation from the US Food and Drug Administration

Financials

- NeuroVive is supplied with approximately MSEK 99.0 in share issue proceeds
- NeuroVive receives SEK 28.2 Million in a directed new share issue

Strategy and communications

- NeuroVive updates its strategy and sharpens its focus on primary mitochondrial diseases
- NeuroVive hosts the company's first Capital Markets Day
- NeuroVive hosts the Mitochondria Day for the second time

Other

 NeuroVive announces settlement in dispute with CicloMulsion AG

Important events after the reporting period

 NeuroVive proposes a rights issue of approximately MSEK 74 before issue costs. The rights issue is quaranteed to 90%.

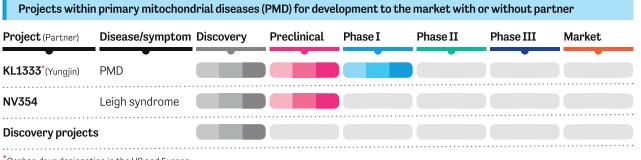
Financial information fourth quarter (Oct-Dec 2019)*

- Net revenues: KSEK 49 (5)
- Other operating income: KSEK 1,000 (1,009)
- Loss before tax: KSEK 27,112 (19,978)
- Loss per share: SEK -0.15 (-0.25)
- Diluted loss per share: SEK -0.15 (-0.25)

Financial information full year 2019 (Jan-Dec 2019)*

- Net revenues: KSEK 34 (5)
- Other operating income: KSEK 3,500 (2,461)
- Loss before tax: KSEK 77,000 (73,494)
- Loss per share: SEK 0.45 (0.94)
- Diluted loss per share: SEK 0.45 (0.94)

Focus on primary mitochondrial diseases. By focusing on drugs for the treatment of primary mitochondrial disorders, NeuroVive achieves several significant advantages. These projects have good potential for securing orphan drug designation, which makes the development of the drugs potentially faster and more cost-effective and will give market exclusivity if market approval is achieved. The company also believes that marketing and sales of mitochondrial drugs are well suited for a small and specialized sales-force.



^{*}Orphan drug designation in the US and Europe.

^{*} APM Alternative perfomance measures, see definition on page 17.

Full speed ahead in our projects for the treatment of primary mitochondrial diseases

2019 was a successful year for NeuroVive. Our most important projects in primary mitochondrial diseases advanced according to plan and KL1333 is in a second clinical trial. We are now focusing entirely on taking KL1333 further in clinical development, and in addition to prepare NV354 for clinical studies. For the company to assure the financial resources needed to further develop these projects, NeuroVives's Board of Directors has resolved on proposing a preferential rights issue of 74 MSEK.



Erik Kinnman CEO NeuroVive

First two parts of the second Phase I KL1333 trial successfully completed

The KL1333 project is in development for the treatment of primary mitochondrial diseases, which are caused by genetic disorders that directly affect cellular energy conversion. KL1333 has received orphan drug designation in both USA and Europe. We successfully completed the first two parts of the Phase I a/b trial, where healthy volunteers were given doses of our drug candidate.

These parts of the trial show that KL1333 is safe to use and that no serious side effects were experienced by the participants. These initial parts of the trial have also given us knowledge of tolerable dose levels, which is important for upcoming trials with patients.

The recruitment of patients to the third and final part of the Phase I a/b trial is expected to start shortly. The patients included in this part of the trial suffer from a primary mitochondrial disease with severe symptoms such as pronounced fatigue, muscle function loss, intractable

diabetes and reduced cardiac muscle function. This final part of the trial is planned to continue until summer 2020. The next important step in the development of KL1333 is the Phase II efficacy study, planned to start during the first half of 2021. In preparation for this study, existing clinical patient data are analyzed to optimize the outcome measures and patient inclusion criteria.

NV354 - in preparation for clinical phase

Leigh syndrome is a severe primary mitochondrial disease where the most serious symptoms are attributable to the loss of neurological functions, which leads to e.g. developmental delays and epilepsy. Other severe symptoms are muscle weakness, impairment of cardiac, kidney and lung function and eye movement disturbances. Very few children with Leigh syndrome live beyond 5 years of age. NV354 is being developed to provide these patients with an alternative energy source and thereby alleviate the symptoms, improve quality of life and prolong life. Preclinical safety studies are ongoing and we plan to commence a Phase I trial in 2021. NeuroVive will therefore have two important projects in clinical phase next year.

Non-core assets

NeuroSTAT is being developed for the management of moderate to severe traumatic brain injury, which affects three million people each year. This project has an approved IND application and FastTrack status from FDA and is ready to enter a Phase II efficacy study. For NeuroSTAT we seek a partner and non-dilutive funding to finance the planned efficacy study.

In line with the increased focus on PMD, NeuroVive will not invest further in **NV556** development activities.

Financing

NeuroVive's Board of Directors has proposed a preferential rights issue of 74 MSEK. The purpose is to assure the company the resources needed to finance the important concluding patient part of the ongoing KL1333 Phase Ia/b study, prepare KL1333 for an efficacy study, as well as prepare NV354 for a first clinical study during first half of next year. The rights issue is guaranteed to 90%. The proceeds from the rights issue will together with the company's resources be focused on KL1333 and NV354.

Value creation in several dimensions

We are now entering 2020 with energy and determination to continue delivering our updated strategy, where the focus lies on developing effective therapies for this group of patients with primary mitochondrial diseases for which no effective treatment options are currently available. It is the Board's and mine conviction that we through the strategic focus best optimize shareholder value.

The ambition to significantly improve life for patients with mitochondrial diseases is motivating on a personal level for everyone who works at NeuroVive, and also holds potential to generate significant medical and financial value.

Erik Kinnman, CEO





KL1333 – for treatment of primary mitochondrial diseases

Ongoing clinical Phase Ia/b study

Recruitment of 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 12 in every 100,000 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.

The candidate drug, KL1333, is a potent modulator of cellular levels of NAD+, a central coenzyme in the cell's

energy metabolism, and is intended for 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 has been granted orphan drug designation in Europe and the United States. Orphan drugs generally allow for a faster and less costly route to the market, as well as a higher market price for the drug.

Activities in the fourth quarter

NeuroVive completes recruitment of healthy volunteers in the second part of its ongoing KL1333 clinical Phase Ia/b study.

Objectives for 2019

Clinical Phase Ia/b study in Europe:

- Start the study (2019) 🗸
- Present initial results (2019) ✓
- Complete the Phase Ia part with healthy volunteers (04 2019/01 2020)

Objectives for 2020/2021

- Start the Phase Ib part with patients (Q1 2020)
- Conclude the Phase Ia/b study and report results (H2 2020)
- Initiate clinical Phase II efficacy study (H1 2021)







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.

Activities in the fourth quarter

NV354 preclinical safety studies have continued and the compound production has been scaled up. The produced material has also been quality assured according to GMP (Good Manufacturing Practice).

Objectives for 2019

- Present further results from preclinical in vivo dose-response studies (2019)
- Scale up compound production (2019) ✓
- Initiate preclinical safety studies (2019) √

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 June 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

Partnership with Oroboros Instruments

In February 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.

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). Biomarker data from the studies have also given signals of clinical effect. 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.

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 NASH patients 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: candidate drug in pre-clinical development

Preclinical results have shown that the greatest potential for the project is within the subgroup of NASH patients with liver fibrosis. NV556 is best suited as a complement to NASH therapy focused on the metabolic disease processes.





Consolidated Statement of Comprehensive Income

Revenues

The consolidated turnover during the full year of 2019 was KSEK 49 (5). Other operating revenues for the full year were KSEK 3,500 (1,009) and relates to grants from Vinnova for the NV354 project. During the full year of 2019 the consolidated turnover was 134 (5) KSEK and are mainly revenues from research compunds sold by the partner Oroboros. Other operating revenues for the full year amounted x (2,461) KSEK and were related to grants from Vinnova for the project NV354.

Results of operations

The operating loss for the forth quarter was KSEK 27,223 (20,130) and for the full year the operating loss amounted KSEK 77,074 (73,360). The net loss before tax for the forth quarter amounted to KSEK 27,112 (19,978). For the full year the loss before tax was 77,000 (73,494).

The operating loss was affected by other external expenses, which for full year were KSEK 63,133 (55,812). Expenses related to development projects, as a part of external expenses, have affected the result with KSEK 45,093 (37,922) whereof KSEK 25,860 (22,691) relates to project in clinical phase. Personnel expenses during the full year amounts to KSEK 14,872 (14,454). Other operating expenses amount to, KSEK 325 (789) and pertains to exchange-rate losses.

		1 Oct, 2019	1 Oct, 2018	1 Jan, 2019	1 Jan, 2018
(SEK 000)	Note	31 Dec, 2019	31 Dec, 2018	31 Dec, 2019	31 Dec, 2018
Net sales		49	5	134	5
Other operating income		1,000	1,009	3,500	2,461
		1,049	1,014	3,634	2,466
Operating expenses					
Other external expenses		-23,461	-14,375	-63,133	-55,812
Personnel cost		-4,168	-3,414	-14,872	-14,454
Depreciation and write-down of tangible and intangible assets		-622	-3,330	-2,379	-4,771
Other operating expenses		-20	-25	-325	-789
		-28,271	-21,144	-80,708	-75,826
Operating income		-27,223	-20,130	-77,074	-73,360
Profit/loss from financial items					
Result from other securities and receivables related to non current					
assets		-	-	-	66
Financial income		-	86	_	407
<u>Financial costs</u>		-10	-	-46	-607
		111	152	75	-134
Profit/loss before tax		-27,112	-19,978	-77,000	-73,494
Income tax	2	-	-	-	
Profit/loss for the period		-27,112	-19,978	-77,000	-73,494
Other comprehensive income					
Items that may be reclassified to profit or loss					
Translation differences on foreign subsidiaries		-2	4	3	4
Total comprehensive income for the period		-27,114	-19,974	-76,997	-73,490
Loss for the period attributable to:					
Parent company shareholders		-27,107	-14,858	-76,994	-68,373
Non-controlling interests		-5	-5,120	-6	-5,121
		-27,112	-19,978	-77,000	-73,494
Total comprehensive income for the period					
Parent company shareholders		-27,110	-14,854	-76,991	-68,370
Non-controlling interests		-4	-5,120	-6	-5,120
		-27,114	-19,974	-76,997	-73,490
Earnings per share before and after dilution(SEK) based on average					
number of shares		-0.15	-0.25	-0.45	-0.87

Consolidated Statement of Financial Position

Financial position

The equity/assets ratio was 86 (84) percent as of 31 December 2019, and equity was KSEK 127,795 (97,012). The equity includes funds from therights issue completed i February, which provided the company with KSEK 81,849 after deduction of issue costs and compensation for guarantee commitments of KSEK 17,184 and funds from the directed issue with KSEK 25,931 after deduction of issue costs of KSEK 2,281 completed in March. Cash and cash equivalents amounted to KSEK 58,319 (25,951) as of 31 December 2019, an increase of KSEK 32,368 from the beginning of the year. Total assets as of 31 December 2019 were KSEK 148,492 (115,308).

The board continuously monitors and evaluates the company's funding need and financial position. The Board of Directors announced on February 19, 2020 that it intends to issue shares with preferential rights to existing shareholders of approximately SEK 74 million, subject to approval by the Annual General Meeting. The Rights issue is guaranteed to 90 percent through subscription and guarantee commitments.

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 Dec, 2019	31 Dec, 2018
ASSETS		
Non-current assets	4	
Intangible assets Development costs	<u> </u>	51,706
Patents	21,501	20,121
Other Intangible assets	1,479	1,613
Other Intallylible assets	74,686	73,440
Tangible assets	,	,
Equipment	99	140
Rigth of use asset leases	687	
Firm del conte	786	140
Financial assets Other long-term securities	13,101	17 101
Other long-term securities	13,101	13,101 13,101
	13,101	13,101
Total non-current assets	88,573	86,681
Current assets		
Other receivables	1,141	1,432
Prepaid expenses and accrued income	459	1,244
Cash and cash equivalents	58,319	25,951
	59,919	28,627
TOTAL ASSETS	148,492	115,308
EQUITY AND LIABILITIES		
Equity attributable to the shareholders of the parent company		
Share capital	9,298	4,585
Additional paid in capital	592,980	489,913
Translation reserve	619	616
Retained earnings Total equity attributable to the shareholders of the parent	-475,107 127,790	-398,113 97,001
Total equity and ibutable to the shall enotice s of the parent	127,700	37,001
Non-controlling interests	5	11
Total equity	127,795	97,012
Long-term liabilities		
Other longtrem liabilities	361	
	361	
Short-term liabilities		
Accounts payable	14,234	10,162
Other liabilities	811	808
Accrued expenses and deferred income	5,292	7,326
	20,336	18,296
Total liabilities	20,697	18,296
TOTAL FOLITY AND LYADY TYPO	440,400	445 700
TOTAL EQUITY AND LIABILITIES	148,492	115,308

Consolidated Statement of Changes in Equity

	Fauity attr	hutable to	the shareholde	re of the parer	nt company		
-		Additional	LIIC SIIAI CIIULUC	15 UI LIIC PAI CI	it company	Non-	
	Share-	paid in	Translation	Retained		controlling	Total
(SEK 000)	capital	capital	reserve	earnings	Total	interests	eauity
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	127,790	5	127,795
Opening balance, 1 January 2018	2,616	427,226	613	-329,740	100,716	5,131	105,846
Comprehensive profit/loss for the period							
Profit/loss for the period	-	-		-68,373	-68,373	-5,121	-73,494
Other comprehensive income							
Translation differences	-	-	3	-	3	1	4
Other comprehensive profit/loss for the period, net							
after tax	-	-	3	-	3	1	4
Total comprehensive profit/loss	-		3	-68,373	-68,370	-5,120	-73,490
Transactions with shareholders							
Rights Issue	1,969	62,687	_	-	64,656	-	64,656
Total transactions with shareholders	1,969	62,687	-	-	64,656	-	64,656
Closing balance, 31 December 2018	4,585	489,913	616	-398,113	97,002	11	97,012

^{*}Total equity includes funds from the February 11, 2019 completed rights issue with KSEK 99,033 less expenses and guarantees KSEK 17,184 and the directed rights issue completed March 7, 2019 with KSEK 28,212 less expenses KSEK 2,281.

Consolidated Statement of Cash Flows

Cash flow and investments

Operating cash flow for the fourth quarter was KSEK -21,697 (-11,821). For the full year the operating cash flow amounted -73,014 (-63,829). The cash flow effect related to investments in intangibles equals KSEK -2,626 (-3,791) for the full year. Cash flow for the fourth quarter equals KSEK-21,450 (-12,421). Cashflow for the full year equals KSEK 32,364 (-3,046).

(SEK 000)	1 Oct, 2019 31 Dec, 2019	1 Oct, 2018 31 Dec, 2018	1 Jan, 2019 31 Dec, 2019	1 Jan, 2018 31 Dec, 2018
Cash flow from operating activities	<u> </u>	,	,	,
Operating income	-27,223	-20,130	-77,074	-73,360
Adjustments for non-cash items:				
Depreciation	879	473	2,379	1,914
Impaired Value	-	3,324	-	3,324
Result from other securities and receivables related to non current assets		-	121	66
Interest received	-	86	-	407
Interest paid		-	-46	-606
Net cash from operating activities before changes in working capital	-26,343	-16,246	-74,621	-68,255
Changes in working capital				
Increase/decrease of other current assets	316	-810	1,077	859
Increase/decrease of other short-term liabilities	4,812	5,301	1,131	3,567
Changes in working capital	5,128	4,490	2,208	4,426
Cash flow from operating activities	-21,216	-11,756	-72,413	-63,830
Investing activities				
Acquisition of intangible assets	-157	-1,146	-2,626	-3,791
Acquisition of tangible assets		-	-69	-82
Increase in other financial assets		11	-	1
Cash flow from investing activities	-157	-1,145	-2,695	-3,872
Financing activities				
New share issue	-	480	107,780	64,656
Amoritization lease liabilities	-77	-	-309	-
Cash flow from financing activities	-77	480	107,471	64,656
Cash flow for the period	-21,450	-12,421	32,364	-3,046
Cash and cash equivalents at the beginning of the period	79,773	38,371	25,951	28,992
Effect of exchange rate changes on cash	-4	-	4	5
Cash and cash equivalents at end of period	58,319	25,951	58,319	25,951

Parent Company Income Statement

Parental company

Company earnings after tax for the full year amounts to KSEK -76,947 (-73,226). Most of the Group's operations are conducted within the parent company. Accordingly, no further specific information regarding the parent company is presented.

(SEK 000)	Note	1 Oct, 2019 31 Dec, 2019	1 Oct, 2018 31 Dec, 2018	1 Jan, 2019 31 Dec, 2019	1 Jan, 2018 31 Dec, 2018
Net sales		49	5	134	5
Other operating income		1,000	1,009	3,500	2,461
		1,049	1,014	3,634	2,466
Operating expenses					
Other external expenses		-23,525	-14,345	-63,469	-55,777
Personnelcost		-4,168	-3,414	-14,872	-14,454
Depreciation and write-down of tangible and intangible assets		-536	-3,095	-2,036	-4,536
Other operating expenses		-20	-26	-325	-789
		-28,250	-20,880	-80,701	-75,556
Operating income		-27,201	-19,867	-77,068	-73,090
Profit/loss from financial items					
Result from other securities and receivables related to non current					
assets		121	66	121	66
Interest income and other similar profit items		-	86	-	400
Interest expenses and other similar loss items		-	1	-1	-602
		121	152	120	-136
Profit/loss before tax		-27,080	-19,714	-76,947	-73,226
Income tax	2	-	-	-	-
Profit/loss for the period		-27,080	-19,714	-76,947	-73,226

Statement of Comprehensive Income, Parent Company

(SEK 000)	Note	1 Oct, 2019 31 Dec, 2019	1 Oct, 2018 31 Dec, 2018	1 Jan, 2019 31 Dec, 2019	1 Jan, 2018 31 Dec, 2018
Profit/loss for the period		-27,080	-19,714	-76,947	-73,226
Other comprehensive income		-	-	-	-
Total comprehensive profit/loss for the period		-27,080	-19,714	-76,947	-73,226

Parent Company Balance Sheet

(SEK 000)	Note	31 Dec, 2019	31 Dec, 2018
ASSETS			
Non-current assets			
Intangible assets	1	F4 F00	F4 F00
Development costs		51,706	51,706
Patents		21,501	20,121
Other intangible assets		1,479	1,613
Tangible assets		74,686	73,440
Equipment		99	140
Equipment		99	140
Financial assets		99	140
Other long-term placement		13,100	13,101
Shares in subsidiaries	3	23,625	23,625
Silares ili subsidiaries	3	36,726	36,726
		30,720	30,720
Total non-current assets		111,511	110,305
TOGAL HOLL-CALL CITE 455C65		111,011	110,303
Current assets			
Short term receivables			
Other receivables		1,138	1,430
Prepaid expenses and accrued income		459	1,244
Trepaid expenses and accrued income		1,597	2,674
		1,397	2,074
Cash and bank balances		58,272	25,871
Total current assets		59,869	28,545
10001 0011 0110 0330 03		00,000	20,040
TOTAL ASSETS		171,380	138,850
		,	,
EQUITY AND LIABILITIES			
Equity			
Restricted equity			
Share capital		9,298	4,585
Statutory reserve		1,856	1,856
Development expenditure reserve		14,106	12,725
		25,260	19,167
Unrestricted equity		•	,
Share premium reserve		103,067	62,687
Retained earnings		100,027	111,945
Profit/loss for the period		-76,947	-73,226
·		126,146	101,406
		,	
Total equity		151,406	120,573
Short-term liabilities			
Accounts payable		14,234	10,162
Other liabilities		467	808
Accrued expenses and deferred income			
Accrued expenses and deferred income		5,273	7,307
		19,974	18,277
TOTAL EQUITY AND LIABILITIES		171,380	138,850
		1,1,000	100,000

Notes

Note 1 — Intangible assets

(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 30 Dec. 2019	51,706	21,501	1,479	74,686

(SEK 000)	Development costs	Patents	Other	Total
ACCUMULATED COST				
Opening balance 1 Jan. 2018	51,941	28,405	2,864	83,210
Additions	-	3,791	-	3,791
Impaired value	-235	-3,089	-	-3,324
Closing balance 31 Dec. 2018	51,706	29,107	2,864	83,677
ACCUMULATED DEPRECIATION		·		
Opening balance 1 Jan. 2018	-	-7,778	-1,117	-8,895
Depreciation for the period	-	-1,675	-134	-1,809
Closing balance 31 Dec. 2018	-	-8,986	-1,251	-10,237
Residual value 31 Dec. 2018	51,706	20,121	1,613	73,440

Note 2 - Tax

The group's total loss carry-forwards amounts to KSEK 544,635 as of 31 December 2019 (448,548). The parent company's total loss carry-forwards amounts to SEK 518,809 as of 31 December 2019 (422,775). 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 subsidiarie, 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. 2019
(SEK 000)	31 Dec. 2019
Eskil Elmér, CSO	6
Magnus Hansson, CMO	3
Total	9

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 the above mentioned transactions and remuneration to senior executives no transactions with related parties have occured.

Segment information

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

Human resources

The average number of employees of the group for the period January to September 2019 was 9 (9), 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

Annual report 2019	Week 17, 2020
Interim Report January-March 2020	May 20, 2020
Interim Report January-June 2020	August 21, 2020
Interim Report January-September	November, 2020
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.

Please note that the time of the Annual General Meeting has changed compared to what has been communicated earlier.

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 continious development activities, to out-license projects or enter strategic partnerships.

No other significant changes in relation to risk or uncertainties occurred during the current period.

In 2004, NeuroVive entered into a License Agreement with CicloMulsion AG under which NeuroVive licensed the rights to use and develop products based on a certain pharmaceutical technology.

In March 2013, CicloMulsion AG commenced an arbitration seeking declaratory relief aimed at establishing the company's rights to royalties, which CicloMulsion AG claims that NeuroVive is obliged to pay under the terms of the License Agreement. CicloMulsion AG also made other claims in relation to NeuroVive's obligations under the License Agreement.

A partial award issued in 2016 was set aside by the Scania and Blekinge Court of Appeal with the exception of the question for which the Tribunal had reserved its decision. NeuroVive appealed parts of the ruling to the Supreme Court. On April 30th, 2019, the Supreme Court announced that the appeal had been rejected. This means that the partial award is ultimately and completely set aside.

Through the ruling from the Supreme Court, NeuroVive was ordered to pay CicloMulsion's court costs of SEK 531,899 and EUR 20,187 for the Supreme Court. The court costs were paid in May 2019.

The former arbitral tribunal was replaced by a Newly Composed Arbitral Tribunal following a request for the release of the arbitrators filed by CicloMulsion. The constitution of the Newly Composed Arbitral Tribunal was finalized and the arbitral tribunal initiated its process with the aim of announcing an award in 2020.

On December 16, 2019 the company announced that NeuroVive and CicloMulsion AG have fully and finally settled the dispute. The settlement means that NeuroVive shall not make any payments to CicloMulsion for the claims made in the arbitration. The ownership of the technology shall remain with NeuroVive, who shall thus have exclusive rights thereto, and NeuroVive shall not be liable for any future royalties relating to the technology. The arbitration has been terminated, and each party shall bear its own costs in the arbitration.

NeuroVive is not involved in any disputes after the settlement with CicloMulsion AG.

For more detail of risks and uncertainty factors, refer to the Statutory Administration Report in the Annual Report 2018 and the prospectus published January 22, 2019 for the preferential rights issue carried out in February 2019.

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 2018 on pages 56-69.

IFRS 16, Lease Agreement, replaces IAS 17 and will apply as of January 1, 2018. The standard requires that assets and liabilities attributable to all leases, with some exceptions, are reported in the balance sheet. NeuroVive has lease contracts for office premises that will be reported in the balance sheet as of January 1, 2018. Reporting is made in accordance with transitional rules without recalculation of comparative figures. For further information see page 56 in the Annual Report 2018.

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
Profi/loss before tax	Operating income after profit/loss from finacial items	Measures the result in the business after profit/loss from financial items
Earnings per share before dilution(SEK) based on average number of shares	Profit/loss for the period divided by avarage 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 avarage 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
Equity Ratio %	Eget kapital i procent av balansomslutningen	Shows how much of the company's assets are financed with equity and shows the company's ability to pay
Liquidity Ratio (%)	Current assets divided by current liabilities	Shows on the company's short-term ability to pay



The declaration of the Board of Directors and the CEO

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

Lund, Sweden, February 19, 2020

David Laskow-PooleyDavid BejkerDenise GoodeChairman of the BoardBoard memberBoard member

Magnus PerssonJan TörnellErik KinnmanBoard memberBoard memberChief 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 08:40 a.m. CET on February 19, 2020.

Glossary

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

Alpers Disease. Mitochondrial disease. Also known as Alpers-Hutten-locher'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 potently 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 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 inhibtors 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 strokelike 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 Ophthalmopleqia/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 II 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 for primary mitochondrial disease, and NASH.

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.

In addition to our discovery projects within primary mitochondrial disease, we evaluate the mechanisms for our unique chemistry platforms, mainly within cyclophilin inhibitors.

Marketplace

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).

NeuroVive Pharmaceutical AB (publ)

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