Q3

NeuroVive Pharmaceutical AB
Interim Report January-September 2019

Continued progress in KL1333.

Important events July – September

- NeuroVive initiates second part of its ongoing KL1333 Phase Ia/b clinical study
- NeuroSTAT receives Fast Track designation from the US Food and Drug Administration.

Financial information third quarter (July-September 2019)

- Net revenues: KSEK 0 (0)
- Other operating income: KSEK 1,500 (0)
- Loss before tax: KSEK -15,297 (-14,982)
- Loss per share*: SEK -0.08 (-0.20)
- Diluted loss per share**: SEK -0.08 (-0.20)

Financial information first nine months (January-September 2019)

- Net revenues: KSEK 85 (0)
- Other operating income: KSEK 2,500 (1,452)
- Loss before tax: KSEK -49,888 (-53,516)
- Loss per share*: SEK -0.30 (-0.72)
- Diluted loss per share**: SEK -0.30 (-0.72)

* Profit/loss for the period divided by average number of shares before dilution at the end of the period.
** Profit/loss for the period divided by average number of shares after dilution at the end of the period

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.

Focused business development. NeuroVive's business development has two distinct aims. For the company's projects for primary mitochondrial diseases, we seek partners who can contribute capital and know-how during development to market. For the projects aimed at common indications, our ambition is out-licensing in the preclinical stage for further development to market by the partner.

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

Project (Partner)	Disease/symptom	Discovery	Preclinical	Phase I	Phase II	Phase III	Market
KL1333* (Yungjin)	MELAS/Myopathy						
NV354	Leigh						
NVP025	Myopathy						
Discovery projects							

*Orphan drug designation in the US and Europe.

Focusing on primary mitochondrial diseases

NeuroVive has an exciting future ahead. We have world-class expertise in primary mitochondrial disease – an area with high unmet medical needs, where patients have severe symptoms and a significantly shortened life expectancy, and only limited treatment options are available. We have therefore made a strategic decision to focus our resources on moving KL1333 and NV354 through clinical trials to market on our own. That will help us deliver benefits for patients, treatment options for doctors, and value for shareholders.

This decision is based on four factors that make KL1333 and NV354 – both of which are being developed for the treatment of primary mitochondrial diseases – particularly suitable for NeuroVive to take all the way to market:

- **Unmet medical needs.** There are no effective drugs for those patients with the primary mitochondrial diseases that we are focused on. These patients have severe symptoms and a short life expectancy.
- **Orphan drug designation.** Drug candidates developed for rare diseases can obtain orphan drug designation, which offers a number of benefits including regulatory assistance and scientific advice from pharmaceutical regulators and extended periods of market exclusivity.
- **Cost benefits.** Orphan drugs generally have lower development costs, a shorter time to market and attractive prices compared with drugs for common diseases.
- **Specialist care centers.** In most countries, the care of patients with mitochondrial diseases is assigned to a small number of medical centers with which NeuroVive often has already established relationships, enabling effective marketing and sales with limited investment.

Focusing on primary mitochondrial diseases

During *Global Mitochondrial Disease Awareness Week*, hosted by *International Mito Patients*, NeuroVive arranged a day for patients, family members and doctors to hear about their experiences, insights, requests and hopes. All participants confirmed the high unmet need for new and effective drugs for mitochondrial disease. I would like to take this opportunity to express my sincere gratitude to all those participants who so generously shared their experiences and insights.

Our Capital Markets Day, which we also held recently, also confirmed the attractiveness of the orphan drug market from an investor perspective, not least because development costs are lower than for other drugs and the likelihood of receiving marketing authorization is greater. At our Capital Markets Day, we could also show the strong progress we have made with our projects and how NeuroVive has very few competitors in the mitochondrial disease market. Several presentations also showed there is reason to assume that primary mitochondrial diseases are under-diagnosed and that the need for new drugs is even greater than previously thought.

Of our projects for primary mitochondrial diseases, KL1333 has made the most progress. We recently concluded the first stage of our Phase Ia/b trial with doses in healthy volunteers and have now commenced a multiple dose study in healthy volunteers. In the beginning of 2020, we will begin dosing in patients and initiate a natural history study as a first part of our Phase II program that will progress into controlling efficacy studies in patients, which means that KL1333 has reached a very exciting stage of development. The next project to move into the clinical stage will be NV354. We are now conducting preliminary safety studies in experimental models and scaling up drug production, with the aim of seeking approval during 2020 for starting a first clinical study.

Focused business development to find the right partner for our other projects

Our other projects are aimed at a considerably wider range of disease areas and larger patient cohorts, where we need partners with resources to increase the prospects of moving them successfully onwards.

NeuroSTAT is being developed for the management of moderate to severe traumatic brain injury, which affects three million people each year. This project is ready to enter a Phase II clinical trial to assess the efficacy of NeuroSTAT as soon as we have found a suitable partner to continue advancing the project.

NV556 is being developed for the treatment of fibrosis in patients with nonalcoholic steatohepatitis (NASH). This disease is estimated to affect 3-5% of the global population, which will require a huge amount of documentation in all clinical development phases and mean that moving through clinical trials to registration will prove a major challenge for us. Here too, our aim is to identify a suitable partner for moving the project through clinical trials to market.

Future outlook

A focus on primary mitochondrial diseases will increase our prospects of delivering products with real benefit for severely ill patients at a reasonable cost for development, while creating value for our shareholders. NeuroVive's team of highly experienced experts collaborate regularly with world-class consultants in the field of orphan drugs, who also assist us in our dialogue with regulators. Moreover, we have established partnerships with some of the world's leading clinical centers for the treatment of primary mitochondrial diseases. Our joint aim is to create a better life for these severely ill patients. We are now looking forward to continuously delivering in our projects for primary mitochondrial diseases, also by including patients in our clinical program for our key project, KL1333.

Erik Kinnman, CEO

Phase I

KL1333 - for treatment of primary mitochondrial diseases

Ongoing clinical Phase Ia/b study in the UK

Positive results from the first part of the study

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, heart failure and rhythm disturbances, dementia, movement disorders, stroke-like episodes, deafness, blindness, limited mobility of the eyes, vomiting 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 in primary mitochondrial disorders such as MELAS, KSS, PEO, Pearson and MERRF. KL1333 has been granted orphan drug designation in Europe and the United States, which allows for a faster and less costly route to the market, as well as a higher market price for the drug.

Activities in the third quarter

NeuroVive initiates second part of its ongoing KL1333 Phase Ia/b clinical study in healty volunteers with repeated dosing after successful completion of the first part.

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 (Q4 2019/Q1 2020)

Objectives for 2020/2021

- Start the Phase Ib part with patients (Q1 2020)
- Initiate clinical natural history study (H1 2020)
- Initiate clinical Phase II efficacy study (H1 2021)

Preclinical

NV354 - alternative energy source in primary mitochondrial disease

The project is in preparation for clinical phase

Experimental data has been presented during 2019

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.

The NVP015 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 third quarter

NeuroVive initiates preclinical toxicology studies.

Objectives for 2019

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

Objectives for 2020/2021

- Complete preclinical toxicology studies (H2 2020)
- Initiate clinical natural history study (Q4 2020)
- Initiate Phase I study (H1 2021)

Preclinical

NVP025 - for treatment of mitochondrial myopathy

Favorable effects which may counter disease progression

Ongoing dose response studies for selection of candidate substance

Mitochondrial myopathies (muscle diseases) are among the most common manifestations of primary mitochondrial disorders. The individual conditions that compose mitochondrial myopathies include MELAS (mitochondrial encephalopathy, lactic acidosis and stroke-like episodes), PEO (progressive external ophthalmoplegia), KSS (Kearns-Sayre syndrome) and MERRF syndrome (myoclonic epilepsy with ragged red fibers).

The clinical hallmark of a mitochondrial myopathy includes muscle weakness, exercise intolerance and fatigue and often present with other symptoms of primary mitochondrial disorders. The severity of the disease can range from generally progressive weakness to death. There is a major unmet medical need for new and effective treatment options for mitochondrial myopathies since there is no specific treatment for these serious diseases.

Activities in the third quarter

The NVP025 project has progressed according to plan in the quarter, with continued dose response studies.

Objectives for 2019/2020

- Perform dose-response studies for selection of candidate substance and route of administration.
- Select candidate compound.

Out-licensed projects and commercial partnerships

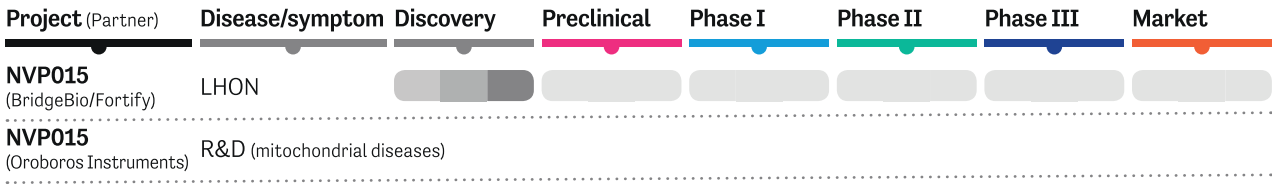
Project for local treatment of LHON

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

Commercial 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 will in turn commercialize and distribute the compounds.

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.



Projects for development by partnering

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 orp-han drug designation in Europe and the US as well as an IND approval and Fast Track designation for clinical deve-lopment 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).

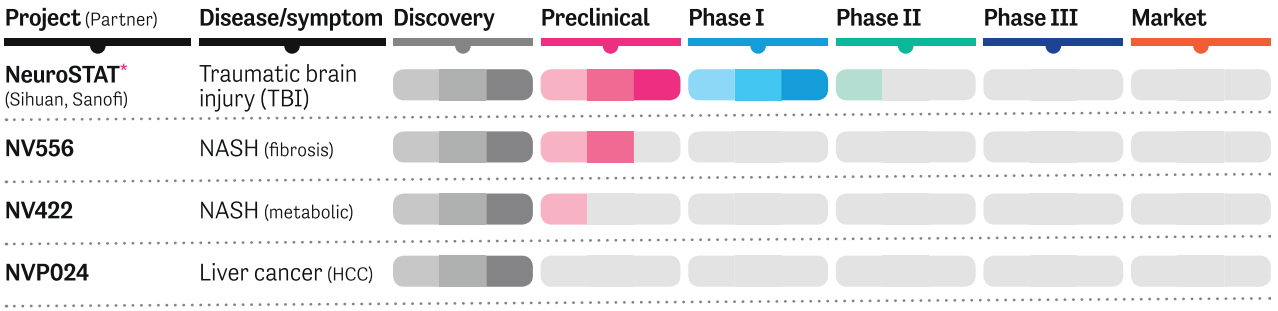
Project status: candidate drug in pre-clinical development

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.

Research projects

NV422 for treatment of NASH and NVP024 for treatment of liver cancer.

NeuroVive has the ambition to enter strategic partnership for all projects not focusing on primary mitochondrial diseases. The two projects that currently are in focus for this business strategy are NeuroSTAT for treatment of traumatic brain injury and NV556, which is developed for treatment of liver fibrosis in NASH. The company has interesting discussions with potential partners regarding NV556 and is actively seeking strategic partnerships for NeuroSTAT.



*Orphan drug designation in the US and Europe.

Consolidated Statement of Comprehensive Income

(SEK 000)	Note	1 Jul, 2019 30 Sep, 2019	1 Jul, 2018 30 Sep, 2018	1 Jan, 2019 30 Sep, 2019	1 Jan, 2018 30 Sep, 2018	1 Jan, 2018 31 Dec, 2018
Net sales		-	-	85	-	5
Other operating income		1,500	-	2,500	1,452	2,461
		1,500	**-**	**2,585**	**1,452**	**2,466**
Operating expenses						
Other external expenses		-13,094	-11,217	-39,671	-41,437	-55,812
Personnel cost		-2,893	-3,249	-10,704	-11,039	-14,454
Depreciation and write-down of tangible and intangible assets		-612	-498	-1,757	-1,441	-4,771
Other operating expenses		-187	-111	-304	-765	-789
		-16,786	**-15,075**	**-52,437**	**-54,682**	**-75,826**
Operating income		**-15,286**	**-15,075**	**-49,852**	**-53,230**	**-73,360**
Profit/loss from financial items						
Result from other securities and receivables related to non current assets		-	-	-	-	66
Financial income		-	94	-	320	407
Financial costs		-11	-1	-37	-606	-607
		-11	**93**	**-37**	**-286**	**-134**
Profit/loss before tax		**-15,297**	**-14,982**	**-49,888**	**-53,516**	**-73,494**
Income tax	2	-	-	-		-
Profit/loss for the period		**-15,297**	**-14,982**	**-49,888**	**-53,516**	**-73,494**
Other comprehensive income						
Items that may be reclassified to profit or loss						
Translation differences on foreign subsidiaries		4	-1	5	4	4
Total comprehensive income for the period		**-15,293**	**-14,983**	**-49,883**	**-53,512**	**-73,490**
Loss for the period attributable to:						
Parent company shareholders		-15,297	-14,982	-49,887	-53,515	-68,373
Non-controlling interests		-	-	-1	-1	-5,121
		-15,297	**-14,982**	**-49,888**	**-53,516**	**-73,494**
Total comprehensive income for the period						
Parent company shareholders		-15,295	-14,917	-49,882	-53,742	-68,370
Non-controlling interests		0	-66	-1	230	-5,120
		-15,295	**-14,983**	**-49,883**	**-53,512**	**-73,490**
Earnings per share before and after dilution(SEK) based on average number of shares		-0.08	-0.20	-0.30	-0.72	-0.87

Revenues

The consolidated turnover during the third quarter of 2019 was KSEK 0 (0). Other operating revenues for the third quarter were KSEK 1,500 (0) and relates to grants from Vinnova for the NV354 project. During the first nine months of 2019 the consolidated turnover was 85 (0) KSEK. Other operating revenues for the first nine months amounted 2,500 (1,452) KSEK and were related to grants from Vinnova for the project NV354.

Results of operations

The operating loss for the third quarter was KSEK 15,286 (15,075) and for the first nine months the operating loss amounted KSEK 49,852 (53,230). The net loss before tax for the third quarter amounted to KSEK 15,297 (14,982). For the fist nine months the loss before tax was 49,888 (53,516).

The operating loss was affected by other external expenses, which for the first nine months were KSEK 39,671 (41,437). Expenses related to development projects, as a part of external expenses, have affected the result with KSEK 27,177 (30,284) whereof KSEK 12,765 (18,214) relates to project in clinical phase. Personnel expenses during the first nine months amounts to KSEK 10,704 (11,039). Other operating expenses amount to, KSEK 304 (765) and pertains to exchange-rate losses.

Consolidated Statement of Financial Position

(SEK 000)	Note	30 Sep, 2019	30 Sep, 2018	31 Dec, 2018
ASSETS				
Non-current assets				
Intangible assets	1			
Development costs		51,706	51,941	51,706
Patents		21,274	22,597	20,121
Other Intangible assets		1,512	1,647	1,613
		74,492	**76,185**	**73,440**
Tangible assets				
Equipment		126	167	140
Rigth of use asset leases		773	-	-
		899	**167**	**140**
Financial assets				
Other long-term securities		13,101	13,102	13,101
		13,101	**13,102**	**13,101**
Total non-current assets		**88,492**	**89,454**	**86,681**
Current assets				
Other receivables		1,312	1,263	1,432
Prepaid expenses and accrued income		605	604	1,244
Cash and cash equivalents		79,773	38,371	25,951
		81,690	**40,238**	**28,627**
TOTAL ASSETS		**170,182**	**129,692**	**115,308**
EQUITY AND LIABILITIES				
Equity attributable to the shareholders of the parent company				
Share capital		9,298	4,579	4,585
Additional paid in capital		592,980	489,440	489,913
Translation reserve		621	386	616
Retained earnings		-448,000	-383,255	-398,113
Total equity attributable to the shareholders of the parent		**154,899**	**111,149**	**97,001**
Non-controlling interests		**11**	**5,361**	**11**
Total equity		**154,910**	**116,510**	**97,012**
Long-term liabilities				
Other longtrem liabilities		448	-	-
		448	**-**	**-**
Short-term liabilities				
Accounts payable		3,915	3,698	10,162
Other liabilities		841	852	808
Accrued expenses and deferred income		10,068	8,632	7,326
		14,824	**13,182**	**18,296**
Total liabilities		**15,272**	**13,182**	**18,296**
TOTAL EQUITY AND LIABILITIES		**170,182**	**129,692**	**115,308**

Financial position

The equity/assets ratio was 91 (90) percent as of 30 September 2019, and equity was KSEK 154,910 (116,510). The equity includes funds from the rights issue completed in 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 79,773 (38,371) as of 30 September 2019, an increase of KSEK 53,822 from the beginning of the year. Total assets as of 30 September 2019 were KSEK 170,182 (129,692).

The board continuously monitors and evaluates the company's funding need and financial position. The board has initiated a process to ensure adequate funding to enable execution of the company's strategy.

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. No information is available for measuring the holding at present value, and NeuroVive makes the assessment that there are no circumstances to indicate that fair value should deviate materially from cost. For this reason, the holding continues to be recognized at cost.

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.

Consolidated Statement of Changes in Equity

	Equity attributable to the shareholders of the parent company						
(SEK 000)	Share-capital	Additional paid in capital	Translation reserve	Retained earnings	Total	Non-controlling interests	Total equity
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	-	-	-	-49,887	-49,887	-1	-49,888
Other comprehensive income							
Translation differences	-	-	5	-	5	-	5
Other comprehensive profit/loss for the period, net after tax	-	-	5	-	5	-	5
Total comprehensive profit/loss	**-**	**-**	**5**	**-49,887**	**-49,882**	**-1**	**-49,883**
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, 30 September 2019	**9,298**	**592,980**	**621**	**-448,000**	**154,899**	**11**	**154,910**
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	-	-		-53,515	-53,515	-1	-53,516
Other comprehensive income							
Translation differences	-	-	-227	-	-227	231	4
Other comprehensive profit/loss for the period, net after tax	**-**	**-**	**-227**	**-**	**-227**	**231**	**4**
Total comprehensive profit/loss	**-**	**-**	**-227**	**-53,515**	**-53,742**	**230**	**-53,512**
Transactions with shareholders							
Rights Issue*	1,963	62,214	-	-	64,176	-	64,176
Total transactions with shareholders	**1,963**	**62,214**	**-**	**-**	**64,176**	**-**	**64,176**
Closing balance, 30 September 2018	**4,579**	**489,440**	**386**	**-383,255**	**111,149**	**5,361**	**116,510**
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 in February 11, 2019 completed rights issue with KSEK 99,033 less expenses and guranties KSEK 17,184 and the directed rights issue completed in March 7, 2019 with KSEK 28,212 less expenses KSEK 2,281.

Consolidated Statement of Cash Flows

(SEK 000)	1 Jul, 2019 30 Sep, 2019	1 Jul, 2018 30 Sep, 2018	1 Jan, 2019 30 Sep, 2019	1 Jan, 2018 30 Sep, 2018	1 Jan, 2018 31 Dec, 2018
Cash flow from operating activities					
Operating income	-15,286	-15,075	-49,852	-53,230	-73,360
Adjustments for non-cash items:					
Depreciation	354	498	1,500	1,441	1,914
Impaired Value	-	-	-		3,324
Result from other securities and receivables related to non current assets		-	-	-	66
Interest received	-	94	-	320	407
Interest paid		-	-37	-606	-606
Net cash from operating activities before changes in working capital	**-14,932**	**-14,484**	**-48,388**	**-52,075**	**-68,255**
Changes in working capital					
Increase/decrease of other current assets	238	1,495	761	1,669	859
Increase/decrease of other short-term liabilities	-3,539	453	-3,801	-1,669	3,567
Changes in working capital	**-3,301**	**1,948**	**-3,040**	**0**	**4,426**
Cash flow from operating activities	**-18,234**	**-12,536**	**-51,429**	**-52,075**	**-63,829**
Investing activities					
Acquisition of intangible assets	-1,238	-944	-2,469	-2,645	-3,791
Acquisition of tangible assets		-45	-69	-82	-82
Increase in other financial assets	-	-	-	-	1
Cash flow from investing activities	**-1,238**	**-989**	**-2,538**	**-2,727**	**-3,872**
Financing activities					
New share issue	-	-	107,780	64,176	64,656
Cash flow from financing activities	**-**	**-**	**107,780**	**64,176**	**64,656**
Cash flow for the period	-19,311	-13,524	53,814	9,375	-3,046
Cash and cash equivalents at the beginning of the period	99,079	51,896	25,951	28,992	28,992
Effect of exchange rate changes on cash	5	-1	8	5	5
Cash and cash equivalents at end of period	**79,773**	**38,371**	**79,773**	**38,371**	**25,951**

Cash flow and investments

Operating cash flow for the third quarter was KSEK -18,234 (-12,536). For the first nine months the operating cash flow amounted -51,429 (-52,075). The cash flow effect related to investments in intangibles equals KSEK -2,469 (-2,645) for the first nine months. Cash flow for the third quarter equals KSEK-19,311 (-13,524). Cashflow for the first nine months equals KSEK 53,814 (9,375).

Parent Company Income Statement

(SEK 000)	Note	1 Jul, 2019 30 Sep, 2019	1 Jul, 2018 30 Sep, 2018	1 Jan, 2019 30 Sep, 2019	1 Jan, 2018 30 Sep, 2018	1 Jan, 2018 31 Dec, 2018
Net sales		-	-	85	-	5
Other operating income		1,500	-	2,500	1,452	2,461
		1,500	**-**	**2,585**	**1,452**	**2,466**
Operating expenses						
Other external expenses		-13,185	-11,218	-39,944	-41,430	-55,777
Personnel cost		-2,893	-3,249	-10,704	-11,039	-14,454
Depreciation and write-down of tangible and intangible assets		-526	-498	-1,500	-1,441	-4,536
Other operating expenses		-187	-110	-304	-765	-789
		-16,791	**-15,076**	**-52,452**	**-54,675**	**-75,556**
Operating income		**-15,291**	**-15,076**	**-49,866**	**-53,223**	**-73,090**
Profit/loss from financial items						
Result from other securities and receivables related to non current assets		-	-	-	-	66
Interest income and other similar profit items		-	94	-	314	400
Interest expenses and other similar loss items		-	-	-1	-602	-602
		-	**94**	**-1**	**-288**	**-136**
Profit/loss before tax		**-15,291**	**-14,982**	**-49,867**	**-53,511**	**-73,226**
Income tax	2	-	-	-	-	-
Profit/loss for the period		**-15,291**	**-14,982**	**-49,867**	**-53,511**	**-73,226**

Parental company

Company earnings after tax for the first six months amounts to KSEK -49,867 (-53,511). Most of the Group's operations are conducted within the parent company. Accordingly, no further specific information regarding the parent company is presented.

Statement of Comprehensive Income, Parent Company

(SEK 000)	Note	1 Jul, 2019 30 Sep, 2019	1 Jul, 2018 30 Sep, 2018	1 Jan, 2019 30 Sep, 2019	1 Jan, 2018 30 Sep, 2018	1 Jan, 2018 31 Dec, 2018
Profit/loss for the period		-15,291	-14,982	-49,867	-53,511	-73,226
Other comprehensive income		-	-	-	-	-
Total comprehensive profit/loss for the period		**-15,291**	**-14,982**	**-49,867**	**-53,511**	**-73,226**

Parent Company Balance Sheet

(SEK 000)	Note	30 Sep, 2019	30 Sep, 2018	31 Dec, 2018
ASSETS				
Non-current assets				
Intangible assets	1			
Development costs		51,706	51,706	51,706
Patents		21,274	22,597	20,121
Other intangible assets		1,512	1,647	1,613
		74,492	**75,950**	**73,440**
Tangible assets				
Equipment		126	167	140
		126	**167**	**140**
Financial assets				
Other long-term placement		13,101	13,101	13,101
Shares in subsidiaries	3	23,625	23,625	23,625
		36,726	**36,726**	**36,726**
Total non-current assets		**111,345**	**112,843**	**110,305**
Current assets				
Short term receivables				
Other receivables		1,308	1,260	1,430
Prepaid expenses and accrued income		605	604	1,244
		1,913	**1,864**	**2,674**
Cash and bank balances		79,707	38,281	25,871
Total current assets		**81,620**	**40,145**	**28,545**
TOTAL ASSETS		**192,965**	**152,988**	**138,850**
EQUITY AND LIABILITIES				
Equity				
Restricted equity				
Share capital		9,298	4,579	4,585
Statutory reserve		1,856	1,856	1,856
Development expenditure reserve		10,610	10,610	10,610
		21,764	**17,045**	**17,051**
Unrestricted equity				
Share premium reserve		103,067	71,101	62,687
Retained earnings		103,523	105,173	114,061
Profit/loss for the period		-49,867	-53,511	-73,226
		156,723	**122,763**	**103,522**
Total equity		**178,487**	**139,808**	**120,573**
Short-term liabilities				
Accounts payable		3,914	3,698	10,162
Other liabilities		502	852	808
Accrued expenses and deferred income		10,062	8,630	7,307
		14,478	**13,180**	**18,277**
TOTAL EQUITY AND LIABILITIES		**192,965**	**152,988**	**138,850**

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	-	2,469	-	2,469
Closing balance 30 Sep. 2019	**51,706**	**31,576**	**2,864**	**86,146**
ACCUMULATED DEPRECIATION				
Opening balance 1 Jan. 2019	**-**	**-8,986**	**-1,251**	**-10,237**
Depreciation for the period	-	-1,316	-101	-1,417
Closing balance 30 Sep. 2019	**-**	**-10,302**	**-1,352**	**-11,654**
Residual value 30 Sep. 2019	**51,706**	**21,274**	**1,512**	**74,492**

(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 517,572 as of 30 September 2019 (428,981). The parent company's total loss carry-forwards amounts to SEK 491,777 as of 30 September 2019 (402,798). 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.

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 no transactions with related parties have occured.

Transactions with related parties

(SEK 000)	1 Jan. 2019 30 Sep. 2019	1 Jan. 2018 30 Sep. 2018
Eskil Elmér, CSO	6	-
Magnus Hansson, CMO	3	-
Total	**9**	**-**

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 (10), of which 4 (4) are women.

Incentive programs/share warrants

Currently there is no incentive program.

Audit review

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

Upcoming financial statements

Year-End Report 2019	February 19, 2020
Interim Report Jan-Mar 2020	May 20, 2020
Interim Report Jan-Jun 2020	August 21, 2020
Interim Report Jan-Sep 2020	November 20, 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 Tuesday 21 April 2020 at 4 pm.

The Nomination Committee for the 2020 AGM comprises:

- Kristina Ingvar (Chair) – for John Fällström
- Andreas Inghammar – Rothesay Ltd
- Michael Vickers – for Maas Biolab LLC

In total, the Nomination Committee represents some 9 % of the votes in NeuroVive as of 30 September 2019.

The Nomination Committee's task ahead of the AGM 2020 is to prepare proposals on the following matters to present to the AGM for resolution:

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

Shareholders wishing to make proposals on the above matters can contact the Committee by email at: *valberedningen@neurovive.com*, or by post at: NeuroVive Pharmaceutical AB, FAO: Nomination Committee, Medicon Village, 223 81 Lund, Sweden.

In order for the Nomination Committee to consider the proposals received with due care, proposals should be received by the Nomination Committee by no later than 1 February 2020.

New American market place

As part of focusing on the company's resources, the Board has decided to cancel NeuroVives' share from the American OTC market and return to the OTC Pink list, effective as of January 1, 2020. NEVPF's share price can be monitored at www.otcmarkets.com or through US brokers.

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 compensate 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 has been finalized and the arbitral tribunal has initiated its process with the aim of announcing an award in 2020. The parties are scheduled to submit respective briefs in course of this year and the first round of submissions took place in July 2019. In addition, in July 2019 CicloMulsion also filed a request to the arbitration institution (Swedish Chamber of Commerce) to release the new arbitrators for several reasons. This request was rejected by the arbitration institution and the arbitral tribunal may proceed according to plan.

The ongoing dispute with CicloMulsion AG may result in further liability for the counterparty's expenses in connection with the dispute as well as future payments under the License Agreement with them, which could have a negative impact on the company's financial position. The Company has not reserved for any future payment obligations as the amount, if any, at this time cannot be calculated.

NeuroVive is not involved in any other disputes.

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.

The declaration of the Board of Directors and the CEO

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

Lund, Sweden, November 20, 2019

David Laskow-Pooley
Chairman of the Board

David Bejker
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

This information is information that NeuroVive Pharmaceutical AB (publ) is obliged to make public pursuant to the Securities Markets Act. The information was submitted for publication, through the agency of the contact person set out above, at 08:30 a.m. CET on 20 November 2019.

Auditor's review report

To the board of NeuroVive Pharmaceutical AB (publ), Corp.Id.No 556595-6538

Introduction

We have performed a review of the condensed interim financial statements (the interim report) for NeuroVive Pharmaceutical AB (publ) at September 30, 2019 and the nine months' period then ended. The Board of Directors and the President are responsible for the preparation and presentation of this interim report in accordance with IAS 34 and the Swedish Annual Accounts Act. Our responsibility is to express a conclusion on this interim report based on our review.

Scope of review

We conducted our review in accordance with the Standard on Review Engagements ISRE 2410 Review of Interim Financial Information Performed by the Independent Auditor of the Entity. A review consists of making inquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with the International Standards on Auditing and other generally accepted auditing practices.

The procedures performed in a review do not enable us to obtain a level of assurance that would make us aware of all significant matters that might be identified in an audit. Therefore, the conclusion expressed based on a review does not give the same level of assurance as a conclusion expressed based on an audit.

Conclusion

Based on our review, nothing has come to our attention that causes us to believe that the interim report, in all material aspects, is not prepared for the Group in accordance with IAS 34 and the Swedish Annual Accounts Act and for the Parent company in accordance with the Swedish Annual Accounts Act.

Emphasis of matter

As described on page 10 in the section Financial position the board has initiated a process to ensure adequate funding to enable execution of the company's strategy.

Stockholm, November 20th, 2019

Mazars SET Revisionsbyrå AB

Michael Olsson
Authorized Public Accountant

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 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 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 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.
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.

NeuroVive is focused on primary mitochondrial diseases, indications with great medical needs.

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 is another clinical phase project. The R&D portfolio also consists of projects for mitochondrial myopathy, NASH and cancer.

NeuroVive's ambition is to take drugs for rare diseases through clinical development and all the way to market, with or without partners. For projects for common indications the goal is out-licensing in preclinical phase. A subset of compounds under NeuroVive's NVP015 program has been licensed to Fortify Therapeutics, a BridgeBio company, for the development of a local treatment 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 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 in certain primary mitochondrial disorders and in various liver diseases.

Marketplace

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

NeuroVive Pharmaceutical AB (publ)

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