



# **Year End Report**January - December 2016

### Important steps forward and new research collaborations

#### **Business operations**

#### Important events October - December 2016

- The development of CicloMulsion for acute kidney injury was discontinued and as a consequence, the value of the subsidiary NeuroVive Asia was writtendown by 50 percent and all previously capitalized expenditure in connection with CicloMulsion was recognized as an impaired value
- New business model implemented which encompass out-licensing of projects for common indications, as well as proprietary development of orphan indication projects
- Positive preclinical results obtained in an experimental model for non-alcoholic steatohepatitis (NASH), a very serious and common disease for which no medication is currently available
- In a termination agreement, all rights for NV556 were returned to NeuroVive from Arbutus Biopharma. NeuroVive also received material manufactured by Arbutus valued at USD 1.5 million

#### Important events after the end of the period

- The company's new generation of sanglifehrin-based compounds demonstrate potent inhibitory effects on human hepatocellular cancer cells and the results were presented at a scientific conference
- The company decided to redirect research resources from Asian subsidiary to parent. The operations in Taiwan have been sold to the current Taiwanese shareholders
- A mitochondrial medicine research agreement regarding the NVP015 project was signed with US key opinion leader
- A collaboration agreement was signed with Karolinska Institutet, Stockholm, Sweden, and the indication mitochondrial myopathy was added to the project portfolio

#### Financial information

#### Fourth quarter (October – December 2016)

- Net revenues were SEK 14,000 (0) and other operating income was SEK 14,000 (23,000)
- Loss before tax was SEK 14,580,000 (7,366,000)
- Loss per share\* was SEK 0.34 (1.75)
- Diluted loss per share\*\* was SEK 0.34 (1.75)

#### Twelve months (January-December 2016)

- Net revenues were SEK 14,000 (2,502,000) and other operating income was SEK 104,000 (522,000)
- Loss before tax was SEK 71,845,000 (90,801,000)
- Loss per share\* was SEK 1.67 (3.01)
- Diluted loss per share\*\* was SEK 1.67 (3.01)
- \* Profit/loss for the period divided by the average number of shares before dilution at the end of the period.
- \*\* Profit/loss for the period divided by the average number of shares after dilution at the end of the period.



### Comments from our CEO, Erik Kinnman

The new business model we presented in 2016 means that we are now taking orphan drug projects from clinical development to marketing authorization, and intensifying our focus on drug projects targeting common indications where the goal is to out-license at the preclinical phase. The risk-diversified portfolio provides revenue-stream opportunities for the company in the short term, while building value in the longer term. The drug projects for NASH (fatty liver) announced in the autumn were supplemented with a new liver cancer project at the beginning of the year.

#### An eventful and exciting year

2016 brought progress in several key projects. In addition to the promising results delivered by several of the preclinical out-licensing projects, our NVP015 project – in which we are developing a treatment for genetic mitochondrial disorders attributable to energy regulation dysfunction – also showed positive results. Our partnership with the University of Pennsylvania (Penn) was deepened during the year. During the autumn, the results of the CiPRICS clinical trial did not show any renal protective effects and all development of the CicloMulsion drug candidate for acute kidney injury was subsequently discontinued.

# Important steps in the development of novel treatment options for patients with mitochondrial genetic disorders

In early January 2017, we signed a partnership agreement with Karolinska University Hospital (KI) in Stockholm in the field of genetic mitochondrial disorders. The research team at KI, led by Professor Håkan Westerblad, will study NV556 in experimental models of mitochondrial myopathies. We have also signed a partnership agreement with the Children's Hospital of Philadelphia (CHOP) in the US and Marni J. Falk, M.D., a key opinion leader in the field of mitochondrial medicine. Potential drug candidates in the NVP015 project will be tested in unique experimental models of genetic mitochondrial disorders.

#### Successful projects in NASH and liver cancer

In November, we received positive efficacy data for NV556 and inhibition of fibrosis development in a well-documented model of NASH (fatty liver). In early 2017, we could report that our sanglifehrin-based compounds delivered promising results in a preclinical model of liver cancer. Both liver cancer and NASH hold huge potential commercial value, and if continued preclinical development confirms our present findings, we will initiate out-licensing activities around NV566 for the treatment of NASH by the second half of 2017.



## New business model creates more opportunities and spreads risks

NeuroVive's research is focused on the proprietary development of projects in mitochondrial medicine. The new business model means that we are taking orphan drug candidates all the way to the market, and thereby building value. We are also implementing an accelerated focus on common diseases with a major unmet medical need and thereby high commercial potential. The goal for these projects, to out-license them during the preclinical phase, will enable revenue streams in the short term. Our strong collaborations with academia as well as the industry give us access to the expertise and resources needed to develop our project portfolio in the most efficient way. We are also redirecting research resources to the Parent Company through a divestment of the Taiwan-based subsidiary, which enables a greater focus on the company's project portfolio.

#### Important results pending for NeuroSTAT

Over the next six months, we expect to present the results of NeuroSTAT in TBI patients, from both the completed preclinical efficacy study at Penn and the CHIC Phase II clinical trial at Copenhagen University Hospital in Denmark. These combined results will show the way forward for the project. Assuming a positive outcome, the next step will be a Phase II trial to study the efficacy of NeuroSTAT in TBI patients.

With all the other new and exciting data presented recently, we are looking forward to the continued expansion and development of the promising research and development programs in our portfolio with confidence, and thereby increasing the company's value for our shareholders.

#### Erik Kinnman

CEO, NeuroVive Pharmaceutical AB February 21, 2017



### **Operations**

NeuroVive is focused on the research and development of targeted drug candidates that maintain mitochondrial integrity and function for indications with a high unmet medical need. NeuroVive creates value in projects by working in partnerships, and by networking with leading research institutions in mitochondrial medicine, as well as experts with resources in drug development and production. The drug development process is comprehensive and carefully regulated, and NeuroVive strives to make this process as cost-efficient and successful as possible.

# Business model focused on orphan drugs and outlicensing of early-phase projects

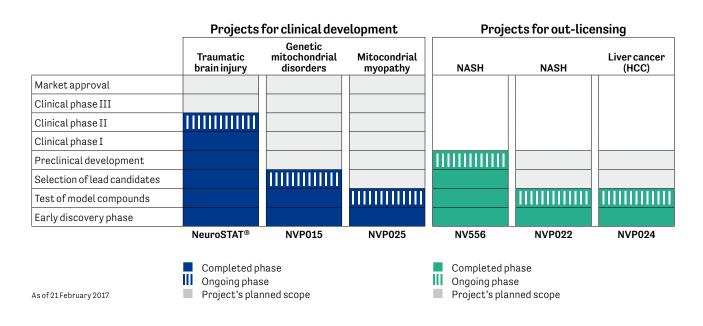
The Company has a dual business model. One component comprises proprietary drug development for rare diseases with a major unmet medical need, where the company intends to take projects through clinical development and to the market. The other component consists of projects for common indications with high commercial potential, for out-licensing at the preclinical phase. NeuroVive maintains its research and development focus in mitochondrial medicine with the aim of helping patients for whom few, or no, treatment options are currently available.

### CLINICAL DEVELOPMENT PROJECTS Moderate to severe traumatic brain injury (TBI)

In collaboration with the University of Pennsylvania (Penn), NeuroVive is evaluating the preventive effect of NeuroSTAT in an experimental TBI model. The first two of three substudies, in total, have been successfully conducted and completed. Positive results from the first substudy show that NeuroSTAT crosses the blood-brain barrier and that concentration levels in the blood and brain are achieved. The third and final substudy, in which the effects of NeuroSTAT in a TBI model are being studied, is ongoing and expected to conclude in spring 2017.

In combination, these preclinical studies will show how NeuroSTAT works in the treatment of TBI. These results will form the basis for decisions regarding the continuation of the clinical development. Positive results will be used to supplement the ongoing CHIC (Copenhagen Head Injury Ciclosporin) Phase II clinical trial, in which NeuroSTAT is being assessed in conjunction with the clinical treatment of patients. Project costs for the continued clinical development of NeuroSTAT will only be financed with funds granted by major international institutions or, alternatively, through commercial partners.

### Project overview





At year-end, CHIC had 16 patients. Based on the current rate of recruitment, the trial results are expected to be presented by mid-2017. The primary goal of the CHIC trial is to assess the safety and pharmacokinetics of NeuroSTAT in the blood and cerebrospinal fluid of patients with severe traumatic brain injury (TBI) based on two different dosage regimens. Secondarily, exploratory measurements will be carried out to evaluate the efficacy of NeuroSTAT at the mitochondrial level, and how NeuroSTAT affects various biochemical processes following a brain injury. More information about the trial is available in the public database ClinicalTrials.gov.

#### <u>About TBI</u>

Traumatic brain injury (TBI) is caused by external violence to the head resulting in immediate damage to nerve cells. The damage continues to worsen for several days after the trauma, which in many cases has a significantly negative effect on the overall injury. At present, there are no approved treatments for the prevention of these secondary injuries. In the US, some 2.2 million people are affected annually, causing more than 50,000 deaths and 280,000 hospitalizations. The direct and indirect costs associated with TBI are an estimated USD 60 billion, and a large number of patients suffer moderate to severe functional disabilities requiring intensive care and various forms of support (www.nih.gov). The aim is that better preventive therapies for secondary brain damage, such as NeuroSTAT, will lead to higher survival rates, and significantly improve quality of life and neurological function of patients post-TBI.

#### Genetic mitochondrial disorders

Genetic mitochondrial disorders are congenital metabolic diseases that affect cellular energy conversion. The disorders can manifest differently and are viewed as syndromes, depending on the combination of signs and research discoveries.

#### NVP015 - Complex 1 Dysfunction

Results from experimental studies of the novel series of prodrugs developed by researchers at NeuroVive and Isomerase show that these compounds demonstrate good stability in the bloodstream as well as uptake by target organs such as muscle tissue. The results also demonstrate metabolism in the mitochondrion, which is an important milestone for the project. The most promising compounds from this series are currently undergoing further testing in various experimental models and the selection of a lead candidate is expected by the second half of 2017.

After the end of the period, it was announced that a preclinical collaboration agreement had been signed with the Children's Hospital of Philadelphia (CHOP) and Marni J. Falk, M.D., a well-established researcher in the field of mitochondrial medicine. Dr. Falk's research team at CHOP will evaluate compounds from NVP015 in various cutting-edge experimental disease models and study energy metabolism and disease progression in models of mitochondrial complex I dysfunction. Marni J. Falk is an Attending Physician and Director of the Mitochondrial Disease Clinical Center at CHOP, a major center for children and adults with mitochondrial disorders, and a leader in this field of research. Dr. Falk's experience ranges from early-phase research to clinical development, with expertise across the entire drug development spectrum. CHOP is one of the largest children's hospitals in the world and one of the highest-ranked children's hospitals in the US.

#### About Complex 1 Dysfunction

One of the most common causes of mitochondrial diseases relates to Complex I Dysfunction, i.e. energy conversion in the first of the five protein complexes in the mitochondrion that are involved in effective energy conversion does not function normally. This is apparent in disorders including Leigh's 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 concept initiated by NeuroVive's CSO Dr. Eskil Elmér and his colleagues by 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. Results from the NVP015 project were published in August 2016 in the reputable journal Nature Communications<sup>1)</sup>.

1) Ehinger JK et al. (2016) Nat. Commun.7:12317

#### NVP025 - Mitochondrial myopathy

After the end of the period, it was announced that a partnership agreement had been signed with Karolinska University Hospital in Stockholm regarding the development of a therapeutic option for mitochondrial myopathy. Under the partnership agreement, the research team at Karolinska University Hospital, headed by Professor Håkan Westerblad, will be using NeuroVive's cyclophilin inhibitor NV556 as a model compound studying its efficacy in experimental models of mitochondrial myopathy.

The research team at Karolinska University Hospital has previously published results<sup>1)</sup> showing that another cyclophilin inhibitor, cyclosporine, exhibits mitochondrial



protective effects by inhibiting cyclophilin D and thus preventing muscle fiber weakness in an experimental model of mitochondrial myopathy. They have also demonstrated that patients with mitochondrial myopathy have elevated levels of cyclophilin D, the target molecule for NeuroVive's NV556 compound. NV556 is expected to have a higher specificity and tolerability profile than cyclosporine, which may facilitate dosing. The NV556 model compound being studied in this partnership has cyclophilin D as its target molecule and therefore has a different and complementary mode of action compared with NVP015 compounds, which target the respiratory chain of the cell's energy production.

#### About Mitochondrial myopathy

Mitochondrial myopathies are a group of neuromuscular diseases caused by damage to the mitochondria. Some of the more common mitochondrial myopathies include Kearns-Sayre syndrome, MERRF syndrome (myoclonus epilepsy with ragged-red fibers), and MELAS (mitochondrial encephalomyopathy with lactic acidosis and stroke-like episodes). The symptoms of mitochondrial myopathies include muscle weakness, exercise intolerance and fatigue, and are often accompanied by other symptoms of genetic mitochondrial disorders such as heart failure or rhythm disturbances, dementia, movement disorders, stroke-like episodes, deafness, blindness, droopy eyelids, limited mobility of the eyes, vomiting, and seizures. The prognosis for these disorders ranges in severity from progressive weakness to death.2) There is a high unmet medical need of new and effective treatment options for mitochondrial myopathy.

- 1) Cyclophilin D, a target for counteracting skeletal muscle dysfunction in mitochondrial myopathy. Westerblad H. et al. Human Molecular Genetics, 2015, Vol.24, No 23; 6580-6587.
- 2) http://www.ninds.nih.gov/disorders/mitochondrial\_myopathy/mitochondrial\_myopathy.htm

#### OUT-LICENSING PROJECTS Non-alcoholic steatohepatitis (NASH) NV556 and NVP022

In autumn 2016, positive preclinical results for NV556 were obtained in an experimental model for the severe, chronic and common liver disease NASH (non-alcoholic steatohepatitis). In addition to NV556, NeuroVive is also developing a new class of compounds with a different mode of action, that may serve as complementary treatment for NASH, NVP022. The NVP022 project is based on NeuroVive's core expertise in mitochondrial energy regulation, combined with the expertise of its partner company, Isomerase, in innovative chemistry. Efforts are currently ongoing to confirm the collected data, and to

compile a package for the commencement of out-licensing activities for NV556 in 2017.

#### About NASH

NASH – non-alcoholic steatohepatitis – is a progressive disease that may develop into liver cirrhosis or hepatocellular cancer (HCC). Liver damage in NASH is caused by fat accumulation and inflammatory changes in the liver. NASH is a form of NAFLD (non-alcoholic fatty liver disease), which is one of the most common conditions worldwide. An estimated 20% of the global population suffers from NAFLD, and about one-third of the population in the US. There is a strong association between NASH and variety of metabolic syndromes like diabetes and obesity. Approximately 3-5% of Americans (about 15 million people) suffer from NASH and there are currently no registered drugs for the treatment of this condition.<sup>1)</sup>

1) Vernon G. et al. Aliment Pharmacol Ther. 2011;34(3): 274-85

#### Hepatocellular carcinoma (HCC) NVP024

In partnership with Isomerase, NeuroVive's research team has demonstrated that the company's sanglifehrinbased compounds show potent anti-cancer effects in preclinical models of HCC. After the end of the period, it was announced that the project had participated in the EASL (European Association for the Study of the Liver) HCC Summit in Geneva, Switzerland, on February 2-5, 2017 with a poster presentation. The results presented show that a new model compound, in which the anti-cancer effect has been optimized, show up to 500 times more potent inhibitory effects on human hepatocellular cancer cells (in vitro) compared to the existing cancer drug sorafenib (a registered drug for the treatment of advanced HCC). Furthermore, this compound class also demonstrated anti-cancer activity in a preclinical experimental (in vivo) model of HCC, after oral as well as intraperitoneal dosing. The compounds were not toxic to normal cells and well tolerated in vivo.

#### About hepatocellular carcinoma

Liver cancer is often diagnosed at a late stage of the disease and mortality rates are high. There are two major types of liver cancer: hepatocellular carcinoma (HCC) and intrahepatic bile duct cancer. Various hepatitis virus infections can increase the risk of liver cancer. Patients with liver cirrhosis caused by alcoholism or fatty liver (non-alcoholic steatohepatitis, NASH) are at greater risk of developing hepatocellular cancer. Although liver cancer is less common in northern Europe and the US, HCC is the sixth most-common type of cancer and the third most-common cause of death world-



wide.<sup>1,2)</sup> While surgery, chemotherapy and radiotherapy are important starting points for the treatment of liver tumors, there is a major medical need for more, and effective, complementary medical treatments to increase the survival rate for people with liver cancer.<sup>3)</sup>

- 1) Altekruse SF, McGlynn KA, Reichman ME: Hepatocellular Carcinoma Incidence, Mortality, and Survival Trends in the United States From 1975 to 2005. J Clin Oncol 27(9):1485-91, 2009.
- 2) Forner A, Llovet JM, Bruix J: Hepatocellular carcinoma, Lancet 379 (9822):1245-55,2012.
- 3) http://www.cancerresearchuk.org/helath-professional/cancer-statistics/statistics-by-cancer-type/liver-cancer/Incidence#heading-Nine

#### NeuroVive Pharmaceutical Asia, Inc. subsidiary

After the end of the period, it was announced that research resources and activities in the Taiwan-based subsidiary, NeuroVive Pharmaceutical Asia, Inc., will be redirected to the Parent Company, NeuroVive Pharmaceutical AB. The operations in Taiwan have been sold to the current Taiwanese shareholders. Under the agreement. NeuroVive Pharmaceutical AB will receive about SEK 5 million before administrative expenses. In addition, NeuroVive and its partner Foundation Asia Pacific Ltd., will reacquire the Hong Kong-based subsidiary, Neuro-Vive Pharmaceutical Asia Ltd., which holds the Asian license rights for NeuroSTAT and agreements with the Chinese pharmaceutical company Sihuan Pharmaceutical and Sanofi Korea. The Hong Kong-based company will be owned jointly by NeuroVive Pharmaceutical AB (about 82.5%) and Foundation Asia Pacific Ltd. (about 17.5%). Under the agreement, other assets, which were previously licensed to NeuroVive's Asian company, will be transferred to NeuroVive Pharmaceutical AB.





### **Financial information**

#### Revenues

The consolidated turnover during the fourth quarter of 2016 was SEK 14,000 (0). Other operating revenues for the fourth quarter of 2016 were SEK 14,000 (23,000). The consolidated turnover for twelve months was SEK 14,000 (2,502,000) and the operating revenues amounted SEK 104,000 (522,000).

#### Results of operations

The operating loss for the fourth quarter was SEK 14,863,000 (7,368,000). The operating loss for twelve months was SEK 72,110,000 (91,466,000). The net loss before tax for the fourth quarter amounted to SEK 14,580,000 (7,366,000). The net loss before tax for twelve months was SEK 71,845,000 (90,801,000).

The operating loss was affected by external expenses, which for the fourth quarter were SEK 9,860,000 (3,841,000). External expenses for twelve months were SEK 34,168,000 (48,514,000). Expenses related to development projects have affected the result during the fourth quarter with SEK 3,809,000 (2,433,000). Expenses related to development projects have affected the full year result with SEK 12,001,000 (12,361,000). These expenses relate to development projects that have not reached phase I. Personnel expenses during twelve months amounts to SEK 15,276,000 (15,556,000). Other operating expenses amount to, SEK 21,663,000 (29,220,000) whereof 21,140,000 (28,135,000) relates to former capitalized costs for the CicloMulsion. Since the results of treatment with CicloMulsion showed no benefits in the prevention of acute kidney injury (AKI) during open heart surgery, the Company decided to discontinue the development of CicloMulsion. Thus, all previously capitalized expenditure in connection with CicloMulsion is now obsolete. The remaining portion of other operating expenses pertains to exchange-rate losses.

#### Financial position

The equity/assets ratio was 93 (88) % as of 31 December 2016, and equity was SEK 168,304,000 (154,779,000) compared to beginning of the year. Cash and cash equivalents amounted to SEK 93,251,000 (96,662,000) as of 31 December 2016, a decrease of SEK 3,411,000 from the beginning of the year. Total assets as of 31 December 2016 were SEK 180,717,000 (174,927,000). The Board of Directors works continuously to secure the business operation's need for financing and has tasked the mana-

gement to investigate various financing alternatives to secure long term financing of the Company.

#### Cash flow and investments

Operating cash flow for the fourth quarter was SEK -11,885,000 (-16,783,000). Operating cash flow twelve months 2016 was SEK -57,477,000 (-67,220,000). The cash flow effect related to investments in intangibles equals SEK -8,224,000 (-6,310,000) for the fourth quarter. The cash flow effect related to investments in intangibles equals SEK -18,052,000 (-23,200,000) full year. Cash flow for the fourth quarter equals SEK -20,107,000 (-23,264,000). Cash flow twelve months 2016 equals SEK - 5,180,000 (47,741,000). The Cash flow was positively affected by the share issue of SEK 77,332,000 (119,575,000).

#### Transactions with related parties

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

Apart from remuneration to senior managers including remuneration for consulting services, no purchases or sales between the group and related parties occurred. Transactions with related parties affecting profit/loss for the period are stated below.

(SEK 000)	1 Jan. 2016 31 Dec. 2016	1 Jan. 2015 31 Dec. 2015
Stanbridge byba (owned by Gregory Batcheller, Executive Chairman)	1,066	1,488
Ankor Consultants bvba (owned by Arne Ferstad, Board member)	119	427
Bernsten Consulting	54	
Total transactions with related parties	1,239	1,915

#### 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.

#### Financial instruments

NeuroVive does not hold any financial instruments measured at fair value. The reported value of financial instru-



ments essentially corresponds to fair value. The new holding in unlisted securities classified as "financial assets available for sale" would normally be measured at fair value through other comprehensive income. The holding is, in the absence of a reliable fair value valuation, recognized to its acquisition value, SEK 13,100,000.

#### **Human resources**

The average number of employees of the group for the period January to December was 17 (15), of which 9 (9) are women.

#### Parental company

Due to the decision to discontinue development of CicloMulsion, the value of shares in the NeuroVive Pharmaceutical Asia, Inc. subsidiary decreased approximately 50%, corresponding to SEK 20,870,000, which is the estimated value of CicloMulsion in relevant Asian territories. This had a negative impact of SEK 20,870,000 (0) on the parent company's earnings after financial items. The parent company's loss after tax for twelve months was SEK 87,118,000 (88,139,000). Most of the Group's operations are conducted within the parent company. Accordingly, no further specific information regarding the parent company is presented.

#### 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 to out-license projects directed towards larger indications already in the pre-clinical phase, while orphan indication projects are developed by the company up until market registration. With exception for the decision to terminate the continued development of CicloMulsion, no significant changes in relation to risk or uncertainties occurred during the current period.

In March 2013, CicloMulsion AG commenced arbitration seeking declaratory relief with regard to royalties to be allegedly paid by the Company under a 2004 License Agreement with the Company as well as certain other claims relating to the Company's obligations under the License Agreement. As previously reported, on May 25,

2016, the Tribunal rendered a partial award. The Tribunal held, inter alia, that the Company is obliged to pay, subject to the terms of the License Agreement, future royalties on product sales in certain countries while other claims were dismissed. Regarding the obligation of the Company to pay royalties in other countries, the Arbitral Tribunal reserved its decision for a final award. The arbitration proceeding is continued in this respect but currently suspended by the Arbitral Tribunal due to appeals initiated by each party at the competent Swedish court in Skane. The appeal filed by CicloMulsion AG is mainly based on an alleged infringement of its right to be heard and the Company's appeals refers to an infringement of both its right to be heard and mandatory law. With regard to the latter the Company relies on a recent decision of the European Court of Justice on the impact of European competition law on license agreements, including the obligation to pay royalties. This decision was issued after the partial award was rendered by the Arbitral Tribunal. So far there are no indications as to the prospects of these appeals.

For more detail of risks and uncertainty factors, refer to the Statutory Administration Report in the Annual Report 2015 and the prospectus published 14 April 2016 for the share issue in April/May 2016.

#### 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**

The Annual Report is published	Week 12, 2017
Interim Report Jan-Mar 2017	18 May 2017
Interim Report Jan-Jun 2017	17 August 2017
Interim Report Jan - Sept 2017	21 November 2017
Year-End Report 2017	20 February 2018

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

#### **Annual General Meeting 2017**

NeuroVives Annual General Meeting will be held at Medicon Village, Scheelevägen 2, in Lund on 27 April at 4 pm.

#### 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

### Year End Report 2016



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 same accounting principles as described in the Annual Report for 2015 on pages 54-58. New and revised standards and interpretation statements applicable from 1 January 2016 onwards did not have any effect on the group or parent company's results of operations or financial position.



# **Consolidated Statement of Comprehensive Income**

	10ct, 2016	10ct, 2015	1 Jan, 2016	1 Jan, 2015
Note	31 Dec, 2016	31 Dec, 2015		31 Dec, 2015
	14			2,502
				522
	28	23	118	3,024
	0.000	7.044	7.1.100	10.511
•		······································	······································	-48,514
				-15,556
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				-29,220
•	-14,891	-7,391	-72,228	-94,490
-	-14,863	-7,368	-72,110	-91,466
<u>+</u>			······································	
•	28	_	28	_
	255	36	432	1,100
		-34	-195	-435
	283	2	265	665
	-14,580	-7,366	-71,845	-90,801
2				
	-14,580	-7,366	-71,845	-90,801
-		•	•	
***************************************	500	311	1,782	-667
	-14,080	-7,055	-70,063	-91,468
	-			
<u>#</u>	-14.151	-6.817	-70.241	-90,119
	-429	-549	-1,604	-682
-	-14,580	-7,366	-71,845	-90,801
	-13 703	-6.405	-69 271	-90,207
	·	······································	······································	-1,261
	-14,080	-7,055	-70,063	-91,468
		-	•	
	-0,34	-0,22	-1,67	-3,01
	2	Note 31 Dec, 2016  14  14  28  -9,860 -3,943 -313 -775 -14,891  -14,863  28  283  -14,580  2  -14,580  500 -14,080  -14,151 -429 -14,580  -13,723 -357	Note         31 Dec, 2016         31 Dec, 2015           14         23           28         23           -9,860         -3,841           -3,943         -2,867           -313         -635           -775         -48           -14,891         -7,391           -14,863         -7,368           28         -           255         36           -34         283         2           -14,580         -7,366           2         -14,580         -7,366           500         311         -14,080         -7,055           -14,151         -6,817         -429         -549           -14,580         -7,366         -7,366         -7,366	Note         31 Dec, 2016         31 Dec, 2016         14         14           14         23         104           28         23         118           -9,860         -3,841         -34,168           -3,943         -2,867         -15,276           -313         -635         -1,121           -775         -48         -21,663           -14,891         -7,391         -72,228           -14,863         -7,368         -72,110           28         -         28           255         36         432           -34         -195           283         2         265           -14,580         -7,366         -71,845           2         -14,580         -7,366         -71,845           -14,080         -7,055         -70,063           -14,151         -6,817         -70,241           -429         -549         -1,604           -14,580         -7,366         -71,845           -14,580         -7,366         -71,845



### **Consolidated Statement of Financial Position**

(SEK 000)	Note	31 Dec, 2016	31 Dec, 2015
ASSETS			
Non-current assets			
Intangible assets	1		
Development costs		51,255	59,803
Patents		17,979	13,023
Other Intangible assets		1,917	2,078
		71,151	74,904
Tangible assets			
Equipment		274	316
		274	316
Financial assets			
Other long-term securities		13,102	1
Other long-term receivables		118	148
		13,220	149
Tatalana amanda anta		04.045	BE 700
Total non-current assets	-	84,645	75,369
Current assets	-		
Other receivables		1,650	2,368
Prepaid expenses and accrued income		1,171	528
Cash and cash equivalents		93,251	96,662
Cash and Gash of arvatories		96,072	99,558
			00,000
TOTAL ASSETS		180,717	174,927
	•		
EQUITY AND LIABILITIES			
Equity attributable to the shareholders of the parent company			
Share capital		2,473	1,537
Additional paid in capital		418,339	335,687
Translation reserve		780	-190
Retained earnings		-266,146	-195,906
Total equity attributable to the shareholders of the parent		155,446	141,128
Non-controlling interests		12,858	13,651
Total aquity		168,304	15 4 770
Total equity	•	100,304	154,779
Short-term liabilities			
Accounts payable		6,000	5,207
Other liabilities		483	601
Accrued expenses and deferred income		5,930	14,340
		12,413	20,148
			,
Total liabilities		12,413	20,148
TOTAL EQUITY AND LIABILITIES		180,717	174,927



# **Consolidated Statement of Changes in Equity**

(SEK 000)	Equity attribu	ıtable to th	ne shareholder	s of the paren	tcompany		
		Additional				Non-	
	Share-	paid in	Translation	Retained		controlling	Total
	capital	capital	reserve	earnings	Total	interests	equity*
Opening balance, 1 January 2016	1,537	335,687	-190	-195,906	141,128	13,651	154,779
Comprehensive profit/loss for the period	•		•••••••••••••••••••••••••••••••••••••••	•••••••••••••••••••••••••••••••••••••••	-	•••••••••••••••••••••••••••••••••••••••	
Profit/loss for the period	=	=		-70,241	-70,241	-1,604	-71,845
Other comprehensive income			•	•	_		
Translation differences	-	-	970	-	970	812	1,782
Other comprehensive profit/loss for the period, net after	-	-	970	-	970	812	1,782
tax							
Total comprehensive profit/loss	-	-	970	-70,241	-69,271	-792	-70,063
Transactions with shareholders							
New share issue	936	82,652			83,588	-	83,588
Total transactions with shareholders	936	82,652	-	-	83,588	-	83,588
Closing balance, 30 September 2016	2,473	418,339	780	-266,146	155,446	12,858	168,304
Opening balance, 1 January 2015	1.389	207.812	-102	-105,787	103,312	4.529	107,841
Comprehensive profit/loss for the period	2,000		102	100,707	100,012	4,020	107,011
Profit/loss for the period	_	-	-	-90.119	-90.119	-682	-90,801
Other comprehensive income					,		,
Translation differences	_	-	-88	-	-88	-579	-667
Other comprehensive profit/loss for the period, net after	=	-	-88	-	-88	-579	-667
tax							
Total comprehensive profit/loss	-	-	-88	-90,119	-90,207	-1,261	-91,468
Transactions with shareholders	-	•	-	-	•	-	
New share issue	148	119,427	=	_	119,575	0	119,575
Issue through non-controlling interest	0	8,448	-	-	8,448	10,383	18,831
Total transactions with shareholders	148	127,875	-	-	128,023	10,383	138,406
Closing balance, 30 September 2015	1,537	335,687	-190	-195,906	141,128	13,651	154,779

<sup>\*</sup> Total equity includes funds from the in January completed non cash consideration with SEK 6,809,000 less expenses SEK 553,000 and funds from the in May completed rights issue with SEK 94,421,000 less expenses SEK 17,089,000.



### **Consolidated Statement of Cash Flows**

(SEK 000)	1 Oct, 2016 31 Dec. 2016	10ct, 2015 31 Dec, 2015	1 Jan, 2016 31 Dec, 2016	1 Jan, 2015 31 Dec, 2015
Cash flow from operating activities	,	,	,	
Operating income	-14,863	-7,367	-72,110	-91,466
Adjustments for non-cash items:				
Depreciation	313	635	1,121	1,200
Currency differences on intercompany items	23	-26	48	153
Impaired Value	417	-	21,035	28,135
Disposal of Business	-	-	7	-
Result from shares in associated company	28	-	28	-
Interest received	187	35	363	1,100
Interest paid	68	-34	-126	-435
Net cash from operating activities before changes in working capital	-13,827	-6,757	-49,634	-61,313
Changes in working capital				
Increase/decrease of other current assets	-543	-1,642	-19	-1,255
Increase/decrease of other short-term liabilities	2,485	-8,384	-7,824	-4,652
Changes in working capital	1,942	-10,026	-7,843	-5,907
Cash flow from operating activities	-11,885	-16,783	-57,477	-67,220
Investing activities				
Acquisition of intangible assets	-8,224	-6,310	-18,052	-23,200
Acquisition of tangible assets	-31	-39	-139	-245
Increase in other financial assets	-	-	-6,844	-
Cash flow from investing activities	-8,255	-6,349	-25,036	-23,445
Financing activities				
Share issue minority	-	-132	-	18,831
New share issue	-	-	77,332	119,575
Cash flow from financing activities	-	-132	77,332	138,406
Cash flow for the period	-20,139	-23,264	-5,180	47,741
Cash and cash equivalents at the beginning of the period	112,889	138,049	96,662	49,698
Effect of exchange rate changes on cash	500	366	1,769	-777
Cash and cash equivalents at end of period	93,251	115,151	93,251	96,662



## **Parent Company Income Statement**

(SEK 000)		10ct, 2016	10ct, 2015	1 Jan, 2016	1 Jan, 2015
	Note	31 Dec, 2016	31 Dec, 2015	31 Dec, 2016	31 Dec, 2015
Net sales		_	327	30	327
Other operating income	•	14	28	104	509
		14	355	134	836
Operating expenses					
Other external expenses		-9,020	-2,871	-31,521	-45,774
Personnelcost		-3,336	-2,252	-12,495	-13,376
Depreciation and write-down of tangible and intangible assets	-	-282	-606	-1,006	-1,106
Other operating expenses		-765	-47	-21,660	-29,221
		-13,403	-5,776	-66,683	-89,477
Operating income		-13,389	-5,421	-66,548	-88,641
Profit/loss from financial items					
Result from shares in group company		-9	=	-20,880	=
Result from shares in associated company	***************************************	29	-	29	-
Interest income and other similar profit items		172	3	288	654
Interest expenses and other similar loss items	•	95	-36	-7	-152
		286	-33	-20,570	502
Profit/loss before tax		-13,102	-5,454	-87,118	-88,139
Incometax	2	-	-	-	_
Profit/loss for the period		-13,102	-5,454	-87,118	-88,139

# Statement of Comprehensive Income, Parent Company

#### (SEK 000)

	Note			
Profit/loss for the period	-13,102	-5,454	-87,118	-88,139
Other comprehensive income	-	-	-	-
Total comprehensive profit/loss for the period	-13,102	-5,454	-87,118	-88,139



# **Parent Company Balance Sheet**

(SEK 000)	Note 31 Dec, 2016	31 Dec, 2015
ASSETS		
Non-current assets		
Intangible assets	1	
Development costs	51,020	59,568
Patents	17,979	13,023
Other intangible assets	1,881	2,023
	70,881	74,614
Tangible assets		
Equipment	221	232
P	221	232
Financial assets	17.100	
Other long-term placement	13,102	14.550
Shares in subsidiaries	3 20,870	41,750
	33,972	41,751
Tatal nan annual assata	105.074	110 507
Total non-current assets	105,074	116,597
Current assets		
Short term receivables		
Receivables from group companies	7	334
Other receivables	1,643	1,323
Prepaid expenses and accrued income	515	492
Tropaid expenses and deer ded moonie	2,165	2,149
Cash and bank balances	75,954	75,936
Total current assets	78,119	78,085
TOTALASSETS	183,193	194,682
EQUITYANDLIABILITIES		
Equity	-	
Restricted equity		
Share capital	2,473	1,537
Statutory reserve	1,856	1,856
Development expenditure reserve	9,924	-
	14,253	3,393
Unrestricted equity	•	
Share premium reserve	82,653	119,427
Retained earnings	162,434	141,070
Profit/loss for the period	-87,118	-88,139
	157,969	172,358
	450.000	485.854
Total equity	172,222	175,751
Short-term liabilities		
Accounts payable	5,582	4,192
Other liabilities	473	398
Accrued expenses and deferred income	4,916	14,341
	10,971	18,931
	-	
TOTAL EQUITY AND LIABILITIES	183,193	194,682



### **Notes**

#### Note 1 - Intangible assets

(SEK 000)	Development costs	Patents*	Other	Total
ACCUMULATED COST				
Opening balance 1 Jan. 2016	59,803	18,193	2,899	80,895
Additions	12,487	6,156	_	18,643
Impaired value	-21,035	-	-	-21,035
Closing balance 31 Dec. 2016	51,255	24,349	2,899	78,503
ACCUMULATED DEPRECIATION		•		
Opening balance 1 Jan. 2016	-	-5,170	-821	-5,991
Depreciation for the period	-	-1,200	-161	-1,361
Closing balance 31 Dec. 2016	-	-6,370	-982	-7,352
Residual value 31 Dec. 2016	51,255	17,979	1,917	71,151

(SEK 000)	Development costs	Patents*	Other	Total
ACCUMULATED COST				
Opening balance 1 Jan. 2015	68,368	15,111	400	83,879
Additions	19,570	5,502	79	25,151
Impaired value	-28,135	-	_	-28,135
Reclassification	-	-2,420	2,420	-
Closing balance 31 Dec. 2015	59,803	18,193	2,899	80,895
ACCUMULATED DEPRECIATION		<del>-</del>		
Opening balance 1 Jan. 2015	-	-3,965	-313	-4,s278
Depreciation for the period	-	-1,205	-508	-1,713
Closing balance 31 Dec. 2015	-	-5,170	-821	-5,991
Residual value 31 Dec. 2015	59,803	13,023	2,078	74,904

#### Note 2 - Tax

The group's total loss carry-forwards amount to SEK 299,217,000 as of 31 December 2016 (231,327,000). The parent company's total loss carry-forwards amount to SEK 273,899,000 as of 31 December 2016 (190,736,000). Because the company is loss making, management cannot judge when deductible loss carry-forwards will be utilized.

#### Note 3 – Shares and participations in group companies

These shares are the holding of 71.37% in the subsidiary NeuroVive Pharmaceutical Asia Inc., domiciled in Taiwan. NeuroVive Pharmaceutical Asia Inc. has two fully owned subsidiaries - NeuroVive Pharmaceutical Asia Ltd. domiciled in Hong Kong and NeuroVive Pharmaceutical Taiwan, Inc. domiciled in Taiwan.



### **Affirmation**

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, 21 February 2017

Greg BatchellerArne FerstadBoel FlodgrenChairman of the BoardBoard memberBoard memberMarcus KeepDavid Laskow-PooleyHelena LevanderBoard memberBoard memberBoard member

Anna Malm Bernsten Erik Kinnman

Board member 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 Pharmaceuticals (publ) is obliged to make public pursuant to the EU Market Abuse Regulation and 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 21 February 2017.

### **About NeuroVive**

NeuroVive Pharmaceutical AB is a leader in mitochondrial medicine. The company is committed to the discovery and development of medicines that preserve mitochondrial integrity and function in areas of unmet medical need. The company's strategy is to take drugs for rare diseases through clinical development and into the market. The strategy for projects within larger indications outside the core focus area is out-licensing in the preclinical phase. NeuroVive enhances the value of its projects in an organization that includes strong international partnerships and a network of mitochondrial research institutions, as well as expertise with capacities within drug development and production.

NeuroVive has a project in early clinical phase II development for the prevention of moderate to severe traumatic

brain injury (NeuroSTAT®). NeuroSTAT has orphan drug designation in Europe and in the US. The R&D portfolio consists of several late stage research programs in areas ranging from genetic mitochondrial disorders to cancer and metabolic diseases such as NASH.

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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