



## New business model generates opportunities

## **Business operations**

## Important events July-September 2016

- NeuroVive completed a 10 percent partial acquisition of its business partner, Isomerase Therapeutics
- NeuroVive received a request to terminate the Company's license agreement with Arbutus Biopharma
- NeuroVive's strategy for the treatment of mitochondrial disease was published in Nature Communications

## Important events after the end of the period

- The development of CicloMulsion for acute kidney injury was discontinued and as a consequence the value of the subsidiary NeuroVive Asia has been written-down by 50 percent and all previously capitalized expenditure in connection with CicloMulsion has been recognized as an impaired value in the interim report for the third quarter
- New business model encompassing out-licensing of projects for common indications, as well as proprietary development of orphan indication projects, was communicated
- 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 NVP018 were returned to NeuroVive from Arbutus Biopharma. NeuroVive also received material manufactured by Arbutus valued at USD 1.5 million

## Financial information

## Third quarter (July - September 2016)

- Net revenues were SEK 0 (0) and other operating income was SEK 16,000 (74,000)
- Loss before tax was SEK 34,290,000 (53,948,000), for further information see page 6
- Loss per share\* was SEK 0.86 (1.75)
- Diluted loss per share\*\* was SEK 0.86 (1.75)

## First nine months of the year (January-September 2016)

- Net revenues were SEK 0 (2,502,000) and other operating income was SEK 90,000 (499,000)
- Loss before tax was SEK 57,265,000 (83,435,000), for further information see page 6
- Loss per share\* was SEK 1.42 (2.78)
- Diluted loss per share\*\* was SEK 1.42 (2.78)

<sup>\*</sup> Profit/loss for the period divided by the average number of shares before dilution at the end of the period.

<sup>\*\*</sup>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 CiPRICS Phase II clinical trial, although well conducted, showed that patients treated with CicloMulsion during open heart surgery had no benefit from the treatment in the prevention of acute kidney injury (AKI). The Company will therefore discontinue its development of CicloMulsion. At the same time, after the end of the period, we reported positive results in the NASH project and presented our new business model.

Key lessons from the CiPRICS Phase II trial CiPRICS was conducted in an exemplary manner by a team led by Associate Professor Henrik Bjursten at Skåne University Hospital and we are very satisfied with this rewarding collaboration. The trial confirmed the effectiveness of how NeuroVive works with partners, using a network model for early-phase clinical research projects, and provides a solid basis for future work. However, the unambiguous results of the trial showed that CicloMulsion does not protect against acute kidney injury (AKI) during heart surgery when a heart-lung machine is used.

#### Nature - a seal of quality for NVP015

During the period, the NVP015 project in which acute treatment of energy crisis in patients with genetic mitochondrial disease is developed, attracted attention due to a publication in Nature Communications, one of the world's most prestigious interdisciplinary scientific journals. A publication in Nature requires the highest quality research and is proof that we are on the forefront of mitochondrial medicine. The journal reaches many authorities in the field, and the publication enables us to attract and link up with other experienced and knowledgeable people in the field.

NVP018 - rights regained and valuable materials After the end of the period, we could announce that we have regained all rights to the compound in the NVP018 project from our previous business partner Arbutus Biopharma, which is very pleasing. Our interactions with Arbutus were positive, and we have learnt useful lessons from the various preclinical development activities. The manufactured product itself is very valuable and saves us time in our projects as we see several possible development options for NVP018.

#### Isomerase a strong partner

In partnership with Isomerase, we have been able to advance our prioritized NVP018 and NVP015

development programs efficiently and to generate new compounds that are currently being evaluated in experimental models. In mid-August, we completed the second stage of the previously communicated partial acquisition of Isomerase Therapeutics Ltd, a UK-based research and development company. NeuroVive now owns about 10% of the shares in Isomerase.



Positive results from preclinical NASH trial NVP018 has demonstrated positive effects on fibrosis development in an experimental model for NASH (non-alcoholic steatohepatitis). This indication holds huge potential commercial value, and if further preclinical development confirms these findings, we will be able to initiate out-licensing discussions by the second half of 2017.

## New business model creates opportunities

The NASH project is in line with the Company's new business model, involving a broader and accelerated focus on discovery projects with high commercial potential, where the goal is to out-license at the preclinical phase. At the same time, the Company will focus on proprietary orphan drug projects all the way to marketing approval. Overall, this means that we have several projects in our portfolio that can both create value and provide future revenue streams and at the same time we are spreading risks. Recent events, including the termination of a clinical project and the regaining of our rights to another, are enabling NeuroVive to strengthen its focus and build value in these early-phase projects. We are happy to announce the recruitment of Dr Michele Tavecchio, who has joined our research team this autumn. His expertise in the field of cyclophilin D and related metabolic effects will suit NeuroVive's project portfolio perfectly.

Erik Kinnman CEO, NeuroVive Pharmaceutical AB 22 November 2016



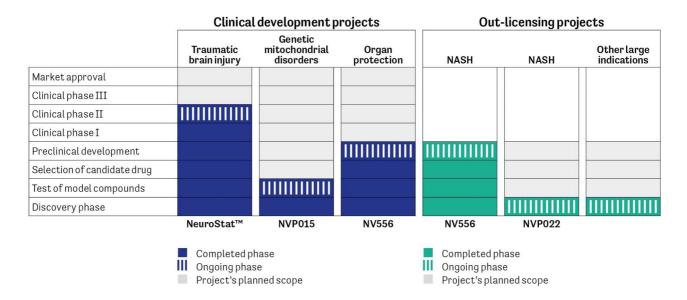
## **Operations**

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 manufacturing. The drug development process is comprehensive and carefully regulated, and NeuroVive strives to make this process as cost-effective as possible by collaborating with various partners.

### Business model focused on orphan drugs and the out-licensing of early-phase projects

After the end of the reporting period, the Company announced its implementation of a business model that will comprise two components. The first component consists of projects for large indications with high commercial potential, such as NASH, for out-licensing in the preclinical phase. The other component comprises proprietary drug development for rare diseases with a major unmet medical need where the company intends to develop the projects through clinical development up until marketing authorization. NeuroVive maintains its research and development focus in mitochondrial medicine with the aim of helping patients for whom there are few or no treatment options currently available.

## Project portfolio



## Kidney protection during major surgery (AKI)

The outcome of the CiPRICS exploratory Phase II clinical trial was presented after the end of the reporting period. The results demonstrated that patients treated with CicloMulsion before open heart surgery did not benefit from the treatment, compared with a placebo, to prevent acute kidney injury (AKI). The CiPRICS trial did not, therefore, reach its primary endpoint. Patients in the active dosage group exhibited a transient, but statistically significant increase of the cystatin C and P-creatinine biomarkers compared with placebo. Due to the unambiguous results, the Company decided to discontinue further development of CicloMulsion.

## Moderate to severe traumatic brain injury (TBI)

In collaboration with the University of Pennsylvania (PENN), NeuroVive is evaluating the preventative effect of NeuroSTAT in an experimental TBI model. The first two of three sub-studies have been successfully carried out and completed. Positive results from the second sub-study demonstrate that NeuroSTAT crosses the blood-brain barrier and concentration levels in blood and the brain. The third and final sub-study where the effect of NeuroSTAT is evaluated in a TBI model, will be conducted at the end of the year and in early 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 by applying for grants from major international institutions or, alternatively, via commercial partners.

At the end of the second quarter, CHIC had recruited 16 patients. Based on the current rate of recruitment, the trial is expected to be fully enrolled by the first quarter of 2017 and the results are estimated to be available in the second quarter of 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 levels. Secondarily, exploratory measurements will be carried out to study both 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 <u>ClinicalTrials.gov</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 following the injury, which often contributes substantially to the damage from the initial 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 hope 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.

#### Mitochondrial respiratory chain disorders (MRCD)

The results of the NVP015 research program into the new pharmacological strategy for the treatment of mitochondrial disease were published in August 2016 in Nature Communications, the third highest-ranked multidisciplinary science journal in the world. The project was conducted by NeuroVive in partnership with Lund University, Newcastle University, Selcia/Mitopharm Ltd and Isomerase Therapeutics Ltd. In the article published in Nature Communications, the research team presents the results of the new treatment strategy, in which succinic acid (succinate) is delivered to cells with complex I dysfunction, a potentially new method for treating patients suffering from diseases caused by mitochondrial complex I dysfunction.

Previous compounds, as described in the Nature Communications journal, are not suitable for studies in more complex experimental models or in vivo, since they lack sufficient plasma stability. To circumnavigate this situation, researchers at NeuroVive and Isomerase have worked within the framework of the NVP015 research program to develop a new series of succinate prodrugs with improved stability in the bloodstream. The most promising compounds from this series are currently being tested in various experimental models. This optimization process has been expanded to include a higher number of interesting compounds than originally planned, and a drug candidate is planned to be selected in the second half of 2017.

The NVP015 project is based on a concept instigated 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. A successful drug candidate from this research program in mitochondrial medicine may potentially be classified as an orphan drug, enabling a faster and less costly market route, as well as a higher price. One of the most common causes of mitochondrial diseases relates to complex I dysfunction, i.e. abnormal functioning of energy conversion in the first of the five protein complexes in the mitochondrion that are involved in effective energy conversion.

## Non-alcoholic steatohepatitis (NASH)

After the end of the reporting period, it was announced that positive preclinical results had been obtained for NVP018 in an experimental model for NASH (non-alcoholic steatohepatitis), a serious, chronic and common liver disease. In addition to NVP018, NeuroVive is developing a new class of compounds with a different mechanism of action, that may be supplemental to the treatment of NASH. The 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 underway to confirm the collected data, and to compile a package for the commencement of out-licensing discussions in 2017.



NASH - non-alcoholic steatohepatitis - is a progressive disease that can lead to cirrhosis and liver cancer. 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 disorders in the world. An estimated 20% of the world population suffers from NAFLD, and about one-third of the US population. There is a strong link between NASH and various metabolic disorders, such as diabetes and obesity. About 3-5% of Americans (about 15 million people) suffer from NASH and there are no FDA-approved treatments at present.<sup>1)</sup>

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

#### Organ protection

Within the framework of NeuroVive's new business model, with a new focus on early-phase projects, both NVP019 and the Company's other cyclophilin inhibitors are currently being assessed in a range of indications, in relation to organ protection in acute and chronic conditions.

#### Ischemic stroke

In line with the increased focus on early-phase projects for out-licensing, the Company has reviewed its portfolio and selected a number of projects with high commercial potential and relatively low risk for further development. The Company has subsequently decided to discontinue development of the NVP014 project for the treatment of stroke.

#### License agreement with Arbutus

In July 2016, NeuroVive received a purported notice of termination from Arbutus Biopharma (previously OnCore Biopharma, Inc.) regarding the license agreement from 2014. The agreement pertained to the development and commercialization of NeuroVive's NV556 compound, developed for per oral treatment of hepatitis B infection (NVP018). The termination was based on a prior decision by Arbutus to discontinue development of the compound, which was announced in October 2015.

After the end of the reporting period, it was announced that the license agreement with Arbutus Biopharma (previously OnCore Biopharma, Inc.), pertaining to the development and commercialization of NeuroVive's NV556 compound for per oral treatment of hepatitis B infection (NVP018), had been formally terminated. Under the termination agreement, NeuroVive is to receive, free of charge, the NVP018 drug substance and materials manufactured by Arbutus Biopharma, valued at approximately USD 1.5 million. Data from preclinical development and chemistry, manufacturing, and control (CMC) has been transferred to NeuroVive. In addition, all license rights to the NV556 compound have been returned to NeuroVive for further development in all potential indications.

#### NeuroVive Pharmaceutical Asia, Inc. subsidiary

Based on the decision to discontinue development of CicloMulsion, the NeuroVive Pharmaceutical Asia, Inc. subsidiary is currently evaluating opportunities for its future operations. Because of the decision to discontinue the development of CicloMulsion, the parent company has written-down the shares of NeuroVive Asia by approximately 50%, which corresponds to the estimated value of CicloMulsion in the relevant Asian territories.

## NeuroVive France SARL subsidiary closed

After the end of the reporting period, it was announced that closure of the dormant subsidiary in Lyon, France would be completed in order to save resources and costs. Closure of the NeuroVive France SARL subsidiary was a natural course of events due to the negative outcome of the CIRCUS trial. As part of this process, all agreements related to research collaboration with the Hospices Civils de Lyon (HCL) hospital and professor Michel Ovize, were also terminated, including OPeRa (Organ Protection & Replacement).

## Financial information

#### Revenues

The consolidated turnover during the third quarter of 2016 was SEK 0 (0). Other operating revenues for the third quarter of 2016 were SEK 16,000 (74,000). The consolidated turnover for the first nine months was SEK 0 (2,502,000) and the operating revenues amounted SEK 90,000 (499,000).



## Results of operations

The operating loss for the third quarter was SEK 34,190,000 (54,056,000). The operating loss for the first nine months was SEK 57,247,000 (84,099,000). The net loss before tax for the third quarter amounted to SEK 34,290,000 (53,948,000). The net loss before tax for the first nine months was SEK 57,265,000 (83,435,000).

The operating loss was affected by external expenses, which for the first nine months were SEK 24,308,000 (44,672,000). Expenses related to development projects have affected the result with SEK 8,204,000 (9,928,000). These expenses relate to development projects that have not reached phase I. Personnel expenses during the first nine months amounts to SEK 11,332,000 (12,689,000). Other operating expenses amount to, SEK 20,888,000 (29,174,000) whereof 20,618,000 (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 has been recognized as an impaired value. The remaining portion of other operating expenses pertains to exchange-rate losses.

### Financial position

The equity/assets ratio was 95 (85) % as of 30 September 2016, and equity was SEK 182,385,000 (154,779,000) compared to beginning of the year. Cash and cash equivalents amounted to SEK 112,889,000 (116,966,000) as of 30 September 2016, an increase of SEK 16,227,000 from the beginning of the year. Total assets as of 30 September 2016 were SEK 192,978,000 (191,109,000).

#### Cash flow and investments

Operating cash flow for the third quarter was SEK -10,137,000 (-13,487,000). Operating cash flow from the first nine months was SEK -45,592,000 (-50,437,000). The cash flow effect related to investments in intangibles equals SEK -3,690,000 (-6,310,000) for the third quarter. The cash flow effect related to investments in intangibles equals SEK -9,828,000 (-19,424,000) for the first nine months. Cash flow for the third quarter equals SEK -20,127,000 (-19,871,000). Cash flow for the first nine months equals SEK 14,960,000 (68,411,000).

#### 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.

Transactions with related parties	1 Jan. 2016	1 Jan. 2015
(SEK 000)	30 Sept 2016	30 Sept 2015
Stanbridge byba (owned by Gregory Batcheller, Executive Chairman)	722	1 100
Ankor Consultants bvba (owned by Arne Ferstad, Board member)	96	377
Bernsten Consulting	54	
Total transactions with related parties	872	1 477

## 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 instruments 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 September was 17 (10), of which 8 (7) 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 the period was therefore SEK 74,037 (82,685). 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 allegedly to be paid by the Company under a 2004 License Agreement 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 partial award was appealed by each party to the competent Swedish court (Hovrätten över Skåne Blekinge). A decision on the appeals is expected by the end of 2017. The arbitration proceeding is continuing regarding the applicable royalty rate in certain countries and an award is expected by the end of 2016 or the beginning of 2017 which will also include a decision on the overall costs of the arbitration proceeding. It cannot be excluded, however, that the Tribunal will decide to stay the arbitration proceeding due to the pending 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 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 2016 21 February 2017
Interim Report January-March 18 May 2017
Interim Report January-June 17 August 2017
Interim Report January-September 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.

The Nomination Committee for the 2017 AGM comprises:

- Anders Ermén, Chairman nominated by Baulos Capital Belgium SA / Fredrik Olsson
- Michael Vickers nominated by Maas Biolab LLC / Marcus Keep
- Andreas Inghammar nominated by Eskil Elmer

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 2017.

#### 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 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**

(SEK 000) Not	e 1 July. 2016	1 July. 2015	1 Jan. 2016	1 Jan. 2016	1 Jan. 2015
·	30 Sept. 2016	30 Sept. 2015	30 Sept. 2016	30 Sept. 2016	31 Dec. 2015
Net sales	_	_	-	2 502	2 502
Other operating income	16	74	90	499	522
	16	74	90	3 001	3 024
Operating expenses					
Other external expenses	-9 172	-19 687	-24 308	-44 672	-48 514
Personnel cost	-4 050	-5 876	-11 332	-12 689	-15 556
Depreciation and write-down of tangible	-278	-220	-808	-565	-1 200
and intangible assets					
Other operating expenses	-20 705	-28 346	-20 888	-29 174	-29 220 <b>-94 490</b>
	-34 206	-54 129	-57 337	-87 100	-94 490
Operating income	-34 190	-54 056	-57 247	-84 099	-91 466
Profit/loss from financial items					
Financial income	21	419	176	1 065	1 100
Financial costs	-121	-311	-194	-401	-435
	-99	108	-17	664	665
Profit/loss before tax	-34 290	-53 948	-57 265	-83 435	-90 801
Income tax 2	-	-	-	-	-
Profit/loss for the period	-34 290	-53 948	-57 265	-83 435	-90 801
Other comprehensive income Items that may be reclassified to profit or loss					
Translation differences on foreign subsidiaries	745	-1 228	1 282	-977	-667
Total comprehensive income for the period	-33 545	-55 176	-55 983	-84 412	-91 468
Loss for the period attributable to:					
Parent company shareholders	-33 919	-53 668	-56 090	-83 302	-90 119
Non-controlling interests	-371 - <b>34 290</b>	-279 <b>-53 948</b>	-1 175 - <b>57 265</b>	-133 - <b>83 435</b>	-682 <b>-90 801</b>
	54 235	33 340	37 203	05 405	
Total comprehensive income for the period					
Parent company shareholders	-33 528	-54 800	-55 548	-83 801	-90 207
Non-controlling interests	-17	-376	-435	-611	-1 261
5	-33 545	-55 176	-55 983	-84 412	-91 468
Farnings per chare before and often					
Earnings per share before and after dilution(SEK) based on average number of shares	-0,86	-1,75	-1,42	-2,78	-3,01



## **Consolidated Statement of Financial Position**

(SEK 000)	Note	30 Sept. 2016	30 Sept. 2015	31 Dec. 2015
ASSETS				
Non-current assets				
Intangible assets	1			
Development costs		47 681	57 659	59 803
Patents		14 703	14 817	13 023
Other Intangible assets		1 956	87	2 078
		64 339	72 563	74 904
Tangible assets				
Equipment		290	347	316
Trip - 2 - 2	-	290	347	316
Financial assets				
Other long-term securities		13 101	-	1
Other long-term receivables	-	119	161	148
		13 220	161	149
				75 340
Total non-current assets		77 849	73 071	75 369
Current assets				
Other receivables		1 574	796	2 368
Prepaid expenses and accrued income		665	277	528
Cash and cash equivalents		112 889	116 966	96 662
		115 128	118 039	99 558
TOTAL ASSETS		192 978	191 109	174 927
(SEK 000)	Note	30 Sept. 2016	30 Sept. 2015	31 Dec. 2015
EQUITY AND LIABILITIES				
Equity attributable to the shareholders of the parent company				
Share capital		2 473	1 537	1 537
Additional paid in capital		418 339	335 798	335 687
Translation reserve		352	-601	-190
Retained earnings		-251 995	-189 090	-195 906
Total equity attributable to the shareholders of the parent		169 169	147 644	141 128
Non-controlling interests		13 216	14 321	13 651
		182 385	161 965	154 779
Total equity				
· ·				
Total equity  Short-term liabilities  Accounts payable		3 642	6 312	5 207
Short-term liabilities		3 642 734	6 312 431	
Short-term liabilities Accounts payable				601
Short-term liabilities Accounts payable Other liabilities	_	734	431	601 14 340
Short-term liabilities Accounts payable Other liabilities	_	734 6 217	431 22 402	5 207 601 14 340 20 148 20 148



## **Consolidated Statement of Changes in Equity**

Total number of shares at end of period: 49,458,645 (30,735,152).

(SEK 000) Equity attributable to the shareholders of the

parent company

	parent compa	any					
					Total equity		
		Additiona	Transla		attributable to the	Non-	
	Share	l paid in	tion	Retained	shareholders of the	controlling	Total
	capital	capital	reserve	earnings	parent company	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							
Profit/loss for the period	-	-	-	-56 090	-56 090	-1 175	-57 265
Other comprehensive income							
Translation differences	-	-	542	-	542	740	1 282
Other comprehensive profit/loss for the	_		542	_	542	740	1 282
period, net after tax							
Total comprehensive profit/loss	-	-	542	-56 090	-55 548	-435	-55 983
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	352	-251 995	169 169	13 216	182 384
Opening balance, 1 January 2015	1 389	207 812	-102	-105 787	103 312	4 529	107 841
Comprehensive profit/loss for the period							
Profit/loss for the period	-	-	-	-83 302	-83 302	-133	-83 435
Other comprehensive income							
Translation differences	-	-	-499	-	-499	-478	-977
Other comprehensive profit/loss for the	-	-	-499	-	-499	-478	-977
period, net after tax  Total comprehensive profit/loss		_	-499	-83 302	-83 801	-611	-84 412
Transactions with shareholders							
New share issue	148	119 427	-	-	119 575	-	119 575
Issue through non-controlling interest	-	8 559	=	-	8 559	10 403	18 963
Total transactions with shareholders	148	127 986	-	-	128 134	10 403	138 573
Closing balance, 30 September 2015	1 537	335 798	-601	-189 089	147 645	14 321	161 966
Opening balance, 1 January 2015	1 389	207 812	-102	-105 787	103 312	4 529	107 841
Comprehensive profit/loss for the	1 307	207 012	102	103 707	103 312	7 327	107 041
Profit/loss for the period	_	_	_	-90 119	-90 119	-682	-90 801
Other comprehensive income				70 117	70 117	002	70 001
Translation differences	_	_	-88	_	-88	-579	-667
Other comprehensive profit/loss for the							
period. net after tax	-	-	-88	-	-88	-579	-667
Total comprehensive profit/loss	-	-	-88	-90 119	-90 207	-1 261	-91 468
Transactions with shareholders							
New share issue	148	119 427	-	-	119 575	-	119 575
Change of ownership in new share issue	-	8 448	-	-	8 448	10 383	18 831
Total transactions with shareholders	148	127 875	-	-	128 023	10 383	138 406
Closing balance, 31 December. 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 July. 2016	1 July. 2015	1 Jan. 2016	1 Jan. 2015	1 Jan. 2015
	30 Sep. 2016	30 Sep. 2015	30 Sep.2016	30 Sep. 2015	31 Dec. 2015
Cash flow from operating activities					
Operating income	-34 190	-54 056	-57 247	-84 099	-91 466
Adjustments for non-cash items:					
Depreciation	278	220	808	565	1 200
Currency differences on intercompany items	12	-39	25	179	153
Impaired Value	20 618	28 135	20 618	28 135	28 135
Disposal of Business	7	-	7	-	
Interest received	21	419	176	1 065	1 100
Interest paid	-121	-311	-194	-401	-435
Net cash from operating activities					
before changes in working capital	-13 375	-25 632	-35 807	-54 556	-61 313
Changes in working capital					
Increase/decrease of other current assets	2 101	1 260	524	387	-1 255
Increase/decrease of other short-term liabilities	1 137	10 885	-10 309	3 732	-4 652
Changes in working capital	3 238	12 145	-9 785	4 119	-5 907
Cash flow from operating activities	-10 137	-13 487	-45 592	-50 437	67 220
Investing activities					
Acquisition of intangible assets	-3 690	-6 310	-9 828	-19 424	-23 200
Acquisition of tangible assets	-10	-39	-108	-266	-245
Increase in other financial assets	-6 291	-	-6 844		
Cash flow from investing activities	-9 991	-6 349	-16 780	-19 690	-23 445
Financing activities					
Share issue minority	-	-35	-	18 963	18 831
New share issue	-	-	77 332	119 576	119 575
Cash flow from financing activities	-	-35	77 332	138 539	138 406
Cash flow for the period	-20 127	-19 871	14 960	68 411	47 741
Cash and cash equivalents at the beginning of the	132 280	138 049	96 662	49 698	49 698
Effect of exchange rate changes on cash	736	-1 212	1 267	-1 143	-777
Cash and cash equivalents at end of period	112 889	116 966	112 889	116 966	96 662



# **Parent Company Income Statement**

(SEK 000) Note	1 July. 2016	1 July. 2015	1 Jan. 2016	1 Jan. 2015	1 Jan. 2015
	30 Sept. 2016	30 Sept. 2015	30 Sept. 2016	30 Sept. 2015	31 Dec. 2015
			_		
Net sales	-	-	9	-	327
Other operating income	16	56	90	481	509
	16	56	99	481	836
Operating expenses					
Other external expenses	-8 782	-19 318	-22 501	-42 903	-45 774
Personnel cost	-3 250	-5 144	-9 160	-11 124	-13 376
Depreciation and write-down of tangible and	-250	-191	-724	-500	-1 106
intangible assets					
Other operating expenses	-20 711	-28 346	-20 895	-29 174	-29 221
	-32 994	-52 999	-53 280	-83 701	-89 477
Operating income	-32 978	-52 944	-53 180	-83 220	-88 641
Profit/loss from financial items					
Result from shares in group company	-20 870	-	-20 870	-	-
Interest income and other similar profit items	33	85	116	651	654
Interest expenses and other similar loss items	-94	-99	-102	-116	-152
	-20 931	-13	-20 856	535	502
Profit/loss before tax	-53 908	-52 957	-74 037	-82 685	-88 139
Income tax 2	-	-	-	-	-
Profit/loss for the period	-53 908	-52 957	-74 037	-82 685	-88 139

# Statement of Comprehensive Income, Parent Company

(SEK 000) Note	1 July. 2016	1 July. 2015	1 Jan. 2016	1 Jan. 2015	1 Jan. 2015
	30 Sept. 2016	30 Sept. 2015	30 Sept. 2016	30 Sept. 2015	31 Dec. 2015
Profit/loss for the period	-53 908	-52 957	-74 037	-82 685	-88 139
Other comprehensive income	-	-	-	-	-
Total comprehensive profit/loss for the period	-53 908	-52 957	-74 037	-82 685	-88 139



# **Parent Company Balance Sheet**

(SEK 000)	Note	30 Sept. 2016	30 Sept. 2015	31 Dec. 2015
ASSETS				
Non-current assets				
Intangible assets	1			
Development costs		47 446	57 425	59 568
Patents		14 704	14 817	13 023
Other intangible assets		1 915	27	2 023
To a the control		64 065	72 268	74 614
Tangible assets Equipment		229	254	232
Equipment		229	254	232
Financial assets				
Other long-term placement		13 102	1	1
Shares in subsidiaries	3	20 870	41 750	41 750
		33 972	41 751	41 751
Total non-current assets		98 265	114 273	116 597
Constant and the				
Current assets				
Short term receivables				
Receivables from group companies		-	6	334
Other receivables		1 567	772	1 323
Prepaid expenses and accrued income		246	275	492
		1 813	1 052	2 149
Cash and bank balances		95 010	94 264	75 936
Total current assets		96 823	95 317	78 085
IOTAL ASSETS		195 088	209 590	194 682
TOTAL ASSETS		195 088	209 590	194 682
(SEK 000)	Note	195 088 30 Sept. 2016	209 590 30 Sept. 2015	194 682 31 Dec. 2015
	Note			
(SEK 000)	Note			
(SEK 000) EQUITY AND LIABILITIES	Note			
(SEK 000)  EQUITY AND LIABILITIES  Equity  Restricted equity	Note			
(SEK 000)  EQUITY AND LIABILITIES  Equity  Restricted equity  Share capital	Note	30 Sept. 2016	30 Sept. 2015	31 Dec. 2015
(SEK 000)  EQUITY AND LIABILITIES  Equity  Restricted equity  Share capital  Statutory reserve	Note	2 473 1 856	30 Sept. 2015 1 537	<b>31 Dec. 2015</b> 1 537
(SEK 000)  EQUITY AND LIABILITIES  Equity  Restricted equity  Share capital  Statutory reserve	Note	30 Sept. 2016 2 473	30 Sept. 2015 1 537	<b>31 Dec. 2015</b> 1 537
(SEK 000)  EQUITY AND LIABILITIES  Equity  Restricted equity  Share capital  Statutory reserve  Development expenditure reserve	Note	2 473 1 856 5 611	30 Sept. 2015 1 537 1 856	31 Dec. 2015 1 537 1 856
(SEK 000)  EQUITY AND LIABILITIES Equity Restricted equity Share capital Statutory reserve Development expenditure reserve  Unrestricted equity	Note	2 473 1 856 5 611 9 940	30 Sept. 2015 1 537 1 856	1 537 1 856 - 3 393
(SEK 000)  EQUITY AND LIABILITIES Equity  Restricted equity Share capital Statutory reserve Development expenditure reserve  Unrestricted equity Share premium reserve	Note	2 473 1 856 5 611	30 Sept. 2015 1 537 1 856	1 537 1 856 - 3 393
(SEK 000)  EQUITY AND LIABILITIES  Equity  Restricted equity  Share capital  Statutory reserve  Development expenditure reserve	Note	2 473 1 856 5 611 9 940	1 537 1 856 - 3 393	1 537 1 856 - 3 393
(SEK 000)  EQUITY AND LIABILITIES Equity  Restricted equity Share capital Statutory reserve Development expenditure reserve  Unrestricted equity Share premium reserve Retained earnings	Note	30 Sept. 2016  2 473 1 856 5 611 9 940  393 648 -144 249 -74 037	30 Sept. 2015  1 537 1 856 - 3 393  195 720 64 777 -82 685	31 Dec. 2015  1 537 1 856 - 3 393  195 720 64 777 -88 139
(SEK 000)  EQUITY AND LIABILITIES Equity  Restricted equity Share capital Statutory reserve Development expenditure reserve  Unrestricted equity Share premium reserve Retained earnings	Note	2 473 1 856 5 611 9 940 393 648 -144 249	30 Sept. 2015  1 537 1 856 - 3 393  195 720 64 777	31 Dec. 2015  1 537 1 856 - 3 393  195 720 64 777
(SEK 000)  EQUITY AND LIABILITIES Equity  Restricted equity Share capital Statutory reserve Development expenditure reserve  Unrestricted equity Share premium reserve Retained earnings Profit/loss for the period	Note	30 Sept. 2016  2 473 1 856 5 611 9 940  393 648 -144 249 -74 037	30 Sept. 2015  1 537 1 856 - 3 393  195 720 64 777 -82 685	31 Dec. 2015  1 537 1 856 - 3 393  195 720 64 777 -88 139
(SEK 000)  EQUITY AND LIABILITIES Equity Restricted equity Share capital Statutory reserve Development expenditure reserve  Unrestricted equity Share premium reserve Retained earnings Profit/loss for the period  Total equity	Note	30 Sept. 2016  2 473 1 856 5 611 9 940  393 648 -144 249 -74 037 175 362	30 Sept. 2015  1 537 1 856 - 3 393  195 720 64 777 -82 685 177 812	1 537 1 856 - 3 393 195 720 64 777 -88 139 172 358
(SEK 000)  EQUITY AND LIABILITIES Equity Restricted equity Share capital Statutory reserve Development expenditure reserve  Unrestricted equity Share premium reserve Retained earnings Profit/loss for the period  Total equity  Short-term liabilities	Note	30 Sept. 2016  2 473 1 856 5 611 9 940  393 648 -144 249 -74 037 175 362 185 302	30 Sept. 2015  1 537 1 856 - 3 393  195 720 64 777 -82 685 177 812 181 205	31 Dec. 2015  1 537 1 856 - 3 393  195 720 64 777 -88 139 172 358 175 751
(SEK 000)  EQUITY AND LIABILITIES Equity Restricted equity Share capital Statutory reserve Development expenditure reserve  Unrestricted equity Share premium reserve Retained earnings Profit/loss for the period  Total equity  Short-term liabilities Accounts payable	Note	30 Sept. 2016  2 473 1 856 5 611 9 940  393 648 -144 249 -74 037 175 362	30 Sept. 2015  1 537 1 856 - 3 393  195 720 64 777 -82 685 177 812	1 537 1 856 - 3 393 195 720 64 777 -88 139 172 358
(SEK 000)  EQUITY AND LIABILITIES  Equity  Restricted equity Share capital Statutory reserve Development expenditure reserve  Unrestricted equity Share premium reserve Retained earnings Profit/loss for the period  Total equity  Short-term liabilities Accounts payable Liabilities to group companies	Note	30 Sept. 2016  2 473 1 856 5 611 9 940  393 648 -144 249 -74 037 175 362 185 302	30 Sept. 2015  1 537 1 856 - 3 393  195 720 64 777 -82 685 177 812 181 205	31 Dec. 2015  1 537 1 856 - 3 393  195 720 64 777 -88 139 172 358 175 751  4 192 -
(SEK 000)  EQUITY AND LIABILITIES Equity Restricted equity Share capital Statutory reserve Development expenditure reserve  Unrestricted equity Share premium reserve Retained earnings Profit/loss for the period  Total equity Short-term liabilities Accounts payable Liabilities to group companies Other liabilities	Note	30 Sept. 2016  2 473 1 856 5 611 9 940  393 648 -144 249 -74 037 175 362 185 302	30 Sept. 2015  1 537 1 856 - 3 393  195 720 64 777 -82 685 177 812 181 205  5 556 - 428	1 537 1 856 - 3 393 195 720 64 777 -88 139 172 358 175 751 4 192 - 398
(SEK 000)  EQUITY AND LIABILITIES Equity  Restricted equity Share capital Statutory reserve Development expenditure reserve  Unrestricted equity Share premium reserve	Note	30 Sept. 2016  2 473 1 856 5 611 9 940  393 648 -144 249 -74 037 175 362 185 302  3 110 - 729 5 947	30 Sept. 2015  1 537 1 856 - 3 393  195 720 64 777 -82 685 177 812 181 205  5 556 - 428 22 401	31 Dec. 2015  1 537 1 856 - 3 393  195 720 64 777 -88 139 172 358 175 751  4 192 - 398 14 341
(SEK 000)  EQUITY AND LIABILITIES Equity Restricted equity Share capital Statutory reserve Development expenditure reserve  Unrestricted equity Share premium reserve Retained earnings Profit/loss for the period  Total equity  Short-term liabilities Accounts payable Liabilities to group companies Other liabilities	Note	30 Sept. 2016  2 473 1 856 5 611 9 940  393 648 -144 249 -74 037 175 362 185 302	30 Sept. 2015  1 537 1 856 - 3 393  195 720 64 777 -82 685 177 812 181 205  5 556 - 428	1 537 1 856 - 3 393 195 720 64 777 -88 139 172 358 175 751 4 192 - 398



Note 1 — Intangible assets

(SEK 000))	<b>Development costs</b>	Patents*	Other	Total
ACCUMULATED COST				
Opening balance 1 Jan. 2016	59 803	18 193	2 899	80 895
Additions	8 375	2 600	-	10 975
Impaired value	-20 497	-	-	-20 497
Closing balance 30 Sept. 2016	47 681	20 793	2 899	71 373
ACCUMULATED DEPRECIATION				
Opening balance 1 Jan. 2016	-	-5 170	-821	-5 991
Depreciation for the period	-	-920	-122	-1 042
Closing balance 30 Sept. 2016	-	-6 090	-943	-7 033
Residual value 30 Sept. 2016	47 681	14 703	1 956	64 340

(SEK 000)	Development costs	Patents*	Other	Total
ACCUMULATED COST				
Opening balance 1 Jan. 2016	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	80 995
ACCUMULATED DEPRECIATION				
Opening balance 1 Jan. 2015	-	-1 395	-31	-4 278
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

<sup>\*</sup> Amortization of patents related to capitalized development costs is recognized as a portion of historical cost of capitalized expenditure from product development because patents are used in development work.

Of total capitalized expenditure for product development, 99 % is for NeuroSTAT, 1 % is for NVP014.

#### Note 2 - Tax

The group's total loss carry-forwards amount to SEK 284,764,000 as of 30 September 2016 (224,171,000). The parent company's total loss carry-forwards amount to SEK 260,946,000 as of 30 September 2016 (185,497,000). 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.



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.

Greg Batcheller Arne Ferstad

Chairman of the Board Board member

Boel Flodgren Marcus Keep
Board member Board member

Helena Levander Anna Malm Bernsten

Board member Board member

David Laskow-Pooley

Board member

Erik Kinnman

Chief Executive Officer

Lund, Sweden, 22 November 2016

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

#### **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 neurological 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)
Medicon Village, SE-223 81 Lund
Tel: +46-46 275 62 20 (switchboard), ir@neurovive.com
www.neurovive.com

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 22 November 2016.



## **Auditor's review report**

To the Board of Directors of NeuroVive Pharmaceutical AB (publ) Corp.ld.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<sup>th</sup>, 2016 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.

Helsingborg, November 22<sup>nd</sup> 2016

Mazars SET Revisionsbyrå AB

Bengt Ekenberg Authorized Public Accountant