



Year End Report January - December 2018

Positioned for clinical progress

Important events January-December 2018

Quarter 1

- Positive experimental efficacy data for NVP025.
- Decision on a rights issue (extraordinary general meeting).

Quarter 2

- NeuroVive and Yungjin reports positive KL1333 phase I clinical study results.
- KL1333 receives FDA Orphan Drug Designation for treatment of mitochondrial diseases.
- Positive efficacy data in an experimental model, entailing a breakthrough for the NVP025 mitochondrial myopathy project.
- NeuroVive initiates collaboration with leading US TBI research organization.
- NeuroVive out-licenses targeted LHON therapy to BridgeBio Pharma's new subsidiary Fortify Therapeutics.
- Oversubscribed preferential rights issue (approximately MSEK 78.5 before issue expenses)
- Annual General Meeting on 27 April in Lund, Sweden.

Quarter 3

- KL1333 mechanism of action published in scientific journal.
- Positive FDA feedback on the NeuroSTAT TBI development plan.
- 4 MUSD grant to Children's Hospital of Philadelphia for NVP015 research.

Quarter 4

- KL1333 clinical trial regulatory approval from the UK regulatory authority (MHRA).
- Signal of clinical efficacy from biomarker measurements in CHIC TBI-study.
- Preclinical NV354 efficacy results in a model for mitochondrial disease.
- Funding 5 million SEK from Vinnova for the development of NV354
- The exercise of warrants of series 2018:1 in November provides the Company with approximately SEK 480 000.
- NeuroVive resolves on a rights issue of MSEK 123.8, subject to approval by the Extraordinary General Meeting, and summons to an extraordinary general meeting.

Important events after the reporting period

- Decision on a rights issue (extraordinary general meeting).
- NeuroVive is supplied with approximately MSEK 99.0 in share issue proceeds before issue costs of approximately MSEK 17.7.

Fourth quarter (October - December 2018)

- Net revenues: SEK 5,000 (0)
- Other operating income: SEK 1,009,000 (9,000)
- Loss before tax: SEK -19,978,000 (-14,779,000)
- Loss per share*: SEK -0,25 (-0,29)
- Diluted loss per share**: SEK -0,25 (-0,29)

Twelve months (January - December 2018)

- Net revenues: SEK 5,000 (27,000)
- Other operating income: SEK 2,461,000 (248,000)
- Loss before tax: SEK -73,494,000 (-71,603,000)
- Loss per share*: SEK -0,94 (-1,33)
- Diluted loss per share**: SEK -0,94 (-1,33)

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

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Comments from our CEO, Erik Kinnman

In summarizing 2018, we can say that it was a very successful year for our focus projects. Following the results of biomarker analyses, the NeuroSTAT project is scientifically more interesting than ever; KL1333 has performed exactly according to plan. NV354 also made decisive progress during the year. Not as visible, but just as important, is the intensive business development that we conduct continuously with the aim of increasing the value of NeuroVive and establishing new revenue flows. The out-licensing to BridgeBio/Fortify and the funding from Vinnova were the most tangible results of this work in 2018.

I would like to thank all existing shareholders who have participated in the issue for your continued support and warmly welcome our new shareholders. We are in a very exciting period in the Company's development. The financial resources now provided ensure the implementation of crucial value-creating activities in the coming year, primarily in our clinical phase projects.

KL1333 – Phase I clinical trial first half of 2019

After our application to conduct a Phase I trial with patients and healthy volunteers was approved by the UK Medicines and Healthcare products Regulatory Agency (MHRA) during the fourth quarter, we have commenced comprehensive preparatory work. The trial is scheduled to start during the first half of 2019 with the purpose of evaluating safety and pharmacokinetics and conducting exploratory efficacy evaluations. The ultimate goal is to develop drugs for the serious mitochondrial disorders MELAS, PEO, KSS and Pearsons syndrome.

NeuroSTAT – preparations for clinical Phase II

Following the positive results from the analyses of biomarkers from patient samples from the CHIC trial, the NeuroSTAT project is more interesting than ever. The results indicate that NeuroSTAT inhibits the secondary injury cascades resulting from brain trauma. We are now preparing an upcoming Phase II clinical trial, while we are seeking external, non-dilutive funding for the trial. Our ambition is to secure financing for the trial so that it can commence during 2019. In the event of a positive outcome of the Phase II trial, we would then be able to proceed with a Phase III trial. However, it is important to remember that all drug development is associated with a large amount of uncertainty and it is never possible to guarantee positive results.

NV354 – alternative energy source for genetic mitochondrial disorder

NV354 is also an important project for us. The initial experimental results are positive and we will continue preclinical development during 2019 with the aim of starting clinical trials during 2020.



These three projects will be in focus in 2019. In addition to our focus projects, we have projects that could potentially generate major value in the long-term.

Intense business development

NeuroVive conducts intense business development. From a business development perspective, this mainly involves three activities. We actively seek interesting *partners* who can contribute capital and knowledge to all of our active projects, but above all, to the projects that have progressed furthest in their development. In parallel, we look for various forms of *external, non-dilutive funding*. The funding of SEK 5 million from Vinnova for the intensified development of the candidate compound NV354 is one result of this work. In addition, we are continuing our work on *out-licensing*. The current focus is NV556, which is being developed for the treatment of liver fibrosis in connection with NASH. The aim is to be able to sign an out-licensing agreement sometime in the first half of 2019.

Erik Kinnman

CEO, NeuroVive Pharmaceutical AB
February 28, 2019



NeuroVive's research and development

NeuroVive has a leading position in mitochondrial research and development. The company's objective is to design novel pharmaceuticals that preserve the integrity and function of mitochondria for indications where there is a significant unmet medical need. Drug development is a comprehensive and carefully regulated process. By working with different partners, NeuroVive strives to make this process as flexible, cost-effective and successful as possible.

Two principle paths

NeuroVive's aim is to help patients who currently have few or no treatment options. The company's business model consists of two parts: the first one involves the development of drugs for rare diseases, and the second one includes the development of mitochondrial drugs for commonly occurring diseases.

Development to the market. Development of drugs for rare diseases is done through preclinical and clinical development to market. NeuroVive's ambition is that these drugs shall be classified as orphan drugs.

Out-licensing in pre-clinical phase. For commonly occurring diseases with high commercial potential, where clinical studies are very extensive and costly, NeuroVive's objective is to out-license the projects in late preclinical phase.

Value creation with limited cost and risk

The diversified project portfolio allows the company to take orphan drugs to the market comparatively quickly, and at a limited cost and risk. At the same time, innovation in common diseases can be industrialized and value created through out-licensing and partnerships.

	Development of orphan drugs					Outlicensed	Drug development for common diseases		
	Brain Injury	Genetic Mitochondrial Disease					NASH		Liver cancer
	Moderate/severe	MELAS/Myopathy	Leigh	Myopathy	LHON		Fibrosis	Metabolic	HCC
Market									
Phase III									
Phase II									
Phase I									
Preclinical									
Lead selection									
Discovery									
	NeuroSTAT®	KL1333	NV354	NVP025	NVP015		NV556	NV422	NVP024

More than 50 million people suffer a traumatic brain injury each year.

The global healthcare cost is estimated to be 400 billion dollars.



Traumatic brain injury (TBI)

Traumatic brain injury (TBI) is caused by external force to the head resulting in immediate damage to nerve cells. The damage continues to worsen for several days after the acute trauma. The most common causes for TBI are trips and falls, traffic accidents, and assault and battery.¹⁾ With more than 50 million new cases occurring each year, TBI is estimated to cost the global economy nearly 400 billion dollars annually in direct and indirect healthcare costs.²⁾ A large number of patients suffer moderate to severe functional disabilities requiring intensive care and various forms of lifelong support.

NeuroSTAT – candidate drug in clinical phase II study

Treatment objective

The aim for NeuroSTAT is to prevent the emergence of neurological and functional secondary brain damage after a traumatic injury, and thereby establish a therapy that will lead to increased survival, improved quality of life and preserved neurological function.

Project status: clinical phase II

NeuroVive's candidate drug for TBI treatment, NeuroSTAT, has been evaluated in a Phase II clinical study (Copenhagen Head Injury Ciclosporin-CHIC) at Copenhagen University Hospital in Denmark. The study, which ended in May 2017, evaluated safety, tolerability and pharmacokinetics of two different doses of the active ingredient ciclosporin as well as passage to the brain in patients with severe traumatic brain injury.

The protective effects in traumatic brain injury and the relationship between efficacy and drug concentrations in the brain, were also assessed in an experimental study at the University of Pennsylvania (Penn). The NeuroSTAT candidate drug has orphan drug designation in both Europe and the US.

Objectives for 2018

- Publication/presentation of results from the CHIC study and from the collaboration with Penn. ✓
- Results from evaluation of biomarkers prior to the upcoming NeuroSTAT development program. ✓
- Secure financing for upcoming Phase II efficacy study.
- Meeting with the FDA prior to development programs in the US. ✓

Fourth quarter news

- NeuroVive reports first NeuroSTAT clinical efficacy signal in traumatic brain injury

Objectives for 2019

- Secure external non-dilutive financing for upcoming Phase II efficacy study.
- Receive approval of IND application for clinical development in the US.
- Start clinical phase II efficacy study if external financing is received

1) www.internetmedicin.se/page.aspx?id=1178

2) Maas A Et al. Traumatic brain injury: integrated approaches to improve prevention, clinical care, and research. The Lancet Neurology. 2017 Nov; 16(12):987.



Genetic mitochondrial diseases can lead to severe symptoms, such as mental retardation, dementia, deafness and blindness.

Genetic mitochondrial diseases

Genetic mitochondrial diseases are metabolic diseases that affect the ability of cells to convert energy. The disorders can manifest differently depending on the organs affected by the genetic defects and are viewed as syndromes. An estimated 12 in every 100,000 people suffer from a mitochondrial disease. Mitochondrial diseases often present in early childhood and lead to severe symptoms, such as mental retardation, heart failure and rhythm disturbances, dementia, movement disorders, stroke-like episodes, deafness, blindness, limited mobility of the eyes, vomiting and seizures.

KL1333 – candidate drug in clinical phase I

Treatment objective

KL1333 is a potent modulator of cellular levels of NAD⁺, a central coenzyme in the cell's energy metabolism. KL1333 has, in preclinical models, been demonstrated to increase mitochondrial energy output, reduce lactate accumulation, diminish the formation of free radicals, and to have longterm beneficial effects on energy metabolism. The candidate drug is intended for oral treatment in primary genetic mitochondrial disorders such as MELAS, KSS, PEO, Pearson and MERRF.

The candidate drug in the KL1333 project has already been granted orphan drug designation in Europe and the United States, and there is also potential for obtaining orphan drug designation for the future drug candidates in the NVP015/NV354 and NVP025 projects. Orphan drug designation allows for a faster and less costly route to the market, as well as a higher market price for the drug.

Project status: clinical phase I

KL1333 is currently being evaluated in clinical phase I studies.

Objectives for 2018

- Results from clinical single-dose Phase Ia study of KL1333 in South Korea, sponsored by Yungjin Pharm. ✓

Fourth quarter news

- NeuroVive receives regulatory approval for the KL1333 clinical trial, from the UK regulatory authority (MHRA).

Objectives for 2019

- Start clinical phase Ia/b study in Europe during first half of 2019.
- Present initial results from the clinical phase Ia/b study.
- Prepare for phase II efficacy studies.

NVP015/NV354 – candidate drug in pre-clinical development

Treatment objective

One of the most common causes of mitochondrial diseases relates to Complex I dysfunction, i.e. when energy conversion in the first of the five protein complexes in the mitochondrion that are essential for effective energy conversion does not function normally. This is apparent in disorders including Leigh syndrome and MELAS, both of which are very serious diseases with symptoms such as muscle weakness, epileptic fits and other severe neurological manifestations. The NVP015/NV354 project is based on a NeuroVive innovation in which the body's own energy substrate, succinate, is made available in the cell via a prodrug technology. A prodrug is an inactive drug that is activated first when it enters the body by the transformation of its chemical structure.

Project status: pre-clinical development

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

Objectives for 2018

- Final results from the collaborative project with Dr. Marni Falk at CHOP for studies of NVP015 compounds in experimental disease models. ✓
- Initial results from CHOP studies of NeuroVive's NVP015 compounds as a therapeutic option for chemical threats. ✓
- Continued experimental in vivo efficacy studies of the selected NVP015 compound, NV354. ✓

Fourth quarter news

- NeuroVive presents first preclinical NV354 efficacy results in a model for mitochondrial disease.
- NeuroVive has been awarded SEK 1.5 million as a first tranche of total SEK 5 million in funding from Vinova, Sweden's innovation agency, and the Swelife call, for intensified development in the NVP015 project, the goal of which is to advance the candidate compound NV354 to clinical studies.


Objectives for 2019

- Present further results from preclinical in vivo dose-response studies.
- Scale up compound production.
- Initiate toxicology studies.
- Run experimental studies in cooperation with CHOP, financed by Department of Defense grants.

Out-licensing of project for local treatment of LHON

On June 18, 2018, NeuroVive out-licensed molecules from NVP015 for a targeted treatment of Leber's Hereditary Optic Neuropathy (LHON) to BridgeBio Pharma's new subsidiary Fortify Therapeutics. Fortify's ambition is to further develop the in-licensed NVP015 chemistry in order to establish a local therapy for LHON.

LHON is caused by mitochondrial DNA mutations in subunits of complex I, and affects primarily retinal cells and visual nerve, and results in severe vision loss. The disease predominantly affects young adult men between 20 to 40 years of age. The prevalence of LHON in Europe is between 1:30 000–1:50 000.



The fatty liver disease NASH has a strong link to diabetes and obesity.

The global NASH market is expected to exceed 25 billion dollars 2026.

Non-alcoholic steatohepatitis

Non-alcoholic fatty liver disease (NAFLD) affects 20-25 percent of the global population. When fat deposits in the liver are combined with inflammation and scar tissue (fibrosis), the disease has progressed to non-alcoholic steatohepatitis (NASH) – a condition that may lead to liver cirrhosis or hepatocellular carcinoma (liver cancer). An estimated 20 percent of people with NAFLD have NASH and there is a strong link between NASH and other metabolic syndromes such as diabetes and obesity. There are no approved drugs for treating NASH at the present time but, by forthcoming treatments, the NASH market is expected to exceed USD 25 billion, globally, by 2026.¹⁾

NV556 – candidate drug in pre-clinical development

Treatment objective

NV556 is a candidate drug with a directly acting anti-fibrotic mechanism of action targeting NASH patients who have progressed from the initial metabolic stage characterized by fat storage and inflammation. NV556 is a potent cyclophilin inhibitor derived from NeuroVive's Sangamide class of compounds.

suited as a complement to NASH therapy focused on the early metabolic stage of the disease. Furthermore, it provides an opportunity to develop projects targeting other types of fibrotic disease. The goal is to reach an agreement with a suitable partner for this niched NASH product.

Project status: pre-clinical development

Preclinical results have shown that the greatest potential for the project is within the subgroup of NASH patients with liver fibrosis, meaning at a later stage of disease progression. This makes NV556 best

Objectives for 2019

- Out-licensing and/or partnership within liver fibrosis and NASH with an opportunity to expand treatment options to other types of fibrotic disease during the first six months of 2019.

1) Global Data, OpportunityAnalyzer: NASH – Opportunity Analysis and Forecasts to 2026

Other projects

NVP025 – selection of lead candidate

Treatment objective

NVP025 is focused on chronic treatment of mitochondrial myopathies by utilizing a potent cyclophilin inhibitor from NeuroVive's Sangamide class of compounds. Mitochondrial myopathies manifest in the MELAS, PEO, KSS, and MERRF syndromes.

The goal is to develop a treatment that protects the mitochondria in the muscles from disturbed calcium handling and subsequent muscular dystrophy, thus preventing the muscle weakness associated with these diseases. In collaboration with the Karolinska Institute in Stockholm, NeuroVive has demonstrated that cyclophilin inhibitors can slow the disease progression and increase survival rates in an experimental mitochondrial myopathy model.

Project status: selection of lead candidate

The company will conduct follow-up dose-response studies in 2018 to be able to choose the optimized drug candidate and route of administration.

Objectives for 2018

- Results from experimental studies of mitochondrial myopathies, carried out at the Karolinska Institute. ✓

Objectives for 2019

- Perform dose-response studies for selection of candidate substance and route of administration during 2019.

NV422 – evaluation of candidate compound

Treatment objective

NV422 targets the metabolic components of NASH by using mild, liver-targeted protonophores to uncouple energy-linked functions and increase energy expenditure in the liver. This removes excess fat storage and thereby counteracts the pathophysiological processes in NASH.

Project status: evaluation of candidate compound

NeuroVive has evaluated various substances within the project in 2018 and has selected a candidate substance, NV422, based on favorable pharmacokinetic profile and good tolerability.

stance, NV422, based on favorable pharmacokinetic profile and good tolerability.

Objectives for 2018

- Proven effect of a model compound in a preclinical NASH model
- Selection of candidate compound ✓
- Initiation of out-licensing activities

Objectives for 2019

- Carry out dose-response studies of NV422 in a pre-clinical NASH model.

NVP024 – evaluation of model compounds

Treatment objective

NVP024 is focused on the anticancer properties of a sub-set of the company's sangamide compounds. Together with international partners, NeuroVive's research team has demonstrated that these compounds show powerful anticancer effects in preclinical models of HCC.

Project status: evaluation of model compounds

Additional confirmatory tests are ongoing, for instance within the framework of a PhD project at Lund University, funded by the Foundation for Strategic Research.

Objectives for 2018

- Confirmatory tests in complementary preclinical experimental models.
- Initial results from the industrial PhD student collaboration with Lund University. ✓

Objectives for 2019

- Perform confirmatory tests in complementary pre-clinical experimental models.
- Select candidate compound.

Financial information

Revenues

The consolidated turnover during the fourth quarter of 2018 was SEK 5,000 (0). Other operating revenues for the fourth quarter of 2018 were SEK 1,009,000 (9,000). The consolidated turnover for the year was SEK 5,000 (27,000) and the operating revenues amounted

SEK 2,461,000 (248,000). Other operating income includes research contributions from BridgeBio of SEK 1,885,000 and research contribution from Vinnova of 576,000 SEK.

Results of operations

The operating loss for the fourth quarter was SEK 20,130,000 (14,920,000). The operating loss for the year was SEK 73,360,000 (71,088,000). The net loss before tax for the fourth quarter amounted to SEK 19,978,000 (14,779,000). The net loss before tax for the year was SEK 73,494,000 (71,603,000).

The operating loss was affected by other external expenses, which for the full were SEK 55,812,000 (46,415,000). During the year, expenses related to development projects, as a part of external expenses, have affected the result with SEK 37,922,000 (27,926,000) whereof SEK 22,691,000 (11,779,000)

relates to project in clinical phase. Personnel expenses during the year amount to SEK 14,454,000 (12,417,000). Depreciation and write-down of tangible and intangible assets during the year, amounts to SEK -4,771,000 KSEK (1,595,000) whereof, SEK -3,791,000 relates to write-down of balanced patents costs for the discontinued project Toxphos. Other operating expenses amount to, SEK 789,000 (10,936,000) and pertains to exchange-rate losses. Previous year SEK 10,936,000 related to disposal of subsidiary. Operating costs for the full year amounts to in total SEK 75,826,000 (71,363,000).

Financial position

The equity/assets ratio was 84 (88) percent as of 31 December 2018, and equity was SEK 97,012,000 (105,846,000) compared to beginning of the year. The equity includes funds from the in April completed rights issue, which provided the company with SEK 64,176,000 after deduction of issue costs and compensation for guarantee commitments of SEK 14,324,000 and funds from the warrants program with redemption period in November of total SEK 480,000. Cash and cash equivalents amounted to SEK 25,951,000 (28,992,000) as of 31 December 2018, an decrease of SEK 3,041,000 from the beginning of the year. Total assets as of 31 December 2018 were SEK 115,308,000

(120,106,000). On December 10, 2018, the Board of Directors announced a preferential rights issue of approximately SEK 123,800,000 before transactions costs, which was approved by the Extraordinary General Meeting on January 17, 2019. The Rights Issue has been subscribed to approximately 60.2 percent, which means that approximately 19.8 percent was allocated to guarantors. Through the Rights Issue, NeuroVive will thus raise approximately MSEK 81.3 after issue expenses estimated to approximately MSEK 17.7 (including compensation for the guarantee commitment of approximately MSEK 9.1).

Cash flow and investments

Operating cash flow for the fourth quarter was SEK -11,821,000 (-9,987,000). Operating cash flow from the year was SEK -63,829,000 (-58,124,000). The cash flow effect related to investments in intangibles equals SEK

-3,791,000 (-4,204,000) for the year. Cash flow for the fourth quarter equals SEK -12,421,000 (-6,178,000). Cash flow for the years equals SEK -3,046,000 (-64,258,000).

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. Apart from remuneration to senior managers including remuneration for consulting services related to last year, no purchases or sales between the group and related parties occurred. During the period, no compensation has been paid under the agreement, in relation to mitochondrial energy regulation projects, with the Research Group at Lund University, which includes CSO Eskil Elmér and CMO Magnus Hansson.

Disclosures regarding transactions between the group and other related parties are stated below.

	1 Jan. 2018	1 Jan. 2017
(SEK 000)	31 Dec. 2018	31 Dec. 2017
Stanbridge bvba (owned by Gregory Batcheller, until Nov 6, 2017, Executive Chairman)	-	560
Total transactions with related parties	-	560

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 holds unlisted securities. These assets should be measured at fair value and are classified as "financial assets measured at fair value through other comprehensive income."

The holding corresponds to 10% in one of NeuroVive's R&D partner companies. No information is available for measuring the holding at present value, and NeuroVive makes the assessment that there are no circumstances

to indicate that fair value should deviate materially from cost. For this reason, the holding continues to be recognized at cost.

Other financial assets belong to the category "loan receivables and accounts receivable" which are valued at accrued acquisition value. The carrying amount of this category is estimated to correspond to fair value.

Human resources

The average number of employees of the group for the period January to December 2018 was 9 (10), of which 4 (5) are women.

Parental company

Company earnings after tax for the year amounts to SEK -73,226,000 (-52,109,000). 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. During the current period, the Board has announced a Preferential Rights Issue. The result from the rights issue was announced on 11 February 2019 and brings the company 99 MSEK before transaction costs, which is expected to finance the company's activities in the coming year. No other significant changes in relation to risk or uncertainties occurred during the current period.

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

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

made other claims in relation to NeuroVive's obligations under the License Agreement.

A partial award issued in 2016 was set aside by the Court of Appeal for Skåne and Blekinge with the exception of the question for which the Tribunal had reserved its decision. NeuroVive has appealed parts of the ruling to the Supreme Court. This proceeding is pending. Decision by the Supreme Court is expected in the first quarter of 2019.

The former tribunal was replaced by a new tribunal following a request for the release of the arbitrators filed by CicloMulsion and the constitution of a new Arbitral Tribunal has been finalized, but they await the decision of the Supreme Court before resuming the arbitration proceedings with the aim of announcing a verdict in 2020.

The scope and the timeline of the further proceeding is currently under discussion. The ongoing dispute with CicloMulsion AG may result in future payment obligations, which could have a negative impact on the company's earnings and financial position. The Company has not reserved for any future payment obligations as the amount at this time cannot be calculated.

NeuroVive is not involved in any other disputes.

For more detail of risks and uncertainty factors, refer to the Statutory Administration Report in the Annual Report 2017 and the prospectus published 22 January 2019 for the preferential rights issue carried out 23 January – 6 February 2019.

Incentive programs/share warrants

Currently there is no incentive program.

Audit review

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

Upcoming financial statements

Interim Report January-March 2019	21 May 2019
Interim Report January-June 2019	21 August 2019
Interim Report January-September 2019	20 November 2019
Year-End Report 2019	19 February 2020

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

Annual General Meeting 2019

NeuroVives Annual General Meeting will be held at Medicon Village, Scheelevägen 2, in Lund on 25 April 2019 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 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 2017 on pages 54-67.

IFRS 9 Financial instruments specifies how an entity should classify, measure and recognize financial assets and financial liabilities. IFRS 9 introduces a new approach for recognizing credit losses based on expected credit losses, which may entail earlier recognition of credit losses. Considering that NeuroVive's revenue generation has been limited to date, the need for impairment is also limited and no quantitative impact has thus arisen. IFRS 9 also introduces new rules for hedge accounting. Since NeuroVive does not apply hedge accounting, the company is not affected by these changes.

Financial instruments are classified in accordance with IFRS 9, based on the company's business model. NeuroVive classifies and measures its financial instruments based on the business model for managing the asset

and the asset's contractual cash flow characteristics. On this basis, NeuroVive will continue to apply the previous method of classification, whereby all financial assets, with the exception of holdings in unlisted securities, are measured at amortized cost, in the category now known as "Financial assets measured at amortized cost." As in preceding years, the unlisted securities will be measured at fair value through other comprehensive income, and the new name of the category will be "Financial assets measured at fair value through other comprehensive income." As in preceding periods, all financial liabilities will be measured at amortized cost. IFRS 9 came into effect on January 1, 2018 and has not therefore had any quantitative impact on NeuroVive.

IFRS 15 "Revenue from contracts with customers". IFRS 15 treats how the accounting of revenues shall be made. Revenue shall according to IFRS 15 be accounted when the customer receives the control over the sold goods or service and the customer has opportunity to use the goods or services. The Group estimate that the new standard has no major impact on the financial statements, but will lead to increased disclosure requirements. IFRS 15 came into effect on January 1, 2018. Since the Group's inflows are still limited, the introduction has not resulted in any quantitative impact or need for additional disclosures on historical inflows.

IFRS 16, Lease Agreement, replaces IAS 17 and will apply as of January 1, 2019. The standard requires that assets and liabilities attributable to all leases, with some exceptions, are reported in the balance sheet. NeuroVive has lease contracts for office premises that will be reported in the balance sheet as of January 1, 2019. Estimated effect at five percent interest is approximately one million kronor. IFRS 16 will be applied retroactively without recalculation of comparative figures, a so-called simplified transition method.

Consolidated Statement of Comprehensive Income

(SEK 000)	Note	1 Oct, 2018 31 Dec, 2018	1 Oct, 2017 31 Dec, 2017	1 Jan, 2018 31 Dec, 2018	1 Jan, 2017 31 Dec, 2017
Net sales		5	-	5	27
Other operating income		1,009	9	2,461	248
		1,014	9	2,466	275
<i>Operating expenses</i>					
Other external expenses		-14,375	-11,910	-55,812	-46,415
Personnel cost		-3,414	-2,449	-14,454	-12,417
Depreciation and write-down of tangible and intangible assets		-3,330	-440	-4,771	-1,595
Other operating expenses		-25	-129	-789	-10,936
		-21,144	-14,929	-75,826	-71,363
Operating income		-20,130	-14,920	-73,360	-71,088
<i>Profit/loss from financial items</i>					
Profit from other securities and receivables that are fixed assets		66	56	66	56
Financial income		86	-56	407	65
Financial costs		-	141	-607	-636
		152	141	-134	-515
Profit/loss before tax		-19,978	-14,779	-73,494	-71,603
Income tax	2	-	-	-	-
Profit/loss for the period		-19,978	-14,779	-73,494	-71,603
<i>Other comprehensive income</i>					
Items that may be reclassified to profit or loss					
Translation differences on foreign subsidiaries		4	-18	4	1
Total comprehensive income for the period		-19,974	-14,797	-73,490	-71,602
<i>Loss for the period attributable to:</i>					
Parent company shareholders		-14,858	-14,778	-68,373	-66,728
Non-controlling interests		-5,120	-1	-5,121	-4,875
		-19,978	-14,779	-73,494	-71,603
<i>Total comprehensive income for the period</i>					
Parent company shareholders		-14,854	-14,940	-68,370	-66,895
Non-controlling interests		-5,120	143	-5,120	-4,707
		-19,974	-14,797	-73,490	-71,602
Earnings per share before and after dilution(SEK) based on average number of shares					
		-0.25	-0.29	-0.94	-1.33

Consolidated Statement of Financial Position

(SEK 000)	Note	31 Dec, 2018	31 Dec, 2017
ASSETS			
Non-current assets			
<i>Intangible assets</i>	1		
Development costs		51,706	51,941
Patents		20,121	20,627
Other Intangible assets		1,613	1,747
		73,440	74,315
<i>Tangible assets</i>			
Equipment		140	162
		140	162
<i>Financial assets</i>			
Other long-term securities		13,101	13,102
		13,101	13,102
Total non-current assets		86,681	87,579
<i>Current assets</i>			
Other receivables		1,432	1,568
Prepaid expenses and accrued income		1,244	1,967
Cash and cash equivalents		25,951	28,992
		28,627	32,527
TOTAL ASSETS		115,308	120,106
EQUITY AND LIABILITIES			
<i>Equity attributable to the shareholders of the parent company</i>			
Share capital		4,585	2,616
Additional paid in capital		489,913	427,226
Translation reserve		616	613
Retained earnings		-398,113	-329,740
Total equity attributable to the shareholders of the parent		97,001	100,716
Non-controlling interests		11	5,131
Total equity		97,012	105,846
<i>Short-term liabilities</i>			
Accounts payable		10,162	7,525
Other liabilities		808	863
Accrued expenses and deferred income		7,326	5,871
		18,296	14,260
Total liabilities		18,296	14,260
TOTAL EQUITY AND LIABILITIES		115,308	120,106

Consolidated Statement of Changes in Equity

(SEK 000)	Equity attributable to the shareholders of the parent company					Non-controlling interests	Total equity
	Share-capital	Additional paid in capital	Translation reserve	Retained earnings	Total		
Opening balance, 1 January 2018	2,616	427,226	613	-329,740	100,716	5,131	105,846
Comprehensive profit/loss for the period							
Profit/loss for the period	-	-		-68,373	-68,373	-5,121	-73,494
Other comprehensive income							
Translation differences	-	-	3	-	3	1	4
Other comprehensive profit/loss for the period, net after tax	-	-	3	-	3	1	4
Total comprehensive profit/loss	-	-	3	-68,373	-68,370	-5,120	-73,490
Transactions with shareholders							
Rights Issue*	1,969	62,687	-	-	64,656	-	64,656
Total transactions with shareholders	1,969	62,687	-	-	64,656	-	64,656
Closing balance, 31 December 2018	4,585	489,913	616	-398,113	97,001	11	97,012
Opening balance, 1 January 2017	2,473	418,339	780	-266,146	155,446	12,858	168,304
Comprehensive profit/loss for the period							
Profit/loss for the period	-	-		-66,728	-66,728	-4,875	-71,603
Other comprehensive income							
Translation differences	-	-	-167	-	-167	168	1
Other comprehensive profit/loss for the period, net after tax	-	-	-167	-	-167	168	1
Total comprehensive profit/loss	-	-	-167	-66,728	-66,895	-4,707	-71,602
Transactions with shareholders							
Share issue	143	8,887	-	-	9,030	-	9,030
Shareholder contribution	-	-	-	-	-	114	114
Change of ownership in share issue	-	-	-	3,134	3,134	-3,134	-
Total transactions with shareholders	143	8,887	-	3,134	12,164	-3,020	9,144
Closing balance, 31 December 2017	2,616	427,226	613	-329,740	100,716	5,131	105,846

*Total equity includes funds from the in April completed rights issue with SEK 78,000,000 less expenses and guranties 14,324,000 SEK and the warrants program TO5 from November with SEK 480,000.

Consolidated Statement of Cash Flows

(SEK 000)	1 Oct, 2018 31 Dec, 2018	1 Oct, 2017 31 Dec, 2017	1 Jan, 2018 31 Dec, 2018	1 Jan, 2017 31 Dec, 2017
<i>Cash flow from operating activities</i>				
Operating income	-20,130	-14,919	-73,360	-71,088
<i>Adjustments for non-cash items:</i>				
Depreciation	473	440	1,914	1,595
Currency differences on intercompany items	-	245	-	-35
Disposal of Business	-	-45	-	10,936
Impairment	3,324	-	3,324	-
Result from shares in associated company	-	-	66	56
Interest received	86	-56	407	65
Interest paid	-	628	-606	-149
Net cash from operating activities before changes in working capital	-16,246	-13,708	-68,255	-58,620
<i>Changes in working capital</i>				
Increase/decrease of other current assets	-810	-2,058	859	-1,273
Increase/decrease of other short-term liabilities	5,236	5,779	3,567	1,769
Changes in working capital	4,425	3,720	4,426	496
Cash flow from operating activities	-11,821	-9,987	-63,829	-58,124
<i>Investing activities</i>				
Acquisition of intangible assets	-1,146	-954	-3,791	-4,204
Acquisition of tangible assets	-	-	-82	-40
Disposal business	-	-	-	-11,035
Increase in other financial assets	1	-	1	-
Cash flow from investing activities	-1,145	-954	-3,872	-15,279
<i>Financing activities</i>				
New share issue	480	4,171	64,656	9,031
Shareholder contribution subsidiary	-	114	-	114
Cash flow from financing activities	480	4,285	64,656	9,145
Cash flow for the period	-12,421	-6,178	-3,046	-64,258
Cash and cash equivalents at the beginning of the period	38,371	35,436	28,992	93,251
Effect of exchange rate changes on cash	-	-266	5	-
Cash and cash equivalents at end of period	25,951	28,992	25,951	28,992

Parent Company Income Statement

(SEK 000)		1 Oct, 2018	1 Oct, 2017	1 Jan, 2018	1 Jan, 2017
	Note	31 Dec, 2018	31 Dec, 2017	31 Dec, 2018	31 Dec, 2017
Net sales		5	-	5	27
Other operating income		1,009	-302	2,461	248
		1,014	-302	2,466	275
<i>Operating expenses</i>					
Other external expenses		-14,345	-11,864	-55,777	-45,857
Personnel cost		-3,414	-2,448	-14,454	-12,190
Depreciation and write-down of tangible and intangible assets		-3,095	-440	-4,536	-1,584
Other operating expenses		-26	141	-789	-
		-20,881	-14,611	-75,556	-59,631
Operating income		-19,867	-14,913	-73,090	-59,357
<i>Profit/loss from financial items</i>					
Result from shares in group company		-	-	-	7,652
Profit from other securities and receivables that are fixed assets		66	-	66	56
Interest income and other similar profit items		86	-56	400	29
Interest expenses and other similar loss items		1	141	-602	-490
		152	141	-136	7,247
Profit/loss before tax		-19,714	-14,772	-73,226	-52,109
Income tax	2	-	-	-	-
Profit/loss for the period		-19,714	-14,772	-73,226	-52,109

Statement of Comprehensive Income, Parent Company

(SEK 000)		1 Oct, 2018	1 Oct, 2017	1 Jan, 2018	1 Jan, 2017
	Note	31 Dec, 2018	31 Dec, 2017	31 Dec, 2018	31 Dec, 2017
Profit/loss for the period		-19,714	-14,772	-73,226	-52,109
Other comprehensive income		-	-	-	-
Total comprehensive profit/loss for the period		-19,714	-14,772	-73,226	-52,109

Parent Company Balance Sheet

(SEK 000)	Note	31 Dec, 2018	31 Dec, 2017
ASSETS			
Non-current assets			
<i>Intangible assets</i>	1		
Development costs		51,706	51,706
Patents		20,121	20,627
Other intangible assets		1,613	1,747
		73,440	74,080
<i>Tangible assets</i>			
Equipment		140	162
		140	162
<i>Financial assets</i>			
Other long-term placement		23,625	23,625
Shares in subsidiaries	3	13,101	13,102
		36,726	36,727
Total non-current assets		110,305	110,969
<i>Current assets</i>			
Other receivables		1,430	1,566
Prepaid expenses and accrued income		1,244	1,967
		2,674	3,533
Cash and bank balances		25,871	28,883
Total current assets		28,545	32,416
TOTAL ASSETS		138,850	143,385
EQUITY AND LIABILITIES			
Equity			
<i>Restricted equity</i>			
Share capital		4,585	2,616
Statutory reserve		1,856	1,856
Development expenditure reserve		10,610	10,610
		17,051	15,082
<i>Unrestricted equity</i>			
Share premium reserve		62,687	8,887
Retained earnings		114,061	157,283
Profit/loss for the period		-73,226	-52,109
		103,521	114,061
Total equity		120,572	129,143
Short-term liabilities			
Accounts payable		10,162	7,525
Other liabilities		808	863
Accrued expenses and deferred income		7,308	5,854
		18,278	14,242
TOTAL EQUITY AND LIABILITIES		138,850	143,386

Notes

Note 1 – Intangible assets

(SEK 000)	Development costs	Patents	Other	Total
ACCUMULATED COST				
Opening balance 1 Jan. 2018	51,941	28,405	2,864	83,210
Additions	-	3,791	-	3,791
Impaired value	-235	-3,089	-	-3,324
Closing balance 31 Dec. 2018	51,706	29,107	2,864	83,677
ACCUMULATED DEPRECIATION				
Opening balance 1 Jan. 2018	-	-7,778	-1,117	-8,895
Depreciation for the period	-	-1,675	-134	-1,809
Impaired value	-	467	-	467
Closing balance 31 Dec 2018	-	-8,986	-1,251	-10,704
Residual value 31 Dec. 2018	51,706	20,121	1,613	73,440

(SEK 000)	Development costs	Patents	Other	Total
ACCUMULATED COST				
Opening balance 1 Jan. 2017	51,255	24,349	2,899	78,503
Additions	686	4,056	-	4,742
Impaired value	-	-	-35	-35
Closing balance 31 Dec. 2017	51,941	28,405	2,864	83,210
ACCUMULATED DEPRECIATION				
Opening balance 1 Jan. 2017	-	-6,370	-982	-7,352
Depreciation for the period	-	-1,408	-135	-1,543
Closing balance 31 Dec. 2017	-	-7,778	-1,117	-8,895
Residual value 31 Dec. 2017	51,941	20,627	1,747	74,315

Note 2 – Tax

The group's total loss carry-forwards amount to SEK 448,548,000 as of 31 December 2018 (361,243,000). The parent company's total loss carry-forwards amounts to SEK 422,775,000 as of 31 December 2018 (335,064,000). 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 82.47% in the subsidiary NeuroVive Pharmaceutical Asia Ltd., domiciled in Hong Kong.



David Laskow-Pooley



David Beijker



Denise Goode

Board of Directors and CEO



Jan Törnell



Erik Kinnman

Board of Directors' declaration

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, 28 February 2019

David Laskow-Pooley
Chairman of the Board

David Beijker
Board member

Denise Goode
Board member


Jan Törnell
Board member

Erik Kinnman
Chief Executive Officer

This Interim Report is published in Swedish and English. In the event of any difference between the English version and the Swedish original, the Swedish version shall prevail.

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

This information is information that NeuroVive 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 28 February 2019.



NeuroVive is a leading company in mitochondrial medicine focusing on indications with great medical needs.

About NeuroVive

NeuroVive Pharmaceutical AB is a leader in mitochondrial medicine, with one project in clinical phase II development for the prevention of moderate to severe traumatic brain injury (NeuroSTAT®) and one project in clinical phase I (KL1333) for genetic mitochondrial diseases. The R&D portfolio also consists of projects for genetic mitochondrial disorders, cancer and NASH. The company advances drugs for rare diseases through clinical development into the market. For projects for common indications the goal is out-licensing in the preclinical phase. A subset of compounds under NeuroVive's NVP015 program has been licenced to Fortify Therapeutics, a BridgeBio company, for local treatment development of Leber's Hereditary Optic Neuropathy (LHON).

What is mitochondrial medicine?

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

NeuroVive's project portfolio includes a large number of cyclophilin inhibitors that serve as organ protection by increasing the mitochondrial resistance to various types of stress and by reducing the development of fibrosis. NeuroVive is also working with several molecules in the project portfolio, focused on the regulation of mitochondrial energy production, in both genetic mitochondrial disorders and prevalent metabolic diseases such as NASH. NeuroVive also has a liver cancer project in which the company is working with a completely new treatment strategy for these types of diseases.

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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Glossary

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

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

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

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

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

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

CHOP. The Children's Hospital of Philadelphia.

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

Clinical study. The examination of healthy or unhealthy humans to study the safety and efficacy of a pharmaceutical or treatment method. Clinical trials are divided into different phases, termed phase I, phase II, phase III. Phase II is usually divided into an early phase (phase IIa) and a later phase (phase IIb). See also "phase (I, II and III)".

COMP. EMA's Committee for Orphan Medicinal Products.

CRO. Contract research organization.

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

EMA. The European Medicines Agency.

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

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

FDA. The United States Federal Food and Drug Administration.

HCC. Hepatocellular carcinoma, liver cancer.

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

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

KSS. Mitochondrial disease, Kearns-Sayre's syndrome. The disease debuts before the age of 20 and is characterized by eye related symptoms with pigment retention in the retina and paralysis of the outer eye muscles, as well as the effects on the cardiac retinal system and the cerebellum with disorders in the coordination of muscle movements (ataxia).

Leigh syndrome.

Leigh syndrome is a serious condition with characteristic changes to the brain that usually affects small children. This disease is caused by faults in energy-producing mitochondria and is also known as subacute (fast onset) necrotizing (tissue destroying) encephalomyopathy (a disease of the brain and muscles).

LHON. Mitochondrial disease, Leber Hereditary Optic Neuropathy. Affects the retina and the optic nerve, but in rare cases symptoms can be found in other parts of the central nervous system. There is no cure, but treatments are focused primarily on compensating for the visual impairment.

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

MELAS. MELAS is an acronym of mitochondrial encephalomyopathy (brain and muscle disease) with lactic acidosis (increased lactic acid levels in the blood) and stroke-like episodes.

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

Mitochondria. That part of each cell that provides effective energy production in the form of conversion of oxygen and nutrients in the body into chemical energy.

Mitochondrial medicine. Field of research and development of pharmaceuticals that protect the mitochondria.

Mitochondrial myopathy. Genetic mitochondrial disease which affects the muscles.

NAFLD. Non-Alcoholic Fatty Liver Disease.

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

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

ODD. Orphan Drug Designation. Facilitates development and commercialization, and may, upon receiving marketing authorization, provide orphan drug status with seven or ten years of market exclusivity (in the US and Europe, respectively).

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

Penn. University of Pennsylvania.

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

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

Phase (I, II and III). The various stages of trials on the efficacy of a pharmaceutical in humans. See also "clinical trial." Phase I examines the safety on healthy human subjects, phase II examines efficacy in patients with the relevant disease and phase III is a large-scale trial that verifies previously achieved results. In the development of new pharmaceuticals, different doses are trialed and safety is evaluated in patients with relevant disease, phase II is often divided between phase IIa and phase IIb.

Preclinical. That stage of drug development that occurs before a candidate drug is trialed on humans.

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

Sangamides. Compound class of cyclophilin-D inhibitors.

TBI. Traumatic Brain Injury. An injury to the brain where some nerve cells are subjected to immediate damage. The injury then continues to exacerbate several days after the incident, which significantly impacts the final extent of damage.