



*Rights issue 2014*

## INVITATION TO SUBSCRIBE FOR SHARES



NEUROVIVE PHARMACEUTICAL AB (PUBL)

# Definitions

The following definitions apply in this prospectus unless otherwise stated:

***"NeuroVive" or the "Company"***

NeuroVive Pharmaceutical AB (publ), corp. ID no. 556595-6538.

***The "Group"***

NeuroVive Pharmaceutical AB (publ), corp. ID no. 556595-6538, and subsidiaries.

***The "NeuroVive Share" or the "Share"***

The NeuroVive Share, which trades on NASDAQ OMX Stockholm, Small Cap.

***"Sihuan"***

Sihuan Pharmaceutical Holdings Group Limited and subsidiary Sun Moral Limited.

***"Fresenius Kabi"***

Fresenius Kabi AG, with which NeuroVive has signed an agreement relating to production of CicloMulsion®/NeuroSTAT®.

***The "Research Team"***

The Research Team at the Mitochondrial Pathophysiology Unit, Faculty of Medicine, Lund University that NeuroVive collaborates with. The Team is led by Associate Professor Eskil Elmér, also NeuroVive's CSO.

***"AktieTorget"***

AktieTorget AB, corp. ID no. 556533-0395.

***"NASDAQ OMX Stockholm"***

NASDAQ OMX Stockholm Aktiebolag, corp. ID no. 556383-9058.

***"Euroclear"***

Euroclear Sweden AB, corp. ID no. 556112-8074.

***"Erik Penser Bankaktiebolag"***

Erik Penser Bankaktiebolag, corp. ID no. 556031-2570.

## PREPARATION AND REGISTRATION OF THE PROSPECTUS

This prospectus has been prepared by NeuroVive's Board of Directors for the forthcoming offering to the Company's shareholders to subscribe for new shares on the basis of preferential rights. The prospectus has been prepared in accordance with the Swedish Financial Instruments Trading Act (1991:980), Commission Regulation (EC) no. 809/2004 dated 29 April 2004 relating to the implementation of the directive of the European Parliament and Council no. 2003/71/EC, as well as the Commission's Delegated Regulation (EU) no. 486/2012 dated 30 March 2012 relating to revisions to regulation (EC) no. 809/2004.

The prospectus has been approved and registered by the Swedish Financial Supervisory Authority in accordance with the provisions in Chapter 2, §§ 25–26 of the Swedish Financial Instruments Trading Act (1991:980).

Approval and registration do not imply that the Swedish Financial Supervisory Authority guarantees the accuracy or completeness of the factual information contained in this prospectus.

With the exception of historical financial data referred to below, the contents of this prospectus have not been subject to any review or audit by the Company's Auditors.

Erik Penser Bankaktiebolag is acting as financial advisor to the Company for the forthcoming new issue and has assisted the Company in preparing this prospectus.

As all the information contained in this prospectus originates from the Company, Erik Penser Bankaktiebolag disclaims all liability towards the Company's shareholders and other direct or indirect consequences resulting from an investment decision or other decisions wholly or partly based on the information contained in this prospectus.

Disputes arising as a result of the contents of this prospectus and associated legal proceedings shall be settled in a Swedish court of law exclusively. Swedish substantive law shall be exclusively applicable to this prospectus, including associated documentation.

## INFORMATION TO INVESTORS

The offer to acquire shares in the Company under the terms of this prospectus is not aimed at shareholders or other investors domiciled in the USA, Canada, Australia, New Zealand, Hong Kong, Japan or South Africa, or any other country where participation in the issue requires additional prospectuses, registration or measures other than those required under Swedish law or contravenes the regulations of such country.

No subscription rights, fully paid-up shares (BTAs), shares or other securities issued by NeuroVive have been registered or will be registered in accordance with the

United States Securities Act 1933, or in accordance with securities legislation in any US state or province of Canada.

Accordingly, no subscription rights, BTAs, shares or other securities issued by NeuroVive can be transferred or offered for sale in the USA or Canada other than in exceptional cases where registration is not required. Any application to acquire shares in contravention of the above may be deemed invalid and may be disregarded.

## MARKET INFORMATION AND FORWARD-LOOKING INFORMATION

This prospectus contains specific historical market data. In cases where information has been obtained from third parties, the Company is responsible for ensuring that such information is accurately reproduced.

To the Company's knowledge, no information has been omitted in a manner so as to render the information inaccurate or misleading in relation to its original sources.

However, the Company has not obtained independent verification of information provided by third parties, implying that no guarantee can be made regarding the accuracy or completeness of the information presented in this prospectus. To the Company's knowledge, no third party as indicated above has a significant interest in the Company.

The information contained in this prospectus relating to future conditions such as statements and assumptions regarding the Company's future performance and market conditions is based on current conditions at the time of publication of the prospectus. Forward-looking information is always associated with uncertainty as it relates to and is dependent on conditions outside the Company's control. Accordingly, no assurance, express or implicit, can be given that the judgments made in this prospectus relating to future conditions will materialize.

Nor does the Company undertake to publish updates or revisions of statements relating to future conditions as a result of new information or similar data that emerges after the date of publication of this prospectus.

## AVAILABILITY OF THE PROSPECTUS

The present prospectus for NeuroVive and the documents referred to herein will be made available in electronic format on the Company's website, [www.neurovive.se](http://www.neurovive.se) and at Erik Penser Bankaktiebolag's website, [www.penser.se](http://www.penser.se) during the period in which the prospectus is valid.

## AUDIT REVIEW

In addition to the information provided in the Audit Report and reports referred to in this prospectus, no information contained herein has been reviewed or audited by the Company's Auditors.

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While every care has been taken in the translation of this invitation, readers are reminded that the original invitation is in Swedish. In the event of discrepancy, the Swedish original shall take precedence.

## FINANCIAL INFORMATION

Year-end Report 2014

21 February 2014

Interim Report January–March 2014

21 May 2014

## Terms in Summary

Issue Amount	SEK 75,806,654 (approx. SEK 75.8 m)		
Preferential rights to subscription	Four (4) subscription rights held on the record day 8 January 2014 confer entitlement to subscribe for one (1) new share. In addition, shareholders and other investors are invited to notify their interest in subscribing for new shares without preferential rights.		
Subscription price	SEK 14 per share.		
Subscription rights	One (1) subscription right is obtained for each share in NeuroVive held on the record day. Four (4) subscription rights confer entitlement to subscribe for one (1) new share.		
Record day	8 January 2014. Closing day of trading in the Company's shares cum rights is 2 January 2014 and the first day of trading in the Company's share ex rights is 3 January 2014.		
Subscription period	13 January – 27 January 2014.		
Subscription without preferential rights	Notification of interest in subscribing for shares without subscription rights can be submitted in the period 13 January– 27 January 2014. Notification of allotment will be made by dispatch of the settlement note, which should be paid in accordance with the printed instructions. For information regarding the principles for allotting shares purchased without subscription rights, see "Terms and Conditions".		
Trading in subscription rights	Trading in subscription rights will take place on NASDAQ OMX Stockholm in the period 13-22 January 2014. In order to prevent a loss of value of the subscription rights, they must either be exercised to subscribe for shares by no later than 27 January 2014 or be sold by no later than 22 January 2014.		
Trading in fully paid-up shares (BTAs)	Trading in BTAs will take place on NASDAQ OMX Stockholm from 13 January 2014 inclusive until the Swedish Companies Registration Office has registered the new share issue. This registration is scheduled for mid-February 2014.		
ISIN codes	the Share	NVP	SE00 0257 5340
	Subscription right	NVP TR	SE00 0562 0333
	Fully paid-up shares (BTAs)	NVP BTA	SE00 0562 0341
Overallocation option	The Annual General Meeting has resolved to authorize the Board of Directors to decide on a further new issue of a maximum of 714,286 shares in the event that the rights issue is oversubscribed. This could raise an additional maximum of SEK 10 m for the Company.		

# Summary

*This summary is made up of disclosure requirements known as “Elements.” These elements are numbered in Sections A–E (A.1–E.7). This summary contains all the Elements required to be included in a summary for these types of securities and issuer (new issue of shares with preferential rights for existing shareholders, rights issue). Because certain Elements do not need to be addressed, there may be gaps in the numbering sequence of the Elements. Even though an Element may be required to be inserted in the summary because of the type of securities and issuer, it is possible that no relevant information can be provided regarding the Element. In this case, a brief description of the Element is included in the summary denoted as “not applicable.”*

## Section A—Introduction and warnings

A.1	Warning	This summary should be read as an introduction to the prospectus. Any decision to invest in the securities should be based on consideration of the prospectus as a whole by the investor. Where a claim relating to the information contained in the Prospectus is brought before a court of law, the plaintiff investor might, under the national legislation of the Member States, have to bear the costs of translating the Prospectus before the legal proceedings are initiated. Civil liability attaches only to those persons who have tabled the summary including any translation thereof, but only if the summary is misleading, inaccurate or inconsistent when read together with the other parts of the prospectus or it does not provide, when read together with the other parts of the prospectus, key information in order to aid investors when considering whether to invest in such securities.
A.2	Consents	Not applicable. The offer does not include financial intermediaries.

## Section B—Information about the issuer

B.1	Legal and commercial name of the issuer	The company's corporate name is NeuroVive Pharmaceutical AB (publ), corp. ID no. 556595-6538.
B.2	Domicile and legal form of the issuer	NeuroVive's registered office is located in the County of Scania, Municipality of Lund, Sweden. The Company was incorporated in Sweden in accordance with Swedish law and operates under Swedish law. NeuroVive is a public limited company and the legal entity is governed by the Swedish Companies Act (2005:551).
B.3	Operations and markets	NeuroVive conducts research and development into pharmaceuticals that protect the mitochondria. The project portfolio consists of a number of different pharmaceutical projects in various development phases, focusing on the three main segments reperfusion injury in myocardial infarction, traumatic brain injury (TBI) and energy-regulating preparations. NeuroVive has two independent projects in the clinical development phase with the potential to meet acute medical need in myocardial infarction and TBI. NeuroVive's drug candidate CicloMulsion® is used in a largely externally funded phase III study in the EU for reperfusion injury in myocardial infarction treatment. At the same time, phase IIa studies are underway on NeuroSTAT® for limiting injury to the brain in acute TBI. NeuroVive is also working on projects including cell protection in mitochondrial disease and products for treating anti-viral indications such as Hepatitis B/C. NeuroVive's business model includes collaborations with large pharmaceutical companies and/or CRO partners (contract research organization) to limit risk and ensure cost-efficiency in the commercialization of the Company's products. The Company's revenues shall also consist of fixed remuneration on out-licensing plus milestones achieved prior to launch as well as ongoing royalty streams based on sales of out-licensed pharmaceuticals. NeuroVive has conducted research and development work since inception. The Company has not commercialized a pharmaceutical, and accordingly, has not generated any sales to date.
B.4a	Trends	The Company's operations, historically and at present, comprise a high proportion of research and development work, meaning that there are no known tendencies for production, inventories or sales. To the best of the Board of Directors' knowledge, with the exception of previously stated general uncertainty and delays to clinical studies, there are no known trends, uncertainty factors, potential liabilities or other claims, undertakings or events that can be expected to have a significant impact on the Company's prospects.
B.5	Group structure	NeuroVive has a subsidiary based in Hong Kong, NeuroVive Pharmaceutical Asia Limited, corp. ID no. 1688859, of which the Company owns 70%. Foundation Asia Pacific Limited owns the remaining 30 percent of the subsidiary.

B.6 Ownership structure

NeuroVive has approximately 2,800 shareholders. The following table indicates shareholders (according to SiS Ownership Service as of 30 September 2013 and subsequent changes known to the Company) holding more than five (5)% of the share capital or votes in the Company. There is only one share class. Each share confers equal rights to a proportion of the Company's assets and profit/loss and confers the right to one vote at the Annual General Meeting. Each share confers the right to one (1) vote at the AGM. To the best of the Board's knowledge, there are no shareholder agreements or other agreements relating to joint influence over the Company that may lead to changes to control of the Company.

**LARGEST SHAREHOLDERS AS OF SEP 30 2013**

Name	No. of share	Votes and capital
Maas Biolab LLC	4,233,736	22.1
Avanza Pension Försäkring AB	2,818,222	14.7
Private Placement Sprl	1,000,000	5.2
Total, ten largest shareholders	8,051,958	42.0%
Total, other shareholders	11,107,088	58.0%
<b>Total, all shareholders</b>	<b>19,159,046</b>	<b>100.0%</b>

\* In turn, Maas Biolab, LLC is 49.66% owned by Board member Marcus Keep, 16.96% owned by CSO Eskil Elmér and 5.13% owned by Board member Helmuth von Moltke. On the same date, Chairman of the Board Gregory Batcheller owned 1.97% of Maas Biolab, LLC.

B.7 Selected historical financial data

The following table shows summary historical financial data for the Group for the financial years 2010, 2011, 2012, Q3 2012 and Q3 2013. The information for 2010, 2011 and 2012 is from the Company's audited Annual Accounts, which have been prepared in accordance with International Financial Reporting Standards (IFRS), as endorsed by the EU, and the Swedish Annual Accounts Act. Data corresponding to unaudited Consolidated Accounts are derived from the Company's Interim Report for the period 1 January-30 September 2013, prepared for the Group in accordance with IAS 34 Interim Reporting and the Annual Accounts Act.

INCOME STATEMENT	1 Jan 2013 - 30 Sep 2013	1 Jan 2012 - 30 Sep 2012	2012	2011	2010
Net sales	5,335	-	-	-	-
Total revenue	6,921	520	1,328	440	108
Operating expenses	-19,981	-11,666	-17,827	-10,161	-4,280
Operating income (EBIT)	-13,060	-11,146	-16,499	-9,721	-4,172
Net financial income/ expense	103	391	596	441	-451
Profit/loss after financial items	-12,957	-10,755	-15,903	-9,280	-4,623
Current tax	-	-	-	-	-
Profit/loss for the period	-12,957	-10,755	-15,903	-9,280	-4,623
FINANCIAL POSITION	30 Sep 2013	30 Sep 2012	31 Dec 2012	31 Dec 2011	31 Dec 2010
<i>Assets</i>					
Non-current assets	43,133	28,699	33,370	20,946	14,292
Current assets	15,781	44,253	38,136	13,296	28,134
<b>Total assets</b>	<b>58,914</b>	<b>72,952</b>	<b>71,506</b>	<b>34,242</b>	<b>42,426</b>
<i>Equity and liabilities</i>					
Equity	50,090	68,227	63,043	32,585	41,449
Long-term liabilities	-	-	-	-	-
Short-term liabilities	8,824	4,725	8,463	1,657	977
<b>Total equity and liabilities</b>	<b>58,914</b>	<b>72,952</b>	<b>71,506</b>	<b>34,242</b>	<b>42,426</b>
CASH FLOW STATEMENT	1 Jan 2013 - 30 Sep 2013	1 Jan 2012 - 30 Sep 2012	2012	2011	2010
Cash flow from operating activities	-12,698	-10,640	-15,789	-9,207	-4,658
Cash flow from investing activities	-7,770	-7,220	-9,718	-6,757	-5,717
Cash flow from financing activities	-	46,322	46,322	410	35,787
Cash flow for the year	-22,227	30,770	24,382	-14,958	25,037
Cash and cash equivalents at beginning of period	37,177	12,795	12,795	27,753	2,716
Exchange rate difference	45	-	-	-	-
Cash and cash equivalents at end of period	14,995	43,565	37,177	12,795	27,753

B.8	Selected pro forma accounts	Not applicable. The prospectus does not contain pro forma accounts.
B.9	Profit forecast	Not applicable. The prospectus does not contain profit forecasts or calculations of estimated profit/loss.
B.10	Audit report qualifications	Not applicable. There are no qualifications in the audit report relating to the historical financial data referred to in the prospectus.
B.11	Working capital	<p>The existing working capital is insufficient for the relevant needs over the coming twelve-month period. The Board intends to raise the requisite working capital for the Company's operations in the coming twelve months through the forthcoming rights issue, which upon full subscription, will increase liquidity by approximately SEK 75.8 m before estimated issue expenses of SEK 6.6 m. The issue proceeds are expected to become available to the Company at the end of February 2014. Underwriting guarantees for SEK 50.0 m of the SEK 75.8 m, or 66.6%, are in place.</p> <p>The Company's working capital shortfall for the coming twelve-month period is estimated to amount to approximately SEK 44.2 m, based on the capital needs analysis prepared. In the event that the Company fails to raise the required capital through the forthcoming rights issue, a shortfall is expected to arise in June 2014.</p> <p>The capital needs analysis considers the capital needs for a number of projects, including investments, that may be reprioritized as a result of future ongoing reassessment. This means that the Company may decide on a lower capital need than that indicated above, without generating close-down expenses or other costs.</p>

## Section C—Information relating to the securities on offer

C.1	Share class	NeuroVive shares, ISIN code SE0002575340.
C.2	Currency	The Shares are denominated in Swedish kronor (SEK).
C.3	Number of shares and nominal value	The number of shares in NeuroVive is 21,659,046. The quotient value is SEK 0.05. All shares have been issued and are fully paid-up.
C.4	Rights pertaining to the Shares	All NeuroVive's shares confer the right to receive dividends. Dividends are non-cumulative. The right to receive dividends devolves upon investors who, on the record day for receiving dividends, are registered as shareholders of the Company. Any dividends can be expected to be paid via Euroclear Sweden AB. All shares confer equal rights to receive dividends and potential surpluses upon liquidation. At the AGM, each share in NeuroVive entitles the holder to one vote and each qualified voter may vote in accordance with the full number of shares held without restriction. All shares confer shareholders with the same preferential rights for the issue of warrants and convertibles to the number of shares held.
C.5	Transferability of shares	Not applicable. There are no restrictions to the free transfer of shares in the Company.
C.6	Marketplace	NeuroVive's shares are listed on NASDAQ OMX Stockholm.
C.7	Dividend policy	NeuroVive has not paid any dividend to date. NeuroVive is currently in a development phase and potential surpluses are intended to be invested in the Company's development. No guarantee can be made that future cash flows will exceed the Company's capital needs or that the AGM will resolve on making dividend payments in the future.

## Section D—Risks

D.1	Key risks that are specific to the Company and sector	A number of risk factors could have a negative impact on NeuroVive's operations and sector. Consequently, it is of significant importance to consider the relevant risks. The pharmaceutical sector in general and clinical studies in particular are associated with a substantial degree of uncertainty and risks relating to delays and the outcome of studies. A positive outcome in pre-clinical and clinical studies, as well as approval from the relevant regulatory authorities are required before sales of the pharmaceutical can begin. It may prove difficult to evaluate NeuroVive's sales potential and there is a risk that revenue fails to materialize. There is a risk that the existing and/or future patent portfolio and other intellectual property held by the Company will not constitute adequate commercial protection. NeuroVive may need to raise additional capital in future. There is a risk that NeuroVive will not be able to raise further capital, enter into partnerships or secure co-financing. A loss of one or several key individuals, employees and consultants may have negative consequences for the Company's operations and profit or loss. If a competitor successfully develops and launches an effective and safe pharmaceutical for mitochondrial protection, this may generate risks in the form of reduced sales potential. Naturally, it is not possible to list all risk factors, and this risk assessment constitutes an overall evaluation of the other information contained in the prospectus, alongside a general evaluation of external factors.
D.3	Key risks specific to the securities on offer	Potential investors should be aware that an investment in the NeuroVive Share implies considerable risk. In the event that there is no liquidity in the Shares, or if trading fails to endure, this may lead to difficulties in selling their Shares. There can be no guarantee that NeuroVive will generate a profit, or that the Shares will increase in value. Share price fluctuations may arise as a result of significant changes in buying and selling volumes and do not necessarily correlate with NeuroVive's underlying value. The stock market in general, and the Company's share specifically, may be affected by psychological factors. Psychological factors and their effects on the share price are often hard to predict and may have a negative impact on NeuroVive's share price.

## Section E—Information about the offer

E.1	Issue amount and issue expenses	Upon full subscription, the Company will raise approximately SEK 75.8 m before issue expenses, which are estimated to amount to approximately SEK 6.6 m, and of which approximately SEK 4 m comprise remuneration for underwriting guarantees. In connection with the new issue, NeuroVive has obtained underwriting guarantees totaling approximately SEK 50 m, corresponding to approximately 66% of the issue amount.
E.2a	Background and motivation	<p>In December 2013, the Company completed a private placement to reputable institutional investors and to one of the founders of the Company's partner in China, Sihuan Pharmaceutical. The issue raised approximately SEK 35 m for the Company. In addition, the Extraordinary General Meeting on 13 December 2013 resolved to execute a share issue with preferential rights to existing shareholders. The issue will raise approximately SEK 75.8 m upon full subscription and before issue expenses, and is underwritten up to SEK 50 m. The EGM also resolved on an overallocation option of approximately SEK 10 m to be exercised in the event of significant interest, and to the extent that the rights issue is fully subscribed.</p> <p>Given the issue is fully subscribed, the proceeds from the new issues will mainly be used to complete ongoing clinical trials on CicloMulsion® and NeuroSTAT® (approx. SEK 10-12 m) and, given a favorable outcome from phase III studies on CicloMulsion®, activities to prepare the market ahead of product launch (approximately SEK 12-15 m). The remaining proceeds will be allocated to research and development projects in Hepatitis B/C (approximately SEK 10-12 m) as well as new cyclophilin inhibitors for heart cell and neuroprotection, which is the basis of the molecules acquired from Biotica Ltd. in 2013 (approximately SEK 14-16 m).</p> <p>The development projects in Hepatitis B/C and new cyclophilin inhibitors for heart cell and neuroprotection, share the same development route, which will generate synergies, mainly at the production stage as well as in some pre-clinical areas.</p> <p>A proportion of the issue proceeds will also be used to finance the Company's investment in the new production facility for CicloMulsion® and NeuroSTAT® (approximately SEK 13 m).</p>
E.3	Terms and conditions	In accordance with the Board of Directors' proposal, NeuroVive's EGM on 13 December 2013 resolved to conduct a new issue of shares with preferential rights for the Company's shareholders, a rights issue. The new issue will increase the share capital by a maximum of SEK 270,738.05, from SEK 1,082,952.30 to a maximum of SEK 1,353,690.35, through the issue of a maximum of 5,414,761 shares, each with a quotient value of SEK 0.05. A holding of 4 shares on the record day of 8 January 2014 confers entitlement to subscribe for 1 new share in the Company at a subscription price of SEK 14 per share. The subscription period is 13 January-27 January 2014.
E.4	Interests material to the issue/offer and potential conflicts of interest	<p>The members of NeuroVive's Board of Directors and senior executives own shares (directly and indirectly) and share warrants in the Company. NeuroVive and its principal owner Maas Biolab LLC (part-owned by Board members), entered into a Patent and Trademark Transfer Agreement on 29 May 2008. In 2011 and 2012, NeuroVive signed agreements with a research team at the Mitochondrial Pathophysiology Unit, Faculty of Medicine, Lund University (including CSO Eskil Elmér and Chairman Gregory Batcheller). The agreements relate to rights and remuneration in the area of mitochondrial energy regulation and ToxPhos, a medical analysis method for determining mitochondrial function in human blood corpuscles. To ensure that no conflicts of interest arise from these agreements, Board members and senior executives affected by the agreements do not participate in decisions and discussions relating to such decisions.</p> <p>There are no further conflicts of interest in NeuroVive's administrative, executive management or governing bodies or in relation to other individuals in senior positions in NeuroVive, nor are there any other physical or legal persons connected with the issue with financial or other relevant interests in the Company.</p> <p>Erik Penser Bankaktiebolag is serving as the Company's financial advisor and issuing house for the new issue. Law firm Lindahl is serving as the Company's legal advisor for the new issue. Erik Penser Bankaktiebolag and Lindahl will receive pre-arranged remuneration for services rendered in connection with the forthcoming new issue. Apart from the aforementioned remuneration, Erik Penser Bankaktiebolag and Advokatfirman Lindahl have no other financial or other interests relating to the new issue.</p> <p>No conflicts of interest are considered to be present between the parties indicated above with financial or other interests in the new issue.</p>
E.5	Sellers of securities and lock-up agreement	Not applicable. The offer comprises newly issued shares. There are no restrictions to prevent shareholders from selling shares in the Company for a specified period after completion of the new issue.
E.6	Dilution effect	The new issue increases the number of shares by a maximum of 5,414,761 shares to a maximum of 27,073,807 shares, which implies an increase of 25%. The dilution effect for shareholders choosing not to participate in the new issue is a maximum of 20% of the votes and capital.
E.7	Expenses charged to investors	Not applicable. No expenses are charged to investors participating in the new issue. In connection with trading in subscription rights and BTAs, however, normal commission is payable in accordance with the applicable terms governing securities trading.



# Risk factors

*An investment in shares is always associated with risk. A number of factors outside NeuroVive's control, alongside a number of factors the effects of which the Company can influence through its actions, may have a negative impact on the Company's operations, results of operations and financial position, which may imply a reduction in the value of the Company's shares and that shareholders lose all or part of their invested capital. Accordingly, when judging NeuroVive's future progress, apart from considering the possibility of positive progress, it is also important to consider the risks of the Company's operating activities. Naturally, it is not possible to describe all the risk factors in this section, implying that an overall evaluation must also include other information in this prospectus, alongside a general evaluation of external factors. The risks and uncertainty factors considered to be significant to NeuroVive's future performance are outlined below. The risks are not indicated in order of importance and are not intended to be comprehensive. Additional risks and uncertainty factors of which NeuroVive is currently unaware may also develop into significant factors influencing the Company's operations and future performance.*

## OPERATIONAL AND SECTOR-RELATED RISKS

### The absence of historical sales revenue

NeuroVive has not launched a pharmaceutical on the market, either independently or through partners. Accordingly, the Company has not made sales of any pharmaceutical or generated any sales revenue.

NeuroVive's candidate drugs are in the clinical and pre-clinical phases respectively. A positive outcome in pre-clinical and clinical studies as well as approval from regulatory authorities are required before pharmaceutical sales can commence. Accordingly, it may be difficult to evaluate

NeuroVive's sales potential and there is a risk that revenues fail to materialize.

### Clinical studies

Before a pharmaceutical can be launched on the market, its safety and efficacy in humans must be ensured for each individual indication, which is conducted through pre-clinical studies in animals and clinical studies in humans. The pharmaceuticals sector in general, and clinical studies in particular, are associated with significant uncertainty and risks relating to delays and the outcome of studies. The outcome of pre-clinical studies does not always correspond to the results obtained in clinical studies. The outcome of early clinical studies does not always correspond to the results of more extensive studies. There is a risk that NeuroVive's planned clinical studies will not indicate adequate safety and efficacy for the Company to obtain the requisite regulatory approval to enable pharmaceuticals sales. If NeuroVive or its collaboration partners fail to adequately demonstrate the safety and efficacy of a pharmaceutical in clinical studies, the Company may be adversely affected, which may lead to failure to obtain approval from regulatory authorities and failure to ensure commercialization alongside reduced or absent cash flow. There is a risk that the collaboration partners conducting the clinical studies are

unable to maintain the clinical and regulatory quality required for future regulatory approval. There is also a risk that the regulatory authorities do not consider the clinical studies the application for regulatory approval is based on to be adequate.

### Research and development

NeuroVive conducts or may come to conduct studies in the pre-clinical and clinical phase for a number of candidate drugs. The results of these studies may be unforeseen and undesirable and, accordingly, the Company's forecast expenses for such studies are associated with a high degree of uncertainty. Unforeseen outcomes of studies may also lead to concepts and studies having to be reevaluated, which implies that new or complementary studies will need to be conducted at significant expense, or that the studies are terminated. This can entail delayed launch or that the registration of the Company's candidate drugs fails to materialize, which would have a negative impact on the Company's expected rate of expansion, results of operations and financial position.

### Adverse events

There is a risk that healthy test subjects or patients participating in clinical trials in NeuroVive's candidate drugs or otherwise come into contact with NeuroVive's products are affected by adverse events. The consequences of such potential adverse events may delay or halt the continued product development and inhibit or prevent the commercial usage of products and thereby affect NeuroVive's sales, results of operations and financial position. Another consequence that cannot be ruled out is that NeuroVive could be sued by healthy test subjects or patients that have been affected by adverse events, whereby NeuroVive may become liable for damages.

### Future funding requirements

Project and product development in the Life Science area is normally capital-intensive and NeuroVive will remain dependent

on its ability to secure funding for its projects in the future. Both the scale and timing of the Company's future capital needs are dependent on a number of factors, including the possibility of success in research and development projects and entering into collaboration and distributor agreements.

However, it is not possible to rule out that the Company will seek new forms of financing, including borrowed capital. It cannot be taken for granted that new capital can be raised when the need arises, that it can be raised on favorable terms or that such raised capital will be sufficient to finance operations according to the Company's plans, which may have a negative effect on the Company's development and investment opportunities. Accordingly, NeuroVive is dependent on future access to capital to the extent it is required. Potential delays relating to clinical studies may imply that cash flow is generated at a later stage than anticipated. In the event that the Company is unsuccessful in raising capital when the need arises, there is a risk of chapter 11 proceedings or bankruptcy.

#### **Manufacturers and suppliers**

Candidate drug CicloMulsion®/NeuroSTAT® (a pharmaceutical preparation with different names and applications) is produced by a Contract Manufacturing Organization, Fresenius Kabi in Austria. The parties (NeuroVive and Fresenius Kabi) have signed an agreement relating to product development and investment in large-scale production for commercial purposes. The parties are currently preparing for the transition from pilot manufacture to full-scale production, which will imply contractual relations and risks, not least relating to manufacture.

There is a risk that Fresenius Kabi or NeuroVive's other current and/or future suppliers and manufacturers do not fully satisfy the Company's quality requirements or otherwise fail to complete their undertaking vis à vis NeuroVive. To a degree, the Company's operations are dependent on collaborations with other parties for the development of products, as well as the commercialization of such products. If existing collaborations prove unsatisfactory or are terminated, the Company may be forced to seek out other collaboration partners, which may prove more costly and/or take longer than the Company currently anticipates. Such a scenario may come to affect the Company's operations and profit/loss negatively.

#### **Collaborations and out-licensing**

NeuroVive is and will remain dependent on collaborations relating to out-licensing of candidate drugs for major clinical studies and/or marketing and sales of pharmaceuticals in future. In addition to existing possibilities for traditional out-licensing, NeuroVive's management is evaluating different types of collaboration with large pharmaceutical companies and/or CROs on an ongoing

basis. There is a risk that no agreements or collaborations can be achieved or that collaboration partners fail to fulfill their undertakings successfully. The failure of collaboration agreements or partners to materialize, or such partners being unsuccessful in bringing a pharmaceutical to market, may lead to reduced or absent revenue for NeuroVive.

#### **Collaboration with Lund University**

Parts of NeuroVive's research are conducted by a research team at the Mitochondrial Pathophysiology Unit, Faculty of Medicine, Lund University. The Company takes a positive view of the proximity to and collaboration with the university and the Company is aware of the risks ensuing from a private business collaborating with a government institution operating under the principle of public access. Even if NeuroVive and the researchers have agreed on data and patent rights as well as confidentiality, there may be a risk that the agreement is not comprehensive, which could imply a risk that NeuroVive is obliged to disclose confidential material. There is no formalized collaboration agreement with Lund University at present. Discussions relating to collaboration agreements are underway with Lund University, although it remains unclear when and if such an agreement will be entered into. In the event that the parties are unable to reach such a collaboration agreement, NeuroVive's operations could be negatively affected.

#### **Studies in China**

Through its Chinese subsidiary, NeuroVive has signed a contract with Sihuan to develop CicloMulsion® and NeuroSTAT® for the Chinese market. The parties' collaboration initially entails clinical studies in China and regulatory work. There is a risk that Sihuan will not fulfill its obligations in the manner NeuroVive expects. Accordingly, NeuroVive's plans relating to the Chinese market are associated with uncertainty and there is a risk that the plans cannot be implemented or will be delayed. This uncertainty is accentuated because the agreement with Sihuan is exclusive, which means that NeuroVive is prevented from entering into an agreement with a different party.

#### **Regulatory approvals and registration**

In order to market and sell a pharmaceutical, approvals and registrations must be obtained from the relevant authority on each market, such as the Food and Drug Administration ("FDA") in the USA, the European Medicines Agency ("EMA") in Europe and the China Food Drug Administration ("CFDA") in China. In the event that NeuroVive is unsuccessful in obtaining the requisite approvals and registrations from the relevant authorities, the Company may be adversely affected in the form of reduced or absent revenue. The regulations and interpretations that currently apply may come to change in the future, which may affect the Company's

ability to satisfy different regulatory requirements. Approval and registration may be withdrawn after having been obtained by the Company or its collaboration partners. Accordingly, changes to regulations and interpretations as well as withdrawn approvals and registrations may comprise future risk factors. To summarize, regulatory decisions may have a negative effect on NeuroVive's potential revenues and the Company's financial position.

#### **Enrollment of healthy test subjects and patients**

NeuroVive intends to enter into agreements with several different service providers for clinical studies at medical clinics and hospitals. A key element of such agreements is to ensure the enrollment of healthy test subjects and patients for the clinical trials. The scope of such enrollment has a fairly significant impact on the schedule for clinical studies. Should one or several of these service providers cancel their collaboration agreements, and if these cannot be replaced with agreements with other providers, this may lead to delays to clinical studies and subsequently delays to registration of the Company's candidate drugs. Such delays may in turn lead to additional costs and deferred future revenue, with a ensuing negative impact on the Company's results of operations and financial position.

#### **Key persons, employees and consultants**

NeuroVive's key persons, employees and consultants have extensive expertise and long-term experience of the Company's field. The loss of one or several individuals may have negative consequences for the Company's operations and results of operations.

#### **Competitors**

The pharmaceutical industry is subject to intense competition. There are many companies, universities and research institutions that conduct pharmaceutical research and development. Should a competitor succeed in developing and launching an effective and safe drug in mitochondrial protection, this may entail risks in the form of reduced sales potential for NeuroVive. Furthermore, companies with global operations that are currently active in associated fields may decide to establish activities in the Company's field. Increased competition may have negative effects on the Company's future sales and profit/loss.

#### **Patents and other intellectual property**

Patents, which are an important part of NeuroVive's assets, have a limited life span. There is a risk that existing and/or future patent portfolios and other intellectual property held by the Company fail to provide adequate commercial protection. If NeuroVive is forced to defend its patent rights against a competitor, this may entail significant costs that may have a negative effect on NeuroVive's operations, results of operations and financial

position. Furthermore, in this type of activity, there is always a risk that NeuroVive may infringe upon, or be accused on infringing on, patents held by third parties. Other parties' patents may also come to restrict the potential for one or several of the Company's future collaboration partners to freely use the affected pharmaceutical or production method. The uncertainty associated with patent protection implies that the outcome of such disputes is difficult to predict. A negative outcome in disputes relating to intellectual property may lead to the loss of patent protection, the Company becoming prohibited from continuing to utilize the relevant right, or the obligation to pay damages. In addition, the costs of a dispute, even in the event of a favorable outcome for NeuroVive, may be significant, which could have a negative impact on the Company's profit/loss and financial position. The above could imply difficulties and delays to commercialization of future pharmaceuticals and thereby also difficulties in generating revenues. This also applies to other intellectual property such as brands.

To some extent, NeuroVive is also dependent on know-how and commercial secrets, which are not protected by legislation in the same way as intellectual property. The Company adopts confidentiality agreements and thereby seeks to secure far-reaching protection of sensitive information. However, it is not always possible to obtain comprehensive protection against unauthorized dissemination of information, implying a risk that competitors gain access to and utilize the know-how developed by NeuroVive to the detriment of the Company and its financial performance.

#### **Development expenses**

In parallel with pre-clinical and clinical studies, NeuroVive will continue to conduct research and development relating to mitochondrial protection and mitochondrial-enhancing drugs. The timing and cost aspects of this area are difficult to determine with any precision. This implies a risk that research and development may become more costly and time-consuming than anticipated.

#### **Product liability**

Considering the nature of NeuroVive's business, it is necessary to consider the Company's product liability (regardless of the origin of the technology it relates to), which arises when the Company develops and commercializes products. The Board of Directors considers NeuroVive's current insurance cover to be satisfactory, given the nature and scope of operations. However, for each planned clinical study, the Company will need to review its insurance cover and in all probability each planned future study will be subject to limitations to the extent of insurance cover and maximum amounts. Accordingly, there is a risk that the Company's insurance cover is unsatisfactory in terms of fully covering future legal claims, which could have a negative impact on NeuroVive's operations and profit or loss.

**Changes in the pharmaceutical industry**

The pharmaceutical industry is characterized by rapid technological change with continuous advancement and improved industrial know-how. Therefore, future success will largely be dependent on the Company's ability to adapt to such external factors, its ability to diversify the product portfolio and to develop new and competitively priced products that satisfy demand from an ever-changing market. If the Company is unable to secure the right price for its products, this would have a negative impact on the Company's results of operations and financial position.

**Cyclical factors**

External factors such as supply and demand, cyclical upturns and downturns, inflation and interest rate fluctuations may have an impact on operating expenses and sales prices. NeuroVive's expenses and future revenue may be adversely affected by such factors, which lie outside the Company's control and may consequently have a negative effect on the Company's operations.

**Currency risk**

Parts of NeuroVive's expenses are paid in euro and other foreign currencies. Furthermore, parts of the Company's future sales revenue may be received in foreign currencies. Exchange rates may undergo significant fluctuations, which could affect NeuroVive's costs and future revenues adversely.

**Political risk**

The Company's research and development work takes place in, and through, many different countries and with, or through, collaboration partners, is intended to generate global sales of pharmaceuticals that provide mitochondrial protection. Risks may arise as a result of changes in legislation, taxation, customs and excise duties, exchange rates and other conditions applying to companies active on international markets. The Company will also be affected by factors relating to political and economic uncertainty in these countries. The aforementioned factors could have negative consequences for the Company's operations and profit or loss.

**Pricing of pharmaceuticals**

NeuroVive's business model involves out-licensing pharmaceuticals. General trends relating to the pricing of pharmaceuticals lie outside the Company's control. In the event that pharmaceutical pricing declines generally, there is a risk that this has a negative effect on NeuroVive's earnings ability. In some countries, the pricing of many types of pharmaceutical is determined by regulatory authorities. In many countries, the pricing of a new pharmaceutical

launched on the market may be regulated by the authorities. In this event, pricing lies outside NeuroVive's control. The lower the pricing assigned to a pharmaceutical, the more restricted NeuroVive's earnings ability will be. Accordingly, there is a risk that the pricing of mitochondrial drugs may be lower than NeuroVive's Board of Directors anticipates.

**Royalties to CicloMulsion AG**

In March 2013, CicloMulsion AG initiated an arbitration procedure whereby CicloMulsion AG is seeking to determine the implication of the agreement between CicloMulsion AG and NeuroVive. CicloMulsion AG wants to determine whether NeuroVive has the right to cancel the agreement between the parties, and how CicloMulsion AG's right to receive royalty would be affected by such cancellation. CicloMulsion AG also wants to obtain information regarding NeuroVive's agreement with Sihuan for reasons including computing royalties. If the outcome of arbitration is in CicloMulsion AG's favor, NeuroVive may be obliged to pay future royalties without being able to cancel the agreement. Accordingly, NeuroVive could become obliged to pay royalties for 15 years after product launch. There is a risk that CicloMulsion AG chooses to include further agreement areas in the arbitration proceedings, which could have a negative impact on the Company's operations.

**Part-owned development projects**

NeuroVive conducts development projects where the collaboration partners are part-owners of the projects and are entitled to receive a portion of future revenues. The contracted allocation of potential future revenues is based on the amounts NeuroVive and the respective collaboration partner have invested in the relevant projects. The initial assumption is that each party is entitled to 50% of revenues. Over time, this may change to an allocation of up to 90% to one party and 10% to the other party, depending on the extent of the relevant party's investment. NeuroVive intends to assume the main responsibility for development and commercialization of these projects and would thus receive a higher share of potential future revenues. However, there is a risk that this fails to materialize, which would imply lower revenues than anticipated.

**Loss carry-forwards**

NeuroVive reported an accumulated deficit of SEK 62,198,000 as of 30 September 2013. However, the Company has not recorded any value for this deficit in its accounts. In future, accumulated deficits may reduce the Company's potential taxable profit and consequently reduce corporation tax arising on potential future profit. The tax effect from accumulated deficits could then potentially be posted to assets in the balance sheet. The Company's future ability

to utilize the accumulated deficit, in full or in part, is determined by factors including changes to NeuroVive's ownership, factors over which the Company does not have any control. If the loss carry-forwards cannot be utilized to reduce future profits, this would mean that the Company's tax expenses could become higher.

## **SECURITIES-RELATED RISKS**

### **Share price performance**

Existing and potential investors should be aware that an investment in NeuroVive is associated with risk and that there can be no guarantee that share price performance will be positive. This implies that there is a risk that investors may lose all of or part of the capital invested. The Share price may fluctuate as a result of factors including variations in the profit/loss posted in the Company's quarterly reports, general trends in the business cycle and variable stock market interest in the Company and the Share. Limited liquidity in the Share could then contribute to accentuating such share price fluctuations. Accordingly, the share price may be affected by factors that lie wholly or partly outside the Company's control. An investment in NeuroVive should be preceded by a careful analysis of the Company, its competitors and external factors, as well as considering general sector data, economic trends and other relevant information. There can be no guarantee that shares in NeuroVive can be sold at a share price that is acceptable to shareholders from time to time.

### **Dilution**

Shareholders that wholly or partly chose not to exercise their subscription rights in the new issue will become subject to dilution of their votes and their proportion of the Company's share capital, implying reduced voting power at shareholders' meetings and

entitlement to a lower portion of the Company's assets and profit/loss. The dilution effect for shareholders choosing not to participate in the new issue is limited to a maximum of approximately 20% of the votes and capital in the Company.

### **Limited liquidity in the Share and share-related securities**

NeuroVive's shares are traded on NASDAQ OMX Stockholm. In addition to trading in the Shares, subscription rights and BTAs will be traded for a limited period in connection with the completion of the new issue. There can be no guarantee that liquidity in the Shares, subscription rights and BTAs will be satisfactory, which implies that there is a risk that the securities are not traded on a daily basis and that the spread between buy and sell prices may be large. If liquidity is limited, this may lead to holders of these securities experiencing difficulties in making changes to their holdings.

### **Dividend**

The Company's Board of Directors has not set a dividend policy and the Company has not paid dividends in recent years as it has generated a loss. There can be no guarantee that NeuroVive will pay dividends in the future.

### **Unsecured guarantee commitments**

In connection with the new issue, NeuroVive has obtained underwriting guarantees totaling up to SEK 50 m, corresponding to approximately 66% of the issue amount. NeuroVive has not requested frozen bank funds or other security to be provided against fulfillment of obligations under guarantee commitments. Accordingly, there is a risk that one or several of the parties that have issued underwriting guarantees will become unable to fulfill their obligations, which could have a negative impact on the Company's ability to successfully complete the new issue.

# Invitation to subscribe for shares in NeuroVive

In accordance with the Board of Directors' proposal, NeuroVive's EGM on 13 December 2013 resolved to conduct a new issue of shares with preferential rights to the Company's existing shareholders, a rights issue. The new issue will increase the share capital by a maximum of SEK 270,738.05, from SEK 1,082,952 to a maximum of SEK 1,353,690.35, through the issue of a maximum of 5,414,761 shares, each with a quotient value of SEK 0.05.

Possession of four (4) shares on the record day of 8 January 2014 confers entitlement to subscribe for one (1) new share in the Company at a subscription price of SEK 14 per share. The subscription period is 13 January-27 January 2014. The new shares confer the same rights to shareholders as existing shares in NeuroVive.

Upon full subscription, the issue will raise approximately SEK 75.8 m before issue expenses.<sup>1</sup> Upon full subscription, the new issue increases the number of shares by a maximum of 5,414,761

shares to a maximum of 27,073,807 shares, which means an increase of 25%. The dilution effect for shareholders deciding not to participate in the new issue is 20%.

In connection with the forthcoming new issue, certain parties have made underwriting guarantees corresponding to a total of SEK 50 m and approximately 66% of the issue amount. Accordingly, the issue is underwritten up to approximately 66%.

In the event of over-subscription, The Board of Directors may exercise the option to issue a further maximum of 714,286 shares. Upon full exercise of this option, the Company would raise an additional total of approximately SEK 10 m. The additional shares that may be issued correspond to a maximum of 3.3% of the capital and votes in the Company, calculated before the new issue. For more information, see Terms and Conditions under the heading Overalllocation Option on pages 18-19.

*For more information, please refer to this prospectus, which has been prepared by NeuroVive's Board of Directors for the forthcoming new issue. NeuroVive's Board of Directors is responsible for the information provided in this prospectus and hereby offers its assurance that all reasonable caution has been exercised to ensure that the information contained in the prospectus, to the best of the Board of Directors' knowledge, corresponds to actual circumstances and that nothing has been omitted that could alter its substance.*

*The shareholders of NeuroVive Pharmaceutical AB (publ)  
are hereby invited to subscribe for shares in the Company with preferential rights  
in accordance with the terms and conditions of this prospectus..*

Lund, Sweden, 8 January 2014  
NeuroVive Pharmaceutical AB (publ)  
The Board of Directors

<sup>1</sup> Issue expenses are estimated at approximately SEK 6.6 m (of which approximately SEK 4 m comprises remuneration to underwriters)

# How to subscribe for shares

## 1. You are allotted subscription rights



For each share in NeuroVive held on the record day 8 January 2014...

...you will receive a subscription right.

**NB: that to prevent a loss of value on your subscription rights, they must either be exercised to subscribe for shares by no later than 27 January 2014, or be sold by no later than 22 January 2014.**

## 2. How to exercise your subscription rights

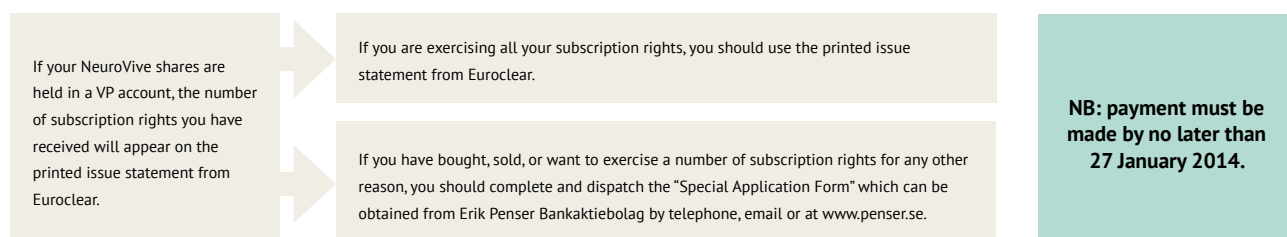


Four subscription rights confer entitlement to subscribe for one new share at SEK 14.

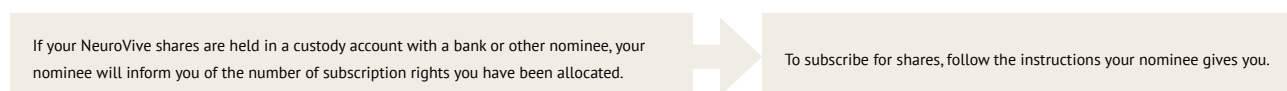
### Example

A shareholder has 1,000 NeuroVive shares on the record day of 8 January 2014. This shareholder receives 1,000 subscription rights. The subscription rights can be exercised to subscribe for 250 new shares at SEK 14 per share. Accordingly, a total of SEK 3,500 would be payable for the new shares. After the share issue, the shareholder will hold 1,250 NeuroVive shares.

## If you have a VP (securities register) account

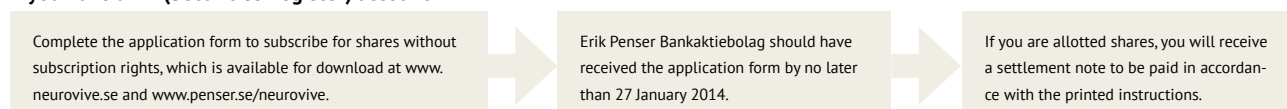


## If you have a custody account

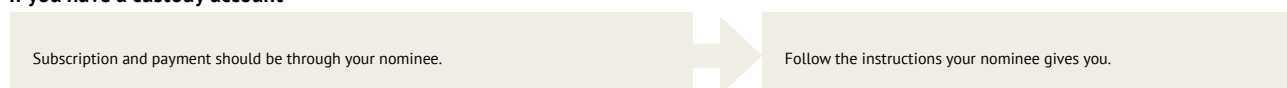


## How to subscribe for shares without subscription rights

### If you have a VP (Securities Register) account



### If you have a custody account



# Background and motivation

NeuroVive conducts research and development aimed at generating candidate drugs for mitochondrial protection, as well as developing pharmaceuticals in other areas where cyclophilin inhibitors are a central mechanism. The project portfolio consists of a number of different pharmaceuticals in various development phases, focusing on three areas: reperfusion injury in myocardial infarction, traumatic brain injury (TBI) and energy-regulating preparations. NeuroVive has two independent projects in the clinical development phase with the potential of meeting substantial patient needs in myocardial infarction and TBI. NeuroVive's candidate drug CicloMulsion® is being used in a largely externally financed phase III study in the EU on reperfusion injury in myocardial infarction. At the same time, phase IIa studies are underway in NeuroSTAT®, intended to limit brain injury in TBI. In addition, NeuroVive is working on a number of projects relating to cell protection in mitochondrial diseases and products for the treatment of anti-viral indications such as Hepatitis B/C. NeuroVive's business model includes collaborations with major pharmaceutical companies and/or CROs (Contract Research Organization) that ensure risk reduction and cost efficient commercialization of the Company's products. The Company's revenues will also comprise fixed remuneration from out-licensing and milestone payments prior to launch as well as ongoing royalty payments, based on sales of out-licensed pharmaceuticals.

NeuroVive is in a promising position where regulatory work and activities to prepare the market have intensified as the Company's first product, CicloMulsion®, is in the decisive clinical phase. To enable the Company's continued operations and sustained strong initiatives in Europe, as well as evaluating US and Asian markets, the Board of Directors considers that the Company needs to strengthen its ownership base and raise additional capital.

In the above context, the Company completed a private placement in December 2013 aimed at reputable institutional investors

and one of the founders of the Company's partner in China, Sihuan Pharmaceutical. The issue raised approximately SEK 35 m for the Company. In addition, the EGM on 13 December 2013 resolved on a new issue with preferential rights for existing shareholders. The issue will raise approximately SEK 75.8 m for the Company upon full subscription and before issue expenses, and is underwritten up to SEK 50 m. The AGM also decided on an overallocation option of approximately SEK 10 m to be utilized given interest is extensive, and to the extent that the rights issue is fully subscribed.

Given the issue is fully subscribed, the proceeds from the new issues will mainly be used to complete ongoing clinical trials in CicloMulsion® and NeuroSTAT® (approx. SEK 10-12 m) and, given a favorable outcome from phase III studies on CicloMulsion®, activities to prepare the market ahead of product launch (approximately SEK 12-15 m). The remaining proceeds will be allocated to research and development projects in Hepatitis B/C (approximately SEK 10-12 m) as well as new cyclophilin inhibitors for heart cell and neuroprotection, which is the basis of the molecules acquired from Biotica Ltd. in 2013 (approximately SEK 14-16 m). The development projects in Hepatitis B/C and new cyclophilin inhibitors for heart cell and neuroprotection share the same development route, which will generate synergies, mainly at the production stage and in some pre-clinical areas.

A proportion of the issue proceeds will also be used to finance the Company's investment in the new production facility for CicloMulsion® and NeuroSTAT® (approximately SEK 13 m).

The combination of a capital injection and new institutional investors alongside key milestones being reached over the next few years, means that the Board of Directors considers that the conditions are now in place to launch the first effective pharmaceuticals for conditions where mitochondrial dysfunction plays a decisive role.

The Board of Directors, NeuroVive Pharmaceutical AB (publ), Lund, Sweden, 8 January 2014.



# CEO's statement

Interest in NeuroVive is growing and 2013 was our most eventful year to date. The key milestones were the listing on NASDAQ OMX Stockholm and the acquisition of molecules from Biotica Ltd. It's also promising that patient enrolment for the ongoing clinical study in reperfusion injury continues at a satisfactory rate and that we've now initiated phase II studies in traumatic brain injury. It's clear that interest in NeuroVive's research has increased over the last six months, which is evident from our trade and academic partnerships.

Over the last year, we've focused mainly on our product CicloMulsion®, which is in the final stages of phase III studies for the treatment of reperfusion injury in myocardial infarction.

Furthermore, we've continued to focus on our product NeuroSTAT®, which is being developed for the treatment of traumatic brain injury (TBI), and the acquired molecules, based on an all-new and unique chemistry platform of cyclophilin inhibitors. A number of well-recognized pharmaceutical companies have shown great interest in the acquired molecules, and the Chinese army has demonstrated considerable interest in NeuroSTAT® and TBI.

Accordingly, NeuroVive is in a promising position, with our first product in a decisive clinical phase while we're also developing a second-generation of products in a number of key therapy areas, and will soon reach the clinical phase here too.

At the same time, the collaboration with Sihuan, China's leading pharmaceutical company in cardiovascular medicine, has increased our presence in China. The trips to Asia have become more frequent and we're strengthening our international position. We're talking to a number of other players in Asia and our knowledge of this market is growing with each trip.

We've already made a great deal of progress with limited funds and intend to continue on the same cost-efficient path. I'm very proud that we've been able to maintain our cost-efficient organization as a result of adopting a clearly defined and carefully considered business model for bringing a product to market. However, the need for capital is unavoidable when taking a pharmaceutical from the development stage to market. Accordingly, the current new issue is a natural key step for NeuroVive. I'm delighted that the private placement in December 2013 attracted new, reputable institutional investors.

By consolidating our resources through these two new issues, the prospects are now in place for maintaining our focus and high tempo in work on maintaining our leadership in mitochondrial medicine. I hope that this journey, and the very solid value we're building on our way, represent an attractive offering to current and new investors.

Lund, Sweden, 8 January 2014



Mikael Brönnergård

# Terms, conditions and instructions

## PREFERENTIAL RIGHTS TO SUBSCRIPTION

Registered shareholders of NeuroVive on the record day 8 January 2014 have preferential rights to subscribe for shares in the forthcoming new issue on the basis of preferential rights. Possession of 4 shares confers entitlement to subscribe for 1 new share in NeuroVive. In addition, shareholders and other investors are invited to notify their interest in subscribing for shares without preferential rights.

## SUBSCRIPTION PRICE

The subscription price is SEK 14 per share. No commission is payable.

## RECORD DAY

The Euroclear record day for determining entitlement to receive subscription rights is 8 January 2014.

The final day of trading in the NeuroVive Share cum rights is 2 January 2014. The Share will trade ex rights from 3 January 2014 inclusive.

## SUBSCRIPTION RIGHTS

The right to subscribe for shares is exercised on the basis of subscription rights. Each share in NeuroVive held on the record day confers the owner with the right to receive 1 subscription right. 4 subscription rights confer the right to subscribe for 1 new share.

## Trading in subscription rights

Trading in subscription rights takes place on NASDAQ OMX Stockholm in the period 13 January– 22 January 2014. Banks and securities institutions can assist in brokering the purchase or sale of subscription rights. Accordingly, individuals wishing to buy or sell subscription rights should approach their bank or securities institution.

For such trading, commission is normally due in accordance with the applicable terms for securities trading.

## SUBSCRIPTION PERIOD

Notification of the intention to subscribe for shares by exercising subscription rights shall be made by simultaneous cash payment in the period 13 January– 27 January 2014.

Please note that unutilized subscription rights become invalid after the end of the subscription period and thereby lose their value.

Unutilized subscription rights will be de-registered from the relevant shareholder's VP account without notification from Euroclear.

To prevent a loss of value on the subscription rights, they must either be exercised to subscribe for shares by no later than 27 January 2014 or be sold by no later than 22 January 2014.

NeuroVive's Board of Directors is entitled to extend the period during which notification of subscription and payment can take place. Any potential extension will be announced in a press release.

## DIRECT-REGISTERED SHAREHOLDERS

Shareholders included in the share register kept by Euroclear on behalf of the Company on the record day will receive a printed issue statement with an attached payment advice. The printed issue statement will contain information including the number of subscription rights allocated. Individuals included in the special register of pledgees/mortgagees etc. associated with the share register will not receive an issue statement and will be notified separately. No separate VP advice indicating registration of subscription rights in the shareholder's VP account will be dispatched.

## Subscription and payment with subscription rights

Notification of the intention to subscribe for shares by exercising subscription rights should be through simultaneous cash payment. Please note that it can take up to three banking days for payment to reach the recipient account. Late payment of amounts of less than SEK 100 will be repaid on request. Subscription and payment should be in one of the following ways:

### 1. Printed payment advice from Euroclear

In the event that all subscription rights received on the record day are exercised for the subscription of shares, the printed payment advice from Euroclear should be used for notification of subscription through payment. Accordingly, the special application form should not be used. No additions or amendments may be made to the printed text on the payment advice. The application is binding.

### 2. Special application form

In the event that subscription rights are acquired or sold, or if the shareholder intends to exercise a number of subscription rights that differs from the pre-printed payment advice from Euroclear for any other reason, the special application form should be used.

Notification of subscription through payment should be according to the instructions on the special application form.

Accordingly, the printed payment advice from Euroclear should not be used. The special application form can be ordered from Erik Penser Bankaktiebolag by telephone, email or downloaded from the website.

Erik Penser Bankaktiebolag should have received the special application form by no later than 5 pm on 27 January 2014. Only one application form per person or company will be considered. In the event that more than one application is submitted, only the last received will be considered. Incomplete or incorrectly completed special application forms may be disregarded. The application is binding.

The completed special application form should be sent or submitted to:

Erik Penser Bankaktiebolag  
New issues/NeuroVive  
PO Box 7405  
103 91 Stockholm  
Sweden

Visiting address: Biblioteksgatan 9  
Tel. + 46 (0)8 463 80 00  
e-mail: [emission@penser.se](mailto:emission@penser.se)  
Website: [www.penser.se/neurovive](http://www.penser.se/neurovive)

#### **NOMINEE-REGISTERED SHAREHOLDERS**

Shareholders who are nominee registered with a bank or stockbroker on the record day will not receive an issue statement from Euroclear. Subscription and payment for nominee-registered shareholders should be made in accordance with the instructions from the relevant bank or stockbroker.

#### **SUBSCRIPTION WITHOUT SUBSCRIPTION RIGHTS**

In the event that the offer is not fully subscribed using preferential rights, the Board of Directors, observing the maximum amount of the issue, will resolve on allotting shares not subscribed for on the basis of preferential rights.

Such allotment will primarily be made to shareholders that have exercised subscription rights under the new issue, in relation to the number of subscription rights that have been exercised to subscribe for shares and, secondarily, to other individuals subscribing for shares, in relation to the subscribed amount, and where this is not possible, to guarantors in relation to the issue amount underwritten.

#### **Application form for subscription of shares without subscription rights**

Notification of subscription of shares without subscription rights should be in the same period as notification of subscription of shares on the basis of subscription rights, i.e. 13 January - 27 January 2014. For direct-registered shareholders, notification of interest to subscribe for shares without subscription rights should be made on an application form to be completed, signed and sent or submitted to Erik Penser Bankaktiebolag at the above address. The application form can be ordered from Erik Penser Bankaktiebolag by telephone, email or downloaded from the website.

Erik Penser Bankaktiebolag should have received the application form by no later than 5 pm on 27 January 2014. Only one application form per person or company will be considered. In the event that more than one application form is submitted, only the last received will be considered. Incomplete or incorrectly completed special application forms may be disregarded. The application is binding. For nominee shareholders the application should be made to the relevant fund manager.

Notification of potential allotment will be provided by dispatch of a contract note, to be paid in accordance with the printed instructions. Only parties allotted shares will be notified.

#### **NON-SWEDISH SHAREHOLDERS**

Shareholders domiciled outside Sweden who wish to participate in the issue should submit the printed payment advice where all subscription rights received are exercised, or the special application form if a different number of subscription rights are exercised, alongside payment to the above address. Payment should be made to Erik Penser Bankaktiebolag's bank account with SEB. The account details are as follows:

Bank: SEB (Skandinaviska Enskilda Banken AB)  
SE-106 40 Stockholm, Sweden  
IBAN no.: SE70 5000 0000 0556 5101 8069  
Bic code: ESSESESS

Please note that as a result of restrictions to securities legislation in the USA, Canada, Australia, New Zealand, Hong Kong, Japan and South Africa, the offer to subscribe for shares is not aimed at shareholders or other parties with their registered address in any of these countries. Shareholders with their registered address in any of these countries are urged to contact Erik Penser Bankaktiebolag to receive payment from sales of subscription rights received, less selling expenses, which such shareholders had otherwise been entitled to. No payment will be made relating to such sales proceeds where the net amount falls below SEK 200.

**FULLY PAID-UP SHARES (BTAS)**

Subscription by payment is registered with Euroclear as soon as this takes place, normally up to three banking days after payment. The subscriber will subsequently receive a VP advice confirming registration of BTAs in the subscriber's VP account. Shareholders with nominee-registered holdings in a bank custody account or with a stockbroker will receive information from the relevant fund manager.

**Trading in fully paid-up shares (BTAs)**

Trading in BTAs will take place on NASDAQ OMX Stockholm from 13 January 2014 until the Swedish Companies Registration Office has registered the new issue. Such registration is expected to take place in mid-February 2014.

**DELIVERY OF SHARES**

BTAs will be replaced by shares as soon as the new issue has been registered with the Swedish Companies Registration Office. After registration, BTAs will be deregistered from the relevant VP account and replaced with shares without any special notification. Such changes to registration are expected to take place in mid-February 2014. The newly issued shares will start trading on NASDAQ OMX Stockholm when the new issue is registered with the Swedish Companies Registration Office.

**RIGHT TO RECEIVE DIVIDENDS**

The newly issued shares confer entitlement to receive dividends for the first time on the record day for dividends that occurs immediately after such date as the Shares have been entered into the Company's share register.

**OTHER INFORMATION**

NeuroVive's Board of Directors is prohibited from interrupting, revoking or suspending the offer to subscribe for shares in the Company under the terms and conditions of this prospectus.

**PUBLICATION OF THE OUTCOME OF THE ISSUE**

The outcome of the issue will be published in a press release on the Company's website, which is expected to take place approximately one week after the end of the subscription period.

**OVERALLOCATION OPTION**

In addition to the Shares encompassed by the current new issue with preferential rights for existing shareholders, the EGM on 13 December 2013 resolved on the Board of Director's potentially issuing a further maximum of 714,286 shares. Exercise of the overallocation option is conditional on the new issue being oversubscribed. The overallocation option will be exercised following a decision by the Board of Directors. Upon full exercise of the overallocation option, the additional shares issued correspond to 3.3% of the capital and votes in the Company, calculated before the new issue.

# Operations

*NeuroVive conducts research and development into of pharmaceuticals that protect the mitochondria, focusing on the clinical development of products with a known mechanism of action. The technology platform for pharmaceutical development primarily comprises cyclosporine A and molecules with a different chemical structure that work as neuroprotective agents by inhibiting cyclophilin enzymes. The collective term for this type of candidate drugs is cyclophilin inhibitors. NeuroVive focuses on three areas: reperfusion injury in myocardial infarction, traumatic brain injury (TBI) and energy-regulating preparations. NeuroVive's candidate drug CicloMulsion® is included in a largely externally financed phase III study in the EU on reperfusion injury in myocardial infarction. At the same time, a phase IIa study is ongoing on NeuroSTAT®, intended to limit brain damage in TBI. NeuroVive's energy-regulating preparation NVP015 is in the pre-clinical development phase. In addition, NeuroVive is working on a number of projects relating to cell protection and products for the treatment of anti-viral indications such as Hepatitis B/C.*



## Strategy

NeuroVive is working according to a strategy that is adapted to the conditions for taking a drug candidate from early discovery phase to finished product. By collaborating with academic institutions and other small biotech and pharmaceutical enterprises focused on mitochondrial medicine, NeuroVive can evaluate projects in early phases and identify potential drug candidates. By NeuroVive subsequently making a selection of various drug candidates internally, and then contracting out much of the preclinical work, it creates a cost-efficient platform for clinical programs.

This strategy sets the focus on taking a product to phase I or phase II to then identify a partner that can co-finance the later clinical phases. This strategy offers NeuroVive the opportunity to retain a compact organization, which helps its competitiveness.

Its extensive network also confers flexibility and cost-efficiency, which contributes to a lower risk profile. Its experienced Board of Directors participates actively in the Company's development.

## Business model

NeuroVive intends to out-license pharmaceuticals to large pharmaceutical companies for registration, marketing and sale. In these cases, the Company's revenues consist of lump-sum payments and out-licensing when milestones are achieved prior to launch, and by ongoing royalty revenues, based on sales of out-licensed pharmaceuticals.

Apart from the possibility of traditional out-licensing, NeuroVive's management is evaluating various types of innovative

collaboration with large pharmaceutical companies and CRO partners with the aim of establishing a risk-reduced and cost-efficient business model. Strategic partnerships with CROs confer greater flexibility, reduce costs and utilize specific expertise better. NeuroVive judges that these strategic partnerships could lead to greater efficiency, reduce the requirements of internal control systems, accelerated time to market, better access to global patient populations and limited overheads. NeuroVive intends to utilize accumulated commercial channels with a selected partner to lay a foundation for the marketing and sale of future pharmaceuticals. In this manner, NeuroVive avoids the need to build internal marketing and sales organizations but can still retain control over product commercialization phases, and thus potentially, secure a higher share of future revenues.

By acquiring technologies and projects in the research segments of heart cell and neuroprotection, mitochondrial protection and partnerships in technology and product development, NeuroVive intends to build critical mass in the Company's current research segments. Eventually, the acquisition and partnership strategy will enhance NeuroVive's prospects of getting new drug candidates to the market in the indications the Company is prioritizing faster. This reduces the risk of long development cycles when developing new pharmaceuticals.

The objective is that this business model results in NeuroVive securing a higher share of future revenues. Retaining control over how products are marketed, also helps extend the indication segments of existing products and introduce next-generation pharmaceuticals for current and new indications to markets. This can be facilitated because marketing and sales organizations are in place and the collaboration partner is familiar with the product segment.

## Vision

NeuroVive will develop and launch pharmaceuticals for cell protection in diseases with a pressing medical need and thus make a difference to patients' lives.

## Objectives

NeuroVive's primary objective is to complete the current phase III trial on CicloMulsion® for reperfusion injury in the treatment of myocardial infarction and to secure marketing approval in France for CicloMulsion®, followed by selected EU countries. In addition, the Company's goal is to complete the phase IIa trial being conducted at the Copenhagen University Hospital and initiate a phase IIb/III multicenter trial on NeuroSTAT® for traumatic brain injury. The Company is also examining alternatives with the aim of managing the anti-viral pharmaceuticals acquired from Biotica Ltd. in 2013. Dialogue has commenced with potential partners and some development is ongoing to maximize the value of this project, which is being run in parallel with the NVP019 (next-generation cyclophilin inhibitor) which is being developed with its focus on heart attack and brain injury. The base compound and critical phases of production processes are the same for these projects, which accordingly, confers coordination gains in development work.

Development work on other drug candidates is ongoing in tandem and NeuroVive's next objectives are presented below. The objectives during the various development phases are to actively seek partnerships to out-license the Company's drug candidates or strategic alliances for shared risk-taking and funding. In China, the objective is to apply for permission to conduct clinical trials on CicloMulsion® and NeuroSTAT® via the collaboration with Sihuan.

Assuming that the following objectives are achieved and the business plan is followed, the Company judges that the timing of commercialization of CicloMulsion® on some selected markets is 2016.

## Objectives for reperfusion injury

### 2014

- Application for clinical trial authorization (China)
- Patient enrolment in phase III trial completed (EU)
- Commencement of complementary phase III trial (China)
- Commencement of new, follow-up study on patients in the phase III trial

### 2015

- Final patient followed up in phase III trial on CicloMulsion®
- Analysis and presentation of results from phase III trial (EU)

### 2016

- Application for marketing authorization for CicloMulsion®

## Objectives for traumatic brain injury (TBI)

### 2014

- Meeting with the FDA on a phase IIb/III trial on NeuroSTAT® for TBI
- Patient enrolment, low dose and high dose, for phase IIa trial in Copenhagen
- Results of low-dose NeuroSTAT® phase IIa trial presented

### 2015 and beyond

- Results of high-dose NeuroSTAT® phase IIa trial on TBI patients
- Identification of an external partner for the execution of phase IIb/III
- Commencement of phase IIb/III (USA, EU, China)

## Objectives in mitochondrial energy regulation NVP015 (collaboration with Mitopharm Ltd.)

### 2014

- Production and continued formulation work on drug candidates produced
- Preclinical toxicology and proof of concept study in animal trials

### 2015 and beyond

- Commencement of phase I trial (depending on the progress of animal trials and formulation work in 2014)
- Application for orphan designation

## Objectives for the next generation of cyclophilin inhibitors, NVP019

### 2014

- Continued preclinical evaluation and formulation work for intravenous preparations
- Preclinical trials on various animal models of heart disease and TBI
- Formulation work and small-scale production

### 2015 and beyond

- Commencement of phase I/II trials in selected patient groups

*The pharmaceutical sector generally and clinical trials particularly are associated with great uncertainty and high cost. Readers should note that NeuroVive's future plans are founded on the Board of Directors' current judgment of when each stage can be executed/completed (see information on future capital needs in the "equity, liabilities and other financial information" section). These future plans are well considered, but readers should be aware that like all future estimates, they may be affected by unforeseen events. The Company cannot directly affect decisions by regulatory authorities on various matters regarding when the marketing of a pharmaceutical may commence.*

## A globally esteemed pharmaceutical company in the research world

NeuroVive is one of the pharmaceutical companies driving development in mitochondrial medicine, and is perceived as an esteemed and significant player in this segment. NeuroVive is active in an ongoing phase III trial in reperfusion injury of the

heart, a collaboration with one of the world's leading research centers in mitochondrial medicine, Hospices Civils de Lyon (HCL). The many years' aggregate experience of large pharmaceutical companies its employees, management and Board possess also contribute to the Company's eminent status. This is apparent in contexts including the successful development of a network of leading neurosurgeons in the Chinese army, where NeuroVive is the only foreign company to have participated that two major Chinese conferences on neurotrauma organized by the Chinese Army. NeuroVive has also been invited to hold lectures at international research conferences such as the 3rd Annual Traumatic Brain Injury Conference in Washington and the 8th International China Pharmaceutical R&D Summit in Shanghai. Academic interest in NeuroVive's research base is evident in trade and academic collaborations with partners including Lund University, the Lyon Teaching Hospital and the University of Pennsylvania in Philadelphia, USA. Additionally, NeuroVive's researchers regularly



have research results published in recognized periodicals such as The Journal of Neurotrauma, The Journal of Neurochemistry, The Journal of Biological Chemistry and The Journal of Experimental Neurology.

## **An effective organization with a knowledge-intensive network**

The pharmaceutical sector has undergone fundamental change that has resulted in pharmaceuticals frequently being produced through completely new business models, which has affected the whole sector, regardless of the size of company. The sector is still in change and progress has largely favored small and medium-sized enterprises. Previously, large, merged pharmaceutical groups dominated the sector and much of research and development work was within high-cost internal organizations. Nowadays, the sector features collaborations and flexible, cost-efficient networks of smaller enterprises.

The traditional business model when in-licensing a drug candidate, including milestone payments and royalties on future revenues is now facing competition. Partnerships between companies are more common, based on a risk diversification model. Often, this is achieved without milestone payments and royalties, by focusing on exploiting both parties' resources to find the fastest way to market. In this way, the smaller enterprise retains control over product development and can retain a larger share of future sales revenues. Many small pharmaceutical enterprises, including NeuroVive, have adapted their operations to this new

business model.

The skill of judging the potential of early research and development projects is now largely held within small and medium-sized pharmaceutical enterprises like NeuroVive. Apart from traditional pharmaceutical companies, various types of contract organization have emerged that deliver service functions to the industry in various phases of the drug development process. These players have adapted their business model to also suit small and medium-sized enterprises.

## **Human resources**

The average number of employees of NeuroVive was one in 2010, two in 2011 and four in 2012. NeuroVive's organization is optimized on the basis of the Company's current needs, and at present, consists of four full-time employees, seven part-time employees and a network of experienced advisers and consultants, which provide all the necessary functions for executing NeuroVive's development plans. This minimizes operational risks and enhances the prospects of successful commercialization of pharmaceuticals. The employees include Mikael Brönnegård (CEO), Eskil Elmér (CSO), Jan Nilsson (COO) and Catharina Jz Johansson (CFO). Catharina Jz Johansson replaced Christian Svensson, becoming NeuroVive's CFO effective 1 December 2013. Gregory Batcheller serves as Executive Chairman on a consulting basis via Stanbridge Corporation BVBA. The organization is planned for expansion, keeping pace with the Company's development projects, even if the intention is to retain its flexibility.





## Partnerships and collaborations

NeuroVive has entered several partnerships and collaborations. The following table illustrates the type of collaboration entered with each partner, and the financial benefit the collaboration may provide for NeuroVive.

Partner	Type of collaboration	Financial benefit
<b>Sihuan Pharmaceutical, China</b>	Strategic business partner for the clinical development, distribution and sale of CicloMulsion® and NeuroSTAT® in China. Exclusive license for China.	Agreement signed in November 2012 including milestone payments in clinical development corresponding to a total of approximately SEK 57m and subsequently 10% royalties on sales revenues.
<b>Mitopharm Ltd, U</b>	Collaboration partner for developing energy-regulation in mitochondrial medicine and orphan drugs. Complements NVP's team with unique chemistry know-how.	This agreement defines ownership and the allocation of future revenues for products in terms of what each partner contributes to product development.
<b>Isomerase Therapeutics, UK</b>	Collaboration partner for developing anti-viral business and a new chemistry platform for cardiovascular and acute neurodegenerative diseases.	Brings NVP unique chemistry and production competence for the next generation of cyclophilin inhibitor.
<b>To-BBB, Netherlands</b>	Collaboration partner for developing specific stroke products. Preclinical collaboration for evaluating technology to facilitate pharmaceutical distribution to the brain.	To-BBB and NVP have entered an agreement based on an EU-funded project, which runs until June 2014 inclusive.
<b>Scandinavian Development Services, Stockholm, Sweden</b>	Consulting partner for regulatory work and clinical trials.	Consultant that deals with all NVP's products in regulatory affairs and production (CMC).
<b>Business Research Ltd. and FAP</b>	Strategic business partner for China and Asia.	NVP AB and FAP have formed NVP Asia Ltd. jointly, which is registered in Hong Kong.
<b>Fresenius Kabi, Austria</b>	CMO (contract manufacturing organization) for the commercial production of CicloMulsion® and NeuroSTAT®.	NVP AB has invested in a new production facility (production line with reserved time slots) to ensure commercial volumes post-launch. Investment costs will be deducted from future orders.
<b>Nomeco, Denmark</b>	Distribution and logistics partner for CicloMulsion® and NeuroSTAT® for clinical trials.	Cost-efficient consultant for clinical trials.
<b>QP Support, Sweden</b>	Quality-assurance consultant	-
<b>Lindeq AS, Norway</b>	Pharmacovigilance consultant	-

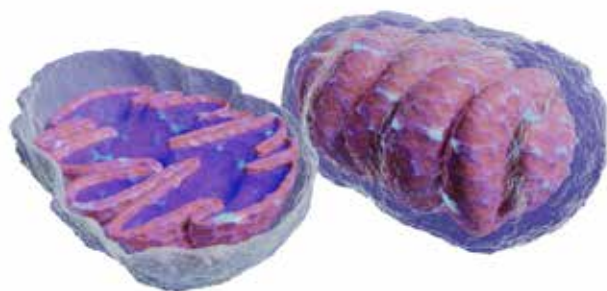
# Research and development

*An unexpected discovery occurred during research into cell transplantation in the central nervous system conducted by Eskil Elmér and colleagues in 1993-94. The researchers discovered that cyclosporine A was a potent neuroprotective agent.<sup>1</sup> Since the early-1980s, cyclosporine A has been used in Novartis's pharmaceutical Sandimmune, an immunosuppressant for organ transplantation. Accordingly, there is extensive safety data for this compound. Professor Elmér's discovery marked the start of basic research in the segment. As of December 2013, the scientific research where the first discovery was published was cited 175 times in various scientific journals, in the segments of cellular basic research and applications in brain-related disease. A number of international and independent research teams have confirmed cyclosporine A as a potent neuroprotective agent in TBI, stroke, and brain damage in cardiac arrest in animal models. NeuroVive has now expanded its project portfolio to also include several major disease indications such as reperfusion injury when treating myocardial infarction, and diseases caused by mitochondrial genetic defects.*

## Research segment

### WHAT IS A MITOCHONDRION?

Mitochondria are present in all cells and serve as the engine and energy supply of the cell, and are decisive for cells being able to withstand and recover from damage. In simple terms, you could say that mitochondria transform the oxygen we breathe in and the food we eat into energy for the cell.



### MITOCHONDRIAL MEDICINE

Mitochondrial disease involves congenitally compromised mitochondrial function, which results in reduced energy production. Accordingly, these are conditions and diseases where mitochondrial function is affected, thus influencing the course of disease. After an injury or in a disease (such as cranial injury or disrupted blood flow to the brain or heart) adjacent cells die or are injured when mitochondrial function is compromised. Research and trials have also demonstrated that defects in mitochondrial structure or function may be the basis of far more diseases and conditions than previously known. Many diseases and conditions could potentially benefit from mitochondrial pharmaceuticals such as myocardial infarction, acute and chronic brain damage, multiple organ failure, diabetes, etc.

NeuroVive is developing what are known as cyclophilin inhibitors, which preserve mitochondrial function, and thus potentially may limit the progression of injury in various organs of the body. NeuroVive is also conducting intensive research in other chemical compounds that may increase mitochondrial energy production. NeuroVive's focus is on mitochondrial dysfunction in acute neurological conditions such as TBI and reperfusion injury after myocardial infarction. The research has also demonstrated a potential relationship between defective mitochondria and the development of a number of serious conditions that currently have no available therapies, such as reperfusion injury after myocardial infarction. There are also many primary genetic diseases that directly affect mitochondrial function, for which no treatment is available.

### Notes

<sup>1</sup> Keep MF, Uchino H, Elmér E. 2003. Introduction: Immunosuppressants as neuroprotective agents. In: Borlongan CV, Isacson O, Sandberg PR, editors. Immunosuppressant analogs in neuroprotection. Totowa: Humana Press. P 3-32.

## THE ROLE OF THE MITOCHONDRION IN ORGAN DAMAGE AND NECROSIS

The mitochondria serve a crucial role in energy production, thus helping cells to withstand and recover from damage. If the nervous system is damaged in cranial injury damage or if blood flow to the brain or heart is disrupted, there is a loss of oxygen and nutrients, which increases the volume of calcium ions in cells. Calcium ions are buffered and stored by the mitochondria with the aim of protecting cells from excessive calcium levels. Excessive calcium levels are very harmful to the cell.<sup>2 3</sup>

If the injury is severe, the mitochondria absorb excessive calcium, triggering increased transition into mitochondria membranes, a process where the enzyme cyclophilin D plays a key role. This process is called mitochondrial permeability transition (mPT) and it results in mitochondria immediately ceasing to produce energy and releasing all the calcium may have stored. Without energy and with increased calcium levels, cell pumps stop and repair enzymes cease to function, which ultimately, kills the cell.<sup>4 5</sup>

Once the mPT process is underway, mitochondrial capacity to process harmful substances known as free radicals is also compromised. The emission of free radicals can damage cells and means surrounding mitochondria are more prone to mPT, triggering a vicious circle, which ultimately can lead to necrosis.<sup>6</sup>

NeuroVive is developing cyclophilin inhibitors, which effectively counter the mPT process, thus preserving mitochondrial energy production and preventing them emitting free radicals and stored calcium. Accordingly, the extent of the primary injury can be limited, and more nerve and heart cells may survive.

NeuroVive has also initiated intensive research into identifying chemical compounds adding that may increase mitochondrial capacity to produce energy. This development program is a natural complement to the cyclophilin program and has been enabled by what the Board regards as an innovative evaluation method in human cells developed by researchers associated with NeuroVive and chemists linked to Mitopharm Ltd., a subsidiary of Selcia Holding Ltd. successful development may generate pharmaceuticals for a series of fairly uncommon pediatric diseases with orphan drug designation, and also potentially, large patient groups, where the body may benefit from extra energy production, in extended surgery and intensive care, for example.

## PRIMARY AND SECONDARY NECROSIS

Primary necrosis affects brain or heart cells directly adjacent to an injury or disease condition. Accidents resulting in cranial injury cause the destruction of cells, and in myocardial infarction, the primary injury affects the cells that suffer the greatest reduction in blood flow and die. After an injury, cells die close to a primary injury either through secondary necrosis (with cells first going into suspended animation, but a lack of energy preventing them from bearing the load and dying) or by committing apoptosis (suicide or programmed cell death).

Necrosis and apoptosis significantly exacerbate the primary injury. For myocardial infarction patients (and stroke patients) it is vital for the final spread of the injury that blood flow is reinstated as soon as possible, achieved in many patients by inserting a catheter via the major blood vessels removing clots from heart or brain blood vessels. But after blood flow is restored, a secondary injury process continues through reperfusion injury with the risk of further tissue damage.

By protecting the body's energy-producing mitochondria, NeuroVive's drug candidates enable the treatment of damaged tissue, which improve the likelihood of damaged cells surviving. NeuroVive's drug candidates also enable the limitation of the spread of the primary injury by protecting adjacent, healthy cells. The Company hopes that its drug candidates will result in reduced necrosis, enhanced organ function and faster clinical recovery. Eventually, the hope is that pharmaceuticals that protect nerve and heart cells will improve individual patient prognoses with fewer days of care and more effective rehabilitation.

### Noter

<sup>2</sup> Mitochondrial dysfunction and oxidative stress in neurodegenerative diseases. *Nature*. 2006 Oct 9;443(7113):787-95.

<sup>3</sup> Hansson MJ, Morota S, Chen L, Matsuyama N, Suzuki Y, Nakajima S, Tanoue T, Omi A, Shibasaki F, Shimazu M, Ikeda Y, Uchino H, Elmer E. Cyclophilin D-sensitive mitochondrial permeability transition in adult human brain and liver mitochondria. *J Neurotrauma*. 2011 Jan;28(1):143-53.

<sup>4</sup> Rasola A, Bernardi P. Mitochondrial permeability transition in Ca(2+)-dependent apoptosis and necrosis. *Cell Calcium*. 2011 Sep;50(3):222-33. Epub 2011 May 23. Review.

<sup>5</sup> Baines CP, Kaiser RA, Purcell NH, Blair NS, Osinska H, Hambleton MA, Brunskill EW, Sayen MR, Gottlieb RA, Dorn GW, Robbins J, Molkentin JD. Loss of cyclophilin D reveals a critical role for mitochondrial permeability transition in cell death. *Nature*. 2005 Mar 31;434(7033):658-62.

<sup>6</sup> Hansson MJ, Månsson R, Morota S, Uchino H, Kallur T, Sumi T, Ishii N, Shimazu M, Keep MF, Jegorov A, Elmer E. Calcium-induced generation of reactive oxygen species in brain mitochondria is mediated by permeability transition. *Free Radic Biol Med*. 2008 Aug 1;45(3):284-94.

## Research and development strategy

NeuroVive was incorporated in 2000 (then named NeuroPharma i Sverige AB) with the aim of commercializing the work on developing cyclosporine-based pharmaceuticals for acute conditions and diseases affecting the brain. The initial focus was on neuroprotection, primarily in TBI. Subsequently, NeuroVive extended its project portfolio to encompass several major disease indications. The Company is working on evaluating new drug candidates and technologies for potential in-licensing or acquisition with the aim of extending and strengthening its priority business segments.

NeuroVive's R&D strategy includes regularly reviewing and updating its patent portfolio to protect its products. A brief summary of events and progress within the Company's strategy for R&D work from 2010 and beyond follows.

In 2010, NeuroVive conducted R&D in the TBI segment. In that year, it also continued collaborating with to-BBB Technologies BV in stroke, and Hospices Civils de Lyon in reperfusion injury after myocardial infarction. In 2010, research and development expenses were SEK 3,453,000, with NeuroVive investing an additional SEK 2,226,000 in the patent segment. No resources were allocated to sponsorship.

R&D work on NeuroVive's projects intensified in 2011. Planning of a combined phase II/III trial on TBI commenced. The collaboration with Hospices Civils de Lyon intensified when a phase III trial on CicloMulsion® commenced. A collaboration also commenced with Mitopharm Ltd. (then called Selcia Ltd.) on mitochondrial energy regulation and specific versions of cyclosporine and

cyclophilin inhibitors in the year. Consolidated R&D expenses in 2011 were SEK 6,986,000 and NeuroVive invested an additional SEK 662,000 in the patent segment. Additionally, SEK 100,000 was donated to Lund University in 2011.

The Group's R&D work remained intensive in 2012, focusing on clinical trials on CicloMulsion® and NeuroSTAT®, developing the next generation of cyclophilin inhibitor and the production of energy-regulating drug candidates. NeuroVive also conducted preparatory marketing work and regulatory development programs. Consolidated R&D expenses in 2012 were SEK 14,096,000 and NeuroVive invested an additional SEK 641,000 in the patent segment. The Company donated SEK 150,000 to Lund University.

In the first nine months of 2013, the Company incurred R&D expenses of approximately SEK 6,077,000. In March, the Company acquired a portfolio of cyclophilin inhibitors and the associated intellectual property, which it expects to be the base of the forthcoming generation of the Company's products. The Company donated SEK 200,000 to Lund University.

As far as NeuroVive's Board of Directors is aware, there are no pharmaceuticals for direct nerve or heart cell damage available at present, and thus no pharmaceuticals that protect against secondary biochemical injury, or injury caused by oxygen deficiency after cranial injury and blood clots in the brain and/or heart. In TBI, stroke and reperfusion injury after myocardial infarction, there is a substantial need to limit the spread of injury with various types of pharmaceutical.



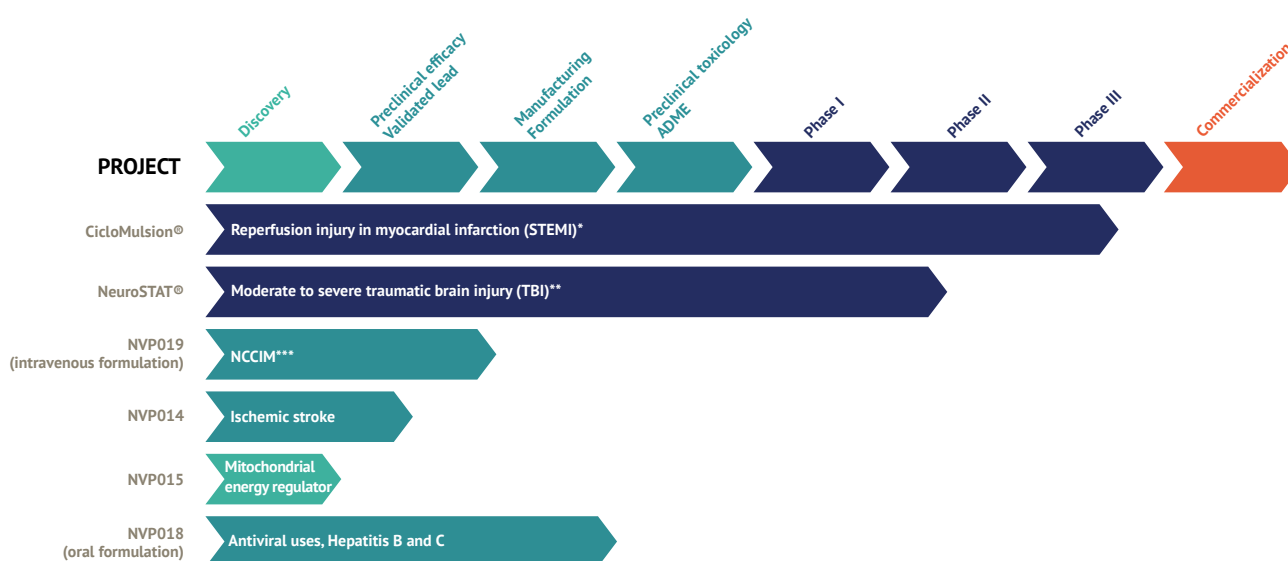
# Project portfolio

*In the years the Company has been active, NeuroVive has conducted research and development. The Company has not commercialized any pharmaceuticals, and accordingly, has not reported any sales. Before commercializing a pharmaceutical is possible, drug candidates have to undergo preclinical and clinical trials to demonstrate their safety and efficacy and to obtain the necessary regulatory permits. It is impossible to specify precisely how long a trial will continue, and the outcomes of preclinical and clinical trials may vary. NeuroVive's current project portfolio and development status, as well as the Company's future plans, based on the Company's current assessment, follow.*

## Project overview

The project portfolio consists of a number of different pharmaceuticals in various development phases. NeuroVive has two independent projects in clinical development phases, with the potential to satisfy substantial medical needs in myocardial infarction and cranial injury. The following image illustrates the development phase of NeuroVive's various projects, and the phases remaining before market launch of pharmaceuticals as possible.

Based on discussions with prospective collaboration partners and with established contacts, NeuroVive has set geographical priorities for the Company's various development projects (for more information, see the review of each project). For information on patents and the revenue rights of each project, see the "legal issues and supplementary information" section.



\* Ongoing clinical external phase III study in the EU. Planning of phase III study in China started.

\*\* Clinical phase I study completed. Ongoing clinical phase II study in Copenhagen. Planning of international phase III study (EU, USA, China) started.

\*\*\* Non Cyclosporin Cyclophilin Inhibiting Molecules.

## CICLOMULSION®

Indication	Current treatment—guidelines	Limitations of current treatment, as judged by NeuroVive's Board	The results of NeuroVive's drug candidate as judged by the Board
Reperfusion injury in myocardial infarction	Emergency treatment with PCI	No pharmaceuticals that protect heart cells that reduce reperfusion injury after PCI currently available	CicloMulsion® reduces reperfusion injury after PCI and improves treatment outcomes after myocardial infarction

### Treating reperfusion injury in myocardial infarction

Heart attack patients often undergo emergency treatment with percutaneous coronary intervention (PCI). This involves opening the coronary arteries and removing blood clots from by inserting a catheter via major blood vessels. Tissue dies and is damaged in myocardial infarction, but even after blood flow is restored, the damage continues to exacerbate through what is known as reperfusion injury, with the risk of further tissue damage and major heart attack. CicloMulsion® is being developed to protect the damaged tissue, which otherwise, is at risk of dying during PCI. From a clinical perspective, there is a very urgent need to develop drugs to protect heart tissue in PCI.

### Clinical trials

An earlier external study demonstrated that treatment with cyclosporine A can reduce reperfusion injury when treating myocardial infarction, and this discovery was published in the New England Journal of Medicine (NEJM, 2008 Jul 31;359(5):473-81). This study, which demonstrated significant reduction in the scale of myocardial infarction, was conducted by Hospices Civils de Lyon using the pharmaceutical Sandimmune, which also contains the compound cyclosporine A. Because NeuroVive's previously conducted phase I trial demonstrated bioequivalence between CicloMulsion® and Sandimmune, the trial conducted by Hospices Civils de Lyon could constitute a phase II trial on CicloMulsion®. This opened the possibility of participation in external clinical trials in Europe, the USA and China. The reason for CicloMulsion's® selection ahead of the intravenous preparation of Sandimmune is that Sandimmune has been reported as causing hypersensitivity reactions. This can be attributed to Sandimmune containing the solvent Cremophor EL®. NeuroVive has developed a Cremophor EL®-free preparation of cyclosporine A for intravenous treatment.

NeuroVive is now participating in a mostly externally funded

phase III trial. The trial is being conducted and executed in France, Belgium and Spain, by Hospices Civils de Lyon. This trial is randomized, placebo-controlled and double blind, with patients receiving an injection of CicloMulsion® (or placebo) prior to reperfusion treatment with PCI. CicloMulsion® is administered in a single, intravenous dose 10-15 minutes prior to PCI, at a dose of 2.5 mg/kg. To date, over 900 patients have been enrolled, of the planned enrolment of a total 972.

NeuroVive supplies the study centers in France, Belgium and Spain with CicloMulsion®, placebo and logistics support for drug distribution. Given a positive outcome of the trial, and assuming that it is classified as pivotal with the aim of presenting proof of the pharmaceutical's market approval, NeuroVive plans to file an application to the French pharmaceutical regulator as the first stage in a European launch. The partnership with Sihuan in China is enabling clinical trials on CicloMulsion® in China as a complement to the phase III trial in Europe for market approval in China. Manufacturing is being conducted by Fresenius Kabi Austria, an internationally recognized player. NeuroVive has invested in parts of a new production facility with Fresenius Kabi with the aim of being able to produce commercial volumes as required.

### Treating traumatic brain injury

TBI is an injury to the brain where the nerve cells are subjected to immediate damage. The injury then continues to exacerbate several days after the incident, which often significantly impacts on the overall damage. The Research Team that NeuroVive has contracted at Lund University has demonstrated that cyclosporine A, the active compound in NeuroSTAT®, has potent neuroprotective characteristics. By inhibiting the cyclophilin enzyme, thus stabilizing the mitochondria, NeuroSTAT® is expected to be able to limit the extent of brain damage.

#### DEVELOPMENT PLANS AND OBJECTIVES FOR CICLOMULSION®

EU	China
2014 and beyond	2014
<ul style="list-style-type: none"> <li>- Safety evaluation</li> <li>- Inclusion of patients in the external phase III trial. Final patient (of 972) enrolled in phase III CIRCUS trial.</li> <li>- Commencement of new follow-up study on patients in phase III trial and presentation of results from the external phase III trial</li> <li>- NDA in France, and after approval, in selected EU countries</li> <li>- Market approval in France and the EU</li> </ul>	<ul style="list-style-type: none"> <li>- Application for clinical trial authorization</li> <li>- Planned commencement of phase III trial in China based on phase I and II data from the EU</li> </ul>
	2015 and beyond
	<ul style="list-style-type: none"> <li>- Results of phase III trial in China presented</li> <li>- Application for market approval in China</li> </ul>

## NeuroSTAT®

#### NEUROSTAT®

Indication	Current treatment—guidelines	Limitations of current treatment, as judged by NeuroVive's Board	The results of NeuroVive's drug candidate as judged by the Board
Traumatic brain injury	<p>Intensive care, potential initial surgery.</p> <p>Treatment of symptoms in accordance with initial clinical assessment according to the GCS (Glasgow Coma Scale), which designates patient condition on injury. Clinical results based on GOS (Glasgow Outcome Scale), i.e. patient condition at a point after the actual injury.</p>	No neuroprotective pharmaceuticals available	Treatment with NeuroSTAT® protects nerve cells, improves GOS, enables fewer days of care, better rehabilitation and quality of life.

#### Clinical trials on NeuroSTAT®

At the end of 2012, NeuroVive was granted regulatory and ethical approval to commence a clinical phase IIa trial. This trial, on patients with acute TBI, commenced in 2013 and is being conducted at Copenhagen University Hospital. This is an open label study that is evaluating two different doses. The first three patients have been enrolled, of a total of 20. The primary end-point of the study is to evaluate the safety and blood concentrations of cyclosporine A. Secondary endpoints are to contribute to

our understanding of NeuroSTAT's® capacity to reduce the extent of patient brain damage by examining biomarkers of mitochondrial function and brain damage markers, etc. NeuroSTAT® is administered as a bolus dose of 2.5 mg/kg as soon after the injury as possible, and then at 5 or 10 mg/kg for five 24-hour periods as a continuous intravenous infusion.

The Company is also preparing a combined international multi-centre trial (phase IIb-/III) on patients with acute TBI to examine whether NeuroSTAT® can serve as a neuroprotective agent and

make a difference in the course of disease and prognosis for TBI patients. NeuroVive has established collaborations with eminent neurosurgeons in Europe, the USA and China for the implementation of its clinical trial program. NeuroVive plans to self-fund the ongoing phase to a trial on TBI. It intends to seek additional funding for the large-scale multinational phase IIb/III trial. The partnership with Sihuan in China is enabling the execution of clinical trials on NeuroSTAT® in collaboration with clinical centers in Europe and the USA, or as independent phase II and phase III trials in China.

The Company has secured orphan drug designation for NeuroSTAT® in moderate to severe cranial injury in the USA and EU, which confers market exclusivity after market approval even if patents no longer apply. Orphan drug designation confers exclusivity for seven years in the USA and ten years in the EU, from the date the Company is granted marketing authorization.

As far as the Company is aware, there is currently no registered and approved pharmaceutical on the market, which in placebo-controlled trials, has demonstrated to protect against necrosis in TBI.

#### Development plan and objectives for NeuroSTAT®

After evaluating new ways to conduct clinical trials with a tailored trial design, NeuroVive has started work on its investigational new drug (IND) application to conduct an international and combined phase IIb/III trial on NeuroSTAT®, with geographical coverage in the USA, Europe and China. In tandem with its regulatory discussions with the FDA in the USA, the Company intends to contact

bodies including the US?? Department of Defense and the NIH, the US counterparty of the Swedish Research Council, with the objective of seeking financial support for this international trial.

Despite this trial being blind, i.e. no one knows whether patients are receiving the active pharmaceutical or placebo, a tailored trial design enables continuous patient follow-ups during the term of the trial through a dedicated evaluation committee. This strategy enables faster evaluation of data, and thus potentially, shorter time to market than in traditional trial design.

Researchers not affiliated to NeuroVive previously conducted a phase II trial on cyclosporine A in the USA on TBI patients. There have been plans in place for several years to conduct a phase III trial in the USA. Researchers previously secured resources to plan the phase III trial, and were also allocated fundable score from the NIH, which generally means securing capital for implementing the trial is more likely. The physicians behind the plan trial have previously expressed an interest in NeuroVive's drug candidate NeuroSTAT®. However, as communicated in a prospectus issued previously issued by NeuroVive, there is some uncertainty surrounding the NIH's priorities and budget, and thus for the implementation of this external trial.

#### DEVELOPMENT PLANS AND OBJECTIVES FOR NEUROSTAT®

EU		USA and China**	
2014 -2015	- Results of phase IIa presented	2014-2015	- Commencement of combined phase IIb/III
	- Discussions with regulatory authorities*	2015 and beyond	- Results of phase IIb/III presented
	- Commencement of combined phase IIb/III		- Application for marketing authorization
2015 and beyond	- Results of phase IIb/III presented		

\* Discussions with the regulatory authorities and regulatory standards will determine the scale of the phase IIb/III program, and consequently, the time to execute a clinical trial, and thus affect the timing of when NeuroSTAT® can come to the market.

\*\* Regulatory standards in China enable approval based on only one phase III trial in China if data from phase I and phase II these available from clinical trials either in the EU or USA. (ref: discussions with two pharmaceutical companies in China and BHR Pharma; Cochrane Review 2011; Progesterone for acute traumatic brain injury). Chinese partnership required.



## Other projects

### NVP014

#### NVP014

Indication	Current treatment—guidelines	Limitations of current treatment, as judged by NeuroVive's Board	The results of NeuroVive's drug candidate as judged by the Board
Stroke	American Heart Association—stabilizing patient, computed tomography and thrombolytic treatment (dissolving a blood clot obstructing a blood vessel)	Brief treatment window for thrombolytic therapy. No existing neuroprotective pharmaceuticals that reduce injury post stroke.	Treatment with NVP014 improves outcomes by reducing nerve cell damage after stroke, fewer days of care for the patient.

In a stroke, the blood-brain barrier is not open to some pharmaceuticals in the same manner as in TBI. In October 2010, NeuroVive and to-BBB Technologies BV, a Dutch biotech enterprise with a technology for transporting pharmaceuticals across the blood-brain barrier, signed an agreement intended to develop pharmaceuticals against stroke and other acute neurological conditions by combining both companies' technologies.

NVP014 (currently jointly owned with to-BBB Technologies BV) consists of cyclosporine surrounded by a sheath of lipids and proteins, which make up a micelle. Micelles developed jointly with to-BBB Technologies BV consist of fat globules with special surface characteristics enabling them to transit the blood-brain barrier more readily and deliver cyclosporine to brain tissue for the desired neuroprotection.

NeuroVive intends to conduct several animal trials on drug candidates produced to corroborate increased penetration across the blood-brain barrier and the efficacy of NVP014 on mitochondrial damage and neuroprotection. Assuming positive outcomes in preclinical animal trials, the compound will then enter a well-defined development phase on subjects including animals, with the aim of generating toxicology and dosage data for the first dose in humans, as is fully consistent with pharmaceutical regulators' standards. NeuroVive and to-BBB Technologies BV secured a EUR 1 m Eureka Eurostars grant in 2011 for this joint preclinical development program.

#### DEVELOPMENT PLAN AND OBJECTIVES FOR NVP014

##### EU

- 2014 and beyond
  - Continued in vivo animal trials and commencement of preclinical toxicology
  - Commencement of phase I trial
  - Selection of strategic partner

## NVP015

NVP015 is NeuroVive's energy-regulating preparation whose aim is to serve as specific intravenous acute therapy for conditions involving cellular energy crisis. NeuroVive is conducting and jointly owns this R&D project with Mitopharm Ltd. The objective is to generate pharmaceuticals for a number of fairly unusual pediatric diseases with orphan drug designation, and potentially, large patient groups where the body can benefit from additional energy production, such as in extended surgery, intensive care, etc. The intention is firstly, to address patients with specific congenital

defects in mitochondrial function (primary mitochondrial disease) and secondly, patients with normal mitochondria but where acute energy shortage is a central component of the condition (secondary mitochondrial disease). There is a possibility of securing orphan drug designation for treating primary mitochondrial diseases such as Leigh syndrome and MELAS. Apart from developing compounds as traditional pharmaceuticals, there may be an opportunity to prepare products defined as food supplements and specific nutrition products for diseases.

### DEVELOPMENT PLAN AND OBJECTIVES FOR NVP015

EU	
2014	<ul style="list-style-type: none"><li>- Production and ongoing formulation work ON designated drug candidates</li><li>- preclinical toxicology and proof of concept studies in animal trials</li></ul>
2015 and beyond	<ul style="list-style-type: none"><li>- Commencement of phase I trial (depending on the progress of animal trials and formulation work in 2014)</li><li>- Application for orphan designation</li></ul>

## NEXT-GENERATION CYCLOPHILIN INHIBITOR

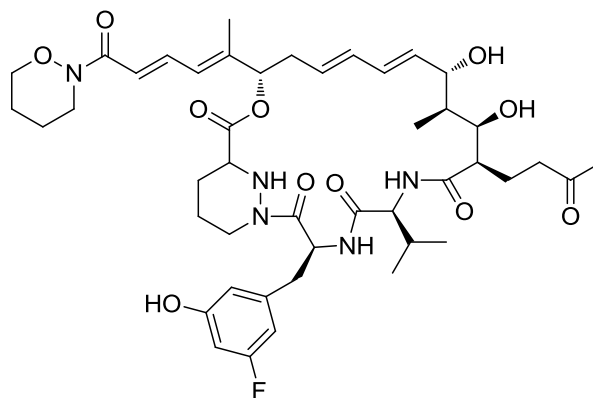
NeuroVive's ambition has been to identify an optimal successor to its current candidates in clinical development. The Company has conducted discussions with several potential partners, and evaluated a number of molecules in dedicated agreements. Some of the molecules screened are specific versions of cyclosporine and other molecular structures, which are potent inhibitors of cyclophilin, can transit the blood-brain barrier and into the brain. The intention is to produce new cyclophilin inhibitors for intravenous use, and as per oral preparations. The target is that the active compound in NeuroVive's current intravenous pharmaceutical preparation, cyclosporine A, may be followed up by more specific pharmaceuticals eventually, which potentially, may have broader applications in segments including neuroprotection and heart cell protection. One such application would be to also be able to treat

chronic neurological conditions such as dementia as a complement to treating acute neurological conditions, which requires the various drug candidates to have per oral preparations and high safety with low risk of adverse events. The development work has identified an array of mitochondria-protecting drug candidates, which will undergo further evaluation for potential in-licensing and development.

Consistent with NeuroVive's ambitions, the Company acquired the rights to potent cyclophilin inhibitors from UK pharmaceutical company Biotica Ltd. in 2013. The aim was to secure the next generation of cyclophilin inhibitor, designated NVP019 by NeuroVive. This acquisition also included anti-viral therapy projects, such as hepatitis B/C, which after complementary preclinical trials and formulation work, is ready for clinical trial, designated NVP018 by NeuroVive.

### NVP019

NVP019 is in development as the next generation of cyclophilin inhibitor focusing on myocardial infarction and brain damage. The drug candidate has been demonstrated as more potent and with more specific efficacy than cyclosporine A (the active compound in NeuroSTAT®/CicloMulsion®). This drug candidate is also potentially even more tolerable than cyclosporine A and effective at lower doses, as well as having significantly longer patent protection than CicloMulsion®. The target is to develop a follow-up preparation to NeuroSTAT®/CicloMulsion® for brain-damaged/reperfusion injury, but also to extend applications to also cover acute heart conditions and brain injury. NVP019 is currently in the early preclinical phase, focusing on intravenous formulation work.



### NVP018

Research and development of anti-viral pharmaceuticals is not directly related to mitochondrial medicine, but viral diseases may potentially be treatable with cyclophilin inhibitors. Accordingly, alternatives are being examined regarding capitalizing on the drug candidate. The business strategy is to maximize the value of this project with limited funds by developing drug candidates up to and including the first dose in humans, with the objective of demonstrating efficacy against viral disease. Discussions are being conducted with potential partners in tandem with this work.

This initiative is also justified by the development of NVP019, a joint production process with NVP018, where the same base compound is used for the oral preparation of NVP018 as in the intravenous preparation of NVP019. Accordingly, there are synergies in formulation work and parts of preclinical development work, which will generate substantial cost savings. The difference between the preparations is in the type of preparation exclusively. The intention is to develop NVP019 to an intravenous formulation and NVP018 into a per oral formulation.

#### DEVELOPMENT PLAN AND OBJECTIVES FOR NEXT-GENERATION CYCLOPHILIN INHIBITOR NVP019

EU	
2014	<ul style="list-style-type: none"><li>- Ongoing preclinical evaluation and formulation work on intravenous preparations</li><li>- Preclinical trials in various animal models of heart disease and TBI</li><li>- Formulation work and small-scale production</li></ul>
2015	<ul style="list-style-type: none"><li>- Commencement of phase I/II trials in selected patient groups</li></ul>

### FUTURE PROJECTS

Additionally, NeuroVive's operations include a number of other future projects.

- The Company is developing and plans to commercialize an analytical method ("ToxPhos"), to determine mitochondrial function in human blood corpuscles. The method can be applied within diagnostics and preclinical toxicology for drug development.
- As previously reported, development work in immunosuppression is a dormant project due to business priorities.

# Market overview

*In the years the Company has been active, NeuroVive has conducted research and development. The Company has not commercialized a pharmaceutical, and accordingly, has not reported any sales. NeuroVive is focusing on the Company's two drug candidates in clinical phases, CicloMulsion® and NeuroSTAT® for the indications of reperfusion injury after myocardial infarction and traumatic brain injury (TBI). NeuroVive's project portfolio also includes new molecules for energy regulation in mitochondria and new cyclophilin inhibitors for neuroprotection and heart cell protection. NeuroVive's earnings capacity is dependent on factors including potential license agreements with large pharmaceutical companies, if and when pharmaceuticals can be launched and the level of market penetration. Destum Partners estimates the total European and US market for the Company's two drug candidates in clinical phases at approximately SEK 7.2 bn (approx. USD 1.1 bn) with 10% market penetration.<sup>1,2</sup> Sihuan, NeuroVive's Chinese partner, estimates the value of the Chinese market for CicloMulsion® and NeuroSTAT® at over SEK 2 bn yearly.*

## Reperfusion injury after myocardial infarction – CicloMulsion®

Each year, an estimated three million patients in the EU and USA are affected by acute coronary artery disease and suffer heart attacks. Mortality is high (approx. 20%) in the first 24 hours after the infarction. There are several types of acute coronary artery disease based on ECG changes, and depending on the type of disease, PCI is implemented to varying degrees. On average, half of all patients undergo PCI with the objective of opening the coronary arteries, to enable improved oxygenation of the heart muscle and prevent new infarctions. Thrombolytic pharmaceuticals are currently an important component of treatment for myocardial infarction, but these pharmaceuticals do not protect the heart from reperfusion injury after PCI.<sup>3,4</sup>

Most patients that undergo PCI treatment develop reperfusion injury, which implies a greater risk of increasing the scale of the myocardial infarction and disruptions to heart rhythm. Similar complications arise in heart surgery. As far as the Company is aware, there are no approved pharmaceuticals available currently that protect against these reperfusion injuries. Accordingly, the development of pharmaceuticals that protect heart cells is a very attractive opportunity to address a market with a condition for which there is no effective therapy. The Company judges that the global market for CicloMulsion® is worth approximately SEK 5 billion per year, driven by an ageing population and a dramatic increase in the population suffering from obesity. Destum Partners estimates that total sales potential for CicloMulsion® four years post-launch is SEK 4.7 billion (approx. USD 700 m), given 10% market penetration, this amounts to SEK 1.5 billion (approx. USD 235 m) in the USA and the five largest EU countries (the UK, Germany, Italy, France and Spain).

## Traumatic brain injury, TBI – NeuroSTAT®

Acute TBI generates a substantial societal health care burden, which means there is a significant market in this segment. The absence of registered and approved pharmaceuticals for treating acute TBI and a pressing medical need also indicates that market penetration may be significant. Based on data from the EU and the USA, the estimated global market for severe TBI is approximately SEK 28 billion (including China and Japan). Other indications in the central nervous system (CNS) are additional, such as stroke and spinal cord damage. Destum Partners estimates the total sales potential of NeuroSTAT® four years after the launch at SEK 3 billion (approx. USD 500 m) in the USA and the five largest EU countries (the UK, Germany, Italy, France and Spain).<sup>7</sup>

As far as the Company is aware, there is no pharmaceutical available on the market at present for treating TBI that can improve neurological and functional outcomes after the primary injury. The result is that the market for TBI features a pressing medical need and substantial health care burden for patients, relatives and wider society. The societal cost for patient care is substantial and includes emergency care costs, rehabilitation and cost related to complications such as epilepsy and various psychiatric and psychological conditions. The estimated total care cost for an individual patient with severe TBI is between SEK 5 and 14 m. In the USA, TBI costs society nearly SEK 100 billion every year.<sup>8,9</sup>

### Notes

- 1 Datamonitor Report 2011.
- 2 Market Report, Destum Partners USA, 2012.
- 3 Global Data Report 2011.
- 4 Market Report Destum Partners, USA, 2012.
- 5 Datamonitor Report, 2011.
- 6 National Bureau of Statistics China, Espicom China Report, Q1 2012.
- 7 Market Report, Destum Partners USA, 2012.

The problem of severe cranial injury has become topical in recent years as a result of new patient groups coming into focus due to the absence of effective neuroprotective pharmaceuticals. Returning US defense personnel and greater concern of the long-term effects and development of Alzheimer's disease in this patient group, as well as cranial injury in various contact sports, have triggered new initiatives to produce effective pharmaceuticals for TBI. The yearly aggregate direct cost for medical care and therapy for severe cranial injury is over SEK 70 billion in the EU and USA. The estimated corresponding yearly indirect cost for production losses (such as lost employment and tax revenue) is over SEK 700 billion.<sup>10 11</sup>

Over three million patients are affected by TBI in the EU and USA every year. The number of patients that are hospitalized is nearly 600,000, and an estimated 250,000 patients suffer long-term disability.<sup>17</sup>

The Centers for Disease Control (CDC) in the US report that over five million US citizens (2% of the population) have some form of disability after TBI. Such patients have a long-term or permanent care need to cope with their daily lives post-injury. TBI can result in a large number of medical after-effects such as functional impairment affecting thinking, feelings, language and speech.

## Other projects

### ACUTE ISCHEMIC STROKE "AIS"—NVP014

The estimated yearly value of the global AIS market is currently approximately SEK 20 billion. Estimated annual market growth is 3-4%, which can be viewed in the context of there being few drug candidates in clinical development phases. A growing ageing population and dramatic increase in the population suffering from obesity are the biggest drivers of the need for neuroprotection in this market.<sup>12 13</sup> Like the market for TBI, the global AIS market is substantial, with a major medical need.

In the EU and USA, around two million patients suffer a stroke each year, 25% of them aged under 65. Estimated yearly mortality post-stroke is over 300,000 and the number that need hospital care is over a million. There are an estimated 200,000 surviving patients with long-term or permanent disability each year. This has a major impact on society, the patients affected and their relatives. Yearly direct health care costs are currently over SEK 350 billion. Yearly indirect costs for lost production (such as lost

employment and tax revenue) is an estimated SEK 200 billion. Destum Partners has estimated the sales potential for NVP014 four years after launch at SEK 1 billion (approx. USD 170 m) in the USA and the five largest EU countries (the UK, Germany, Italy, France and Spain).<sup>14 15 16</sup>

### HEPATITIS B—NVP018

Hepatitis B is caused by a virus transmitted in the blood. This virus can cause severe and chronic hepatitis, which is an infection in the liver. The WHO has stated that over two billion people worldwide have come into contact with the hepatitis B virus and 240 million people have developed chronic hepatitis B. This means the disease is one of the biggest global medical challenges. The chronic disease causes an estimated total of over 600,000 deaths every year depending on it causing advanced cirrhosis of the liver or primary liver cancer (hepatocellular cancer). The disease is present worldwide and is most common in South-east Asia, Eastern Europe and Africa, where the proportion of chronic carriers is over 8%. In Western Europe and the USA, the frequency is less than 1%.

At present there is no therapy that can cure the disease, but rather, the objective of treatment is to get the disease into a calm phase where the risk of complications is lower. Ultimately, the search is for a therapy that can enable the body's immune defense to control the disease (seroconversion). The estimated value of the market for hepatitis B is approximately USD 3 billion, consisting of interferon and nucleoside/nucleotide analogues. Of these, only interferon treatment can achieve the desired immune control (seroconversion), and then in a low share of patients.

Interferon has to be administered as an injection and long-term treatment is linked to severe adverse events, which overall, mean that many patients do not complete treatment. NVP018 has the characteristics of both attacking the virus, simultaneous with it inducing the cells' own interferon protection, as demonstrated in cell systems. If it were possible to produce a tablet form that could produce results equal to current interferon treatment, this would be a major advance.

#### Notes

- 8 National Institutes of Health, 1999, Thurman et al., 1999.
- 9 J Neurology 2012, 19;155-162.
- 10 Datamonitor TBI report 2010.
- 11 J Neurology 2012, 19;155-162.
- 12 Data Monitor Report 2011.
- 13 Market Report Destum Partners, USA, 2012.
- 14 Datamonitor Report 2011.
- 15 J Neurology 2012, 19;155-162.
- 16 Market Report Destum Partners USA, 2012.
- 17 Datamonitor Report 2011.

#### **NEXT GENERATION CYCLOPHILIN INHIBITOR—NVP019**

The goal of developing next-generation cyclophilin inhibitors, focusing on the treatment of severe cardiovascular disease and severe cranial injury, is to produce a follow-up preparation to CicloMulsion® and NeuroSTAT®, and thus retain, and eventually contribute to, NeuroVive's market leadership. The goal is also to extend the application segment in myocardial infarction and reperfusion injury to capture other severe heart conditions and acute conditions where general protection of the vital organs is central to the course of disease (label extension and lifecycle management). These new indications and potential markets have not been analyzed at present.

Drug candidate NVP019 has demonstrated potent and more specific mitochondrial protection than cyclosporine A (the active compound in CicloMulsion® and NeuroSTAT®). NVP019 is also potentially more tolerable than cyclosporine A and effective at lower doses (more potent). Drug candidate NVP019 has a very long-term patent protection. NVP019 is in the early preclinical development phase focusing on intravenous formulation work.

#### **ENERGY-REGULATING PREPARATION—NVP015**

This project is in the early preclinical development phase, the objective being to develop a specific intravenous acute treatment for conditions involving cellular energy crisis. Accordingly, pharmaceuticals in this group need to stimulate energy production in patients with specific congenital defects in mitochondrial function, known as primary mitochondrial disease. Another major potential application is conditions with normally functional mitochondria, but where acute energy shortage is a central component of the disease process, termed secondary mitochondrial disease, such as in long-term surgical procedures, intensive care and critical care patients, as well as various toxicological conditions.

Primary mitochondrial diseases are rare and affect 1 - 6 children per 100,000 births.<sup>1</sup> Accordingly, pharmaceuticals for treating primary mitochondrial disease have orphan drug designation, with better prospects of market approval than traditional pharmaceuticals, firstly through shorter clinical trial programs, and secondly due to the significant medical need. Records of pharmaceuticals that have passed through clinical trials demonstrate that 80% of trial pharmaceuticals with orphan drug designation are approved against only 35% of traditional pharmaceuticals. Accordingly, the time to market for orphan drugs is shorter, with the possibility of treating a large number of primary mitochondrial diseases such as Leigh Syndrome and MELAS. The value of the orphan drug market is several billion Swedish kronor, and the annual cost of treating

just one patient can be in the SEK 200,000 to SEK 1.5 million interval.

### **Competitors**

There is intense competition in the pharmaceutical sector. There are many corporations, universities and research institutions conducting drug research and development. Accordingly, NeuroVive and its collaboration partners face several potential competitors. The Company judges that competition is based on the current situation based on academic and trade studies that are ongoing. However, competition is continuously changing at a pace with the development being conducted.

Competition has positive and negative aspects. If a competitor is first to market in a segment where NeuroVive is active, the competitor's pharmaceutical could be expected to have an immediate impact on the global market, and thus secure the lead in sales and marketing in the struggle for market share. However, there is cause for NeuroVive to welcome competition; if a drug against a specific disease demonstrates clear clinical efficacy, the Company judges that it will trigger major interest, attracting further investment in the relevant market segment.

#### **ONGOING ACADEMIC AND TRADE STUDIES**

NeuroVive faces a number of competitors that are developing drugs for reperfusion injury after myocardial infarction and TBI. However, as far as the Company is aware, no other company has launched any pharmaceutical for neuroprotection or heart cell protection. There are currently over 162 clinical trials registered in the ClinicalTrials.gov database (NIH), which records trials of various treatments of severe TBI, but only a few of them (seven) have been recorded as specific pharmaceutical trials for neuroprotection. The corresponding figures for clinical trials for treating stroke is over 4,000, with only 41 specified as neuroprotection trials. The number of registered clinical trials for reperfusion injury post-myocardial infarction is increasing steadily, and was 75 in November 2013. Readers should note that some of these trials are being conducted by academic groups or institutions rather than pharmaceutical companies.

As far as the Company is aware, there are seven clinical trials with drug candidates addressing neuroprotection within TBI, of which a phase III on progesterone has progressed furthest. In this market segment, the Company judges that its competitive position with NeuroSTAT® is very positive against the background of a known target structure and mechanism of action of cyclosporine A.

The Company judges that competition is less severe in stroke

Note

<sup>1</sup> Orphanet Report Series Nov 2011 no 1

and neuroprotection. Few drug candidates and companies have been identified, which the Company judges as being due to difficulties in getting pharmaceuticals to transit the blood-brain barrier.

Accordingly, the Company also judges its competitive position in this market segment as very positive based on its collaborations with to-BBB Technologies BV and other enterprises in this segment, and the development of pharmaceuticals with characteristics that penetrate the blood-brain barrier.

The Company judges that all the aforementioned market segments are of significant size and feature a significant medical need. Accordingly, NeuroVive judges that the market launch of a neuroprotective or heart cell protective pharmaceutical would generate significant future revenues, even if at that time, there were already one or more pharmaceuticals on the market. Additionally, the Company judges that in the future, there will probably be a selection of neuroprotective pharmaceuticals addressing various phases of brain damage, and perhaps, various types of brain injury. In this respect, the Company judges that NeuroVive is well positioned with the Company's drug candidates targeting a key component in acute brain damage, namely the energy-producing mitochondria.

## CLINICAL COMPETITIVE POSITION

NeuroVive conducts competition analyses of the academic and trade sectors continuously. The following table only illustrates the leading companies and drug candidates that the Company regards as direct competitors to CicloMulsion®/NeuroSTAT® in terms of potential market launch within five to six years. Not all ongoing academic studies are registered in the database of clinical trials, and not all registered trials are viewed as direct competitors of the Company. Accordingly, this summary makes no claims to completeness.

The market segment recording most growth over the past five-year period is reperfusion injury after myocardial infarction, where at present, there are drug candidates in preclinical and clinical development phases. The Company judges that NeuroVive has very good positioning against competitors given its background of the ongoing external phase III trial in Europe and the usage of CicloMulsion®, which contains the active compound (cyclosporine A) and carrier medium already known to the pharmaceutical regulatory authorities.

### CLINICAL COMPETITIVE POSITION

Indication	Company	Drug candidate	Phase
Traumatic brain injury	BHR Pharma	Progesterone	Phase III
	Neuren Pharma	NNZ-2566	Phase II
	Emory Univ US Army	Progesterone	Phase III
	Academic study, London, UK	Tranexamic Acid	Phase III
	Academic study, AUS/NZ	Epoetin Alpha	Phase III
	Sanofi-Aventis	SAR127963	Phase I
	Acorda	AC105	Phase I
	Remedy Pharmaceuticals	RP-1127	Phase II
	Vasopharm	VAS203	Phase II
Stroke	Merck & Co	Astrocyte modulator	Phase I
	D-Pharm	DP-b99	Phase III*
	Mitsubishi Tanabe Pha	Edaravone	Phase II
	NoNO Inc	NA-1	Phase II
	Anavex	Anavex 2-73	Phase I
	ReNeuron	ReN001	Phase I
	GNT Pharma	Neu2000-KL	Phase I
Reperfusion injury	Stealth Peptides	Bendavia	Phase II
	Trophos	TRO40303	Phase II
	PledPharma	PP-099	Phase II
	Herlev Hospital	Melatonin	Phase II
	Fibrex Medical RnD	FX06	Phase II

\* Temporarily suspended by safety committee.

### PRECLINICAL COMPETITIVE POSITION

The following table only illustrates the leading companies and drug candidates that the Company regards as direct competitors to NeuroVive's project portfolio and makes no claims to completeness. There are further studies of drug candidates in academic environments that have not yet been incorporated, and there may be patents that have not yet been made public.

Against the background of an analysis of NeuroVive's current competitive position, the Company judges that NeuroVive's

project portfolio is well positioned in neuroprotection and heart cell protection. The Company's scientific assessment of competing drug candidates in preclinical and clinical phases is that no drug candidate has demonstrated as potent cell protection as cyclosporine A. As far as the Company is aware, cyclosporine A is the only pharmaceutical that has demonstrated the potential to protect the mitochondria of the cell and secure cell energy production to date, and in this way, block several mechanisms that could otherwise lead to necrosis.

### PRECLINICAL COMPETITIVE POSITION

Indication	Company	Drug candidate	Phase
<b>Traumatic brain injury</b>	Stealth Peptides	Small peptides	Discovery
	Sinapsis Pharma	Methamphetamine	Preclinical
	Neurokin	NK-101	Preclinical
	Actelion	Clazosentan	Preclinical
<b>Stroke</b>	Neurokin	NK-102	Preclinical
<b>Reperfusion injury</b>	Gliamed	GM1485	Preclinical
	Scynexis	NICAMS	Preclinical
	Radical Therapeutix	RX-1005	Preclinical



# History

1993-1994

■ Eskil Elmér and colleagues discover that cyclosporine A is potentially neuroprotective once it has transited the blood-brain barrier.

1995

■ Patent application filed and original discovery published.

1997

■ Marcus Keep and Eskil Elmér start up Maas Biolab, LLC in the US.

1999

■ US Patent & Trademark Office grants the patent that forms the foundation of NeuroVive's first project portfolio.

2000

■ NeuroVive formed (then called NeuroPharma i Sverige AB).

2001-02

■ More patents granted on cyclosporine as a neuroprotective pharmaceutical compound.

2003

■ NeuroVive in-licenses patents and trademark rights for operations from Maas Biolab, LLC (transferred to direct ownership in 2008.)

2004

■ NeuroVive in-licenses formulation patent for NeuroSTAT® from CicloMulsion AG of Germany.

2006-07

■ NeuroVive in-licenses formulation patent for NeuroSTAT® from CicloMulsion of Germany. NeuroVive executes two small-scale capital raisings to consolidate and develop its business.

2008

■ Aug Agreement with Fresenius Kabi. Agreement on manufacturing and registration work for NeuroSTAT®.

NeuroVive's IPO on Aktietorget marketplace.

NeuroVive is the highest-turnover share of the 100-plus companies listed on Aktietorget.

2009

■ Sep/Oct SEK 9.5 m new issue and IPO on Aktietorget.  
■ Nov Scientific validation of NeuroSTAT®'s mechanism of action in human brain tissue.

■ Jun Ethical approval of a clinical trial on NeuroSTAT®.  
■ Nov/Dec Clinical trial on NeuroSTAT® conducted. Pharmacokinetic and safety trial on 65 individuals.

2010

■ Mar Acquisition of patents from CicloMulsion AG. NeuroVive exercises its option to purchase patent rights for CicloMulsion®/NeuroSTAT®.

■ Mar Successful results from the NeuroSTAT® trial. NeuroSTAT® demonstrates bioequivalence and a superior safety profile to comparative preparation Sandimmune® Injection.

■ Apr Mikael Brönnegård appointed CEO. Former CEO Eskil Elmér focuses on work as CSO.

May

SEK 39 m new issue, oversubscribed by SEK 41 m, executed.

NeuroVive is the highest-turnover share of the 100-plus companies listed on Aktietorget.

2011

■ Mar Agreement on a phase II/III trial on traumatic brain injury (TBI). Agreement signed with the European Brain Injury Consortium, EBIC, on the execution of a combined phase II/III trial on NeuroSTAT® in traumatic brain injury.

■ Dec Subsidiary incorporated in China. This subsidiary, NeuroVive Pharmaceutical Asia Ltd., started up in Hong Kong to serve the Chinese market. The company is 70% owned by NeuroVive and 30% by collaboration partner Foundation Asia Pacific Ltd.

■ Dec NeuroSTAT® granted orphan drug designation in the US, implying market exclusivity for seven years for moderate to severe traumatic brain injury from the date of marketing authorization.

■ Dec Agreement with Lyon University Hospital for a phase III cardiac trial (CIRCUS trial). CicloMulsion® designated for use on multinational phase III trial on myocardial infarction on up to 1,000 patients.

■ Oct Collaboration agreement with to-BBB technologies BV. Partnership to develop pharmaceuticals that can transit the blood-brain barrier in severe traumatic brain injury.

■ Jun NeuroSTAT® granted orphan drug designation in Europe, implying market exclusivity for ten years for moderate to severe traumatic brain injury from the date of marketing authorization.

2012

■ Jan 200 patients treated in the phase III cardiac trial (CIRCUS trial).

■ Apr Expanded production capacity for NeuroSTAT® and CicloMulsion®. Agreement with Fresenius Kabi enabling expansion to full-scale production of NeuroSTAT® and CicloMulsion®. Relocation to Medicin Village, Lund, Sweden.

■ Apr/May SEK 55 m new share issue completed. Phase III cardiac trial (CIRCUS trial) passes 300 patients and safety checks. Trial continues as planned after safety checks and expanded to include Belgium and Spain.

■ Oct Three new candidate drugs (CDs) for mitochondrial energy regulation developed. Potential for these new CDs to be used in diseases with compromised energy production, which have been developed with Selcia Holdings Ltd.

■ Nov Collaboration agreement with Sihuan Pharmaceutical on CicloMulsion® and NeuroSTAT® in China. This agreement covers the development and commercialization of CicloMulsion® and NeuroSTAT® on the Chinese market.

NeuroVive listed on NASDAQ OMX.

2013

■ Jun Collaboration agreement with Isomerase Therapeutics. This agreement is on the product development and commercialization of the molecules acquired from Biotica Ltd. earlier in the year.

■ Jun First milestone payment of SEK 5.3 m paid to NeuroVive's Asian subsidiary for development in China.

■ Jun First patient enrolled to clinical phase II trial for TBI. Trial on 20 patients at the Copenhagen University Hospital intended to evaluate NeuroSTAT®'s pharmacokinetics and safety in TBI.

■ Apr Listing on NASDAQ OMX Stockholm. NeuroVive's shares trading on NASDAQ OMX Stockholm, Small cap since 10 April.

■ May 700 patients enrolled in the phase III cardiac trial (CIRCUS trial). Trial progressing as planned, and approaching conclusion.

■ Mar Acquisition of new potential cyclophilin inhibitors from Biotica Ltd. The new product portfolio extends operations to anti-viral indications (hepatitis B/C) that may also complement or constitute a new generation of pharmaceuticals in the cerebral and cardiac segment.

# Financial overview

The following tables show extracts from historical financial information for the financial years 2010, 2011 and 2012. The information is sourced from the Company's audited Annual Accounts, which have been prepared in accordance with International Financial Reporting Standards (IFRS), as endorsed by the EU, and the Swedish Annual Accounts Act. Information corresponding to unaudited consolidated accounts for the interim periods 1 January-30 September 2013 and the corresponding period 2012 have been sourced from the Company's Interim Report for the period 1 January-30 September 2013, which has been prepared in accordance with IAS 34 Interim Financial Reporting.

The following summary of the Company's accounts should be examined alongside NeuroVive's audited annual reports and associated notes for the financial years 2010, 2011 and 2012, as well as the unaudited information contained in the Interim Report for the period 1 January-30 September 2013, which have been incorporated into this prospectus is by reference.

## Summary Consolidated Income Statement

(SEK 000)	1 Jan. 2013 - 30 Sep. 2013	1 Jan. 2012 - 30 Sep. 2012	2012	2011	2010
Net sales	5,335	-	-	-	-
Other operating income	1,586	520	1 328	440	108
	<b>6,921</b>	<b>520</b>	<b>1 328</b>	<b>440</b>	<b>108</b>
<b>Operating expenses</b>					
Other external expenses	-15,784	-8,229	-12,793	-7,136	-2,626
Personnel expenses	-4,002	-3,227	-4,565	-2,830	-1,614
Depreciation, amortization and impairment losses	-109	-79	-128	-104	-23
Other operating expenses	-86	-131	-161	-91	-17
	<b>-19,981</b>	<b>-11,666</b>	<b>-17,827</b>	<b>-10,161</b>	<b>-4,280</b>
<b>Operating income</b>	<b>-13,060</b>	<b>-11,146</b>	<b>-16,499</b>	<b>-9,721</b>	<b>-4,172</b>
<b>Financial items</b>					
Financial revenues	267	392	614	442	154
Financial expenses	-164	-1	-18	-1	-605
	<b>103</b>	<b>391</b>	<b>596</b>	<b>441</b>	<b>-451</b>
<b>Profit/loss before tax</b>	<b>-12,957</b>	<b>-10,755</b>	<b>-15,903</b>	<b>-9,280</b>	<b>-4,623</b>
Income tax	-	-	-	-	-
<b>Profit/loss for the period</b>	<b>-12,957</b>	<b>-10,755</b>	<b>-15,903</b>	<b>-9,280</b>	<b>-4,623</b>
Translation differences when translating foreign subsidiaries	4	75	39	-	-
<b>Total comprehensive income for the period</b>	<b>-12,953</b>	<b>-10,680</b>	<b>-15,864</b>	<b>-9,280</b>	<b>-4,623</b>
<b>Profit/loss for the period attribute to:</b>					
Parent company shareholders	-13,793	-10,145	-14,873	-9,237	-4,623
Non-controlling interests	836	-610	-1 030	-43	-
	<b>-12,957</b>	<b>-10,755</b>	<b>-15,903</b>	<b>-9,280</b>	<b>-4,623</b>
<b>Total comprehensive income for the year attributable to:</b>					
Parent company shareholders	-13,790	-10,070	-14,846	-9,237	-4,623
Non-controlling interests	837	-610	-1 018	-43	-
	<b>-12,953</b>	<b>-10,680</b>	<b>-15,864</b>	<b>-9,280</b>	<b>-4,623</b>

## Summary Consolidated Statement of Financial Position

(SEK 000)	30 Sep. 2013	30 Sep. 2012	2012	2011	2010
ASSETS					
<i>Non-current assets</i>					
<b>Intangible assets</b>					
Capitalized expenditure for product development	36,119	25,346	30,042	17,840	11,583
Patents	6,340	2,350	2,416	2,631	2,670
Software	187	267	247	327	-
	<b>42,646</b>	<b>27,963</b>	<b>32,705</b>	<b>20,798</b>	<b>14,253</b>
<b>Property, plant and equipment</b>					
Equipment	487	736	665	148	39
	<b>487</b>	<b>736</b>	<b>665</b>	<b>148</b>	<b>39</b>
Total non-current assets	43,133	28,699	33,370	20,946	14,292
<i>Current assets</i>					
<b>Other receivables</b>	<b>414</b>	<b>497</b>	<b>734</b>	<b>399</b>	<b>191</b>
Prepaid expenses and accrued income	372	191	225	102	190
Cash and cash equivalents	14,995	43,565	37,177	12,795	27,753
Total current assets	15,781	44,253	38,136	13,296	28,134
<b>TOTAL ASSETS</b>	<b>58,914</b>	<b>72,952</b>	<b>71,506</b>	<b>34,242</b>	<b>42,426</b>
EQUITY AND LIABILITIES					
<i>Equity</i>					
Share capital	958	958	958	747	747
Other paid-up capital	98,049	98,049	98,049	51,938	51,528
Provisions	4	75	27	-	-
Accumulated profit or loss	-48,700	-30,205	-34,933	-20,060	-10,826
	<b>50,311</b>	<b>68,877</b>	<b>64,101</b>	<b>32,625</b>	<b>41,449</b>
Non-controlling interests	-221	-650	-1 058	-40	-
Total equity	50,090	68,227	63,043	32,585	41,449
<i>Liabilities</i>					
<b>Long-term liabilities</b>					
Deferred tax liability	-	-	-	-	-
<b>Short-term liabilities</b>					
Accounts payable–trade	3,862	1,274	4,724	818	430
Other liabilities	1,805	718	1,103	142	72
Accrued expenses and deferred income	3,157	2,733	2,636	697	475
Total liabilities	8,824	4,725	8,463	1,657	977
<b>TOTAL EQUITY AND LIABILITIES</b>	<b>58,914</b>	<b>72,952</b>	<b>71,506</b>	<b>34,242</b>	<b>42,426</b>

## Consolidated cash flow summary

(SEK 000)	1 Jan. 2013 - 30 Sep. 2013	1 Jan. 2012 - 30 Sep. 2012	2012	2011	2010
<b>Cash flow from operating activities</b>					
Operating income	-13,060	-11,146	-16,499	-9,721	-4,172
Depreciation and amortization	109	79	128	104	23
Unrealized internal exchange rate differences	-	75	30		
Interest received	297	353	570	411	96
Interest paid	-44	-1	-18	-1	-605
Cash flow from operating activities before change in working capital	-12,698	-10,640	-15,789	-9,207	-4,658
<b>Change in working capital</b>					
Increase/decrease in other current receivables	143	-148	-414	-84	-231
Increase/decrease in other short-term liabilities	-1,901	2,456	3,981	680	-144
	-1,758	2,308	3,567	596	-375
Cash flow from operating activities	-14,457	-8,332	-12,222	-8,611	-5,033
<b>Investing activities</b>					
Purchase of property, plant and equipment	-28	-333	-665	-139	-38
Purchase of intangible assets	-7,742	-6,887	-9,053	-6,618	-5,679
Cash flow from investing activities	-7,770	-7,220	-9,718	-6,757	-5,717
<b>Financing activities</b>					
Bridge finance raised	-	-	-	-	6,050
Amortization of bridge finance	-	-	-	-	-6,050
New share issue	-	46,322	46,322	-	35,787
Issue of share warrants	-	-	-	410	-
Cash flow from financing activities	-	46,322	46,322	410	35,787
Cash flow for the year	-22,227	30,770	24,382	-14,958	25,037
Cash and cash equivalents at beginning of period	37,177	12,795	12,795	27,753	2,716
Exchange rate difference in cash and cash equivalents	45	-	-	-	-
Cash and cash equivalents at end of period	14,995	43,565	37,177	12,795	27,753

## Key figures and selected financial items

	1 Jan. 2013 - 30 Sep. 2013	1 Jan. 2012 - 30 Sep. 2012	2012	2011	2010
Operating margin (%)	Neg.	Neg.	Neg.	Neg.	Neg.
Cash and cash equivalents (SEK 000)	14,995	43,565	37,177	12,795	27,753
Equity ratio (%)	85	94	88	95	98
Total assets (SEK 000)	58,914	72,952	71,506	34,242	42,426
Acid test ratio (%)	179	937	451	802	2,880
Dividend (SEK)	-	-	-	-	-
Earnings per share (SEK)	-0,72	-0,60	-0,85	-0,62	-0,32
No. of shares outstanding	19,159,046	19,159,046	19,159,046	14,942,857	14,942,857

## Definitions of key figures

### OPERATING MARGIN

Operating income divided by total revenue

### EQUITY RATIO

Equity divided by total assets

### ACID TEST RATIO

Current assets excluding inventories divided by short-term liabilities

### EARNINGS PER SHARE

Earnings per share before and after dilution based on the average no. of shares

# Comments on financial summary

## REVENUES AND OPERATING INCOME

In 2011, operating expenses increased to SEK -10,161,000 (-4,280,000). Other external expenses increased from SEK -2,626,000 to SEK -7,136,000, affected by increased consulting expenses linked to intensified development and commercialization, as well as travel expenses. The increase is also partly due to increased personnel expenses, from SEK -1,614,000 to SEK -2,830,000, because the number of employees increased, and expenses relating to the incentive program. Other operating income increased to SEK 440,000 (108,000), of which SEK 402,000 (75,000) was an EU subsidy from Vinnova, Sweden's Governmental Agency for Innovation Systems. This resulted in an operating loss in 2011 of SEK -9,721,000 (-4,172,000). In 2012, other operating income increased to SEK 1,328,000, the majority being an EU subsidy from Vinnova. Operating expenses increased by SEK 7,666,000 to SEK 17,827,000, due to other external expenses and personnel expenses increasing to SEK 12,793,000 and SEK 4,565,000 respectively. The increase in other external expenses was primarily due to operating expenses in the Company's subsidiary in China and expenses for the preparations conducted ahead of the IPO process on NASDAQ OMX Stockholm. The increase in personnel expenses to SEK 4,565,000 (2,830,000) was due to an increased number of employees and increased Directors' fees. Thus the consolidated operating loss was SEK -16,499,000.

Consolidated sales in the first nine months of the year were SEK 5,335,000 (0), consisting of payments received by 70%-owned subsidiary in China, NeuroVive Pharmaceutical Asia Ltd., for milestones achieved according to a collaboration agreement. The majority of the Group's other operating income for the first nine months, of SEK 1,000,586 (520,000), consist of EU subsidies received from Vinnova. The operating loss for the first nine months of SEK -13,060,000 (-11,146,000) was positively affected by the revenues of the subsidiary. However, increased operating expenses mean that the operating deficit was higher than the corresponding period of the previous year. The net loss before tax in the first nine months was SEK -12,957,000 (-10,755,000). The operating loss was affected by increased external expenses, which were SEK -15,784,000 (-8,229,000). For the first nine months, expenses relating to development projects affected profit or loss by SEK -2,562,000 (0). These expenses relate to development projects which have been written off directly to profit or loss effective the fourth quarter of 2012. The Company has also incurred expenses relating to its IPO on NASDAQ OMX, consulting expenses that were higher than the corresponding period of the previous year and expenses for legal counsel coincident with the ongoing arbitration procedure with CicloMulsion AG. Personnel expenses also increased, to SEK -4,002,000 (-3,227,000) due to a higher number of employees than the corresponding period the previous year due to the intensification of development work. Financial expenses amount to SEK -164,000 (-1000), the majority consisting of expenses for a SEK 4,000,000 funding facility.

## BALANCE SHEET

As of 31 December 2011, total assets were SEK 34,242,000 (42,426,000), when equity had decreased to SEK 32,585,000 (41,449,000). The change in 2011 was primarily affected by the loss for the period of SEK -9,280,000 (-4,623,000), and the change in 2010 was affected by an injection of SEK 35,787,000 via a new share issue. Intangible assets increased by SEK 6,545,000 on 2010, relating to the capitalization of development expenses of SEK 6,257,000. The Group's cash position as of 31 December 2011 was SEK 12,795,000, down by SEK 14,958,000. Most of the change is due to the operating loss and the capitalization of development expenses and patents.

Total assets as of 31 December 2012 were SEK 71,506,000, and equity had increased to SEK 63,043,000. The increase was mainly due to the new share issue of SEK 46,322,000 conducted in spring 2012, but was also negatively affected by a net loss of SEK -14,873,000. Intangible assets had increased by SEK 11,907,000 to SEK 32,705,000, of which SEK 12,202,000 was capitalization of development expenses. Equipment increased by SEK 517,000 to SEK 665,000, for equipment used in development projects. The Group's cash position as of 31 December 2012 was SEK 37,177,000. Short-term liabilities increased by SEK 6,806,000 to SEK 8,463,000.

As of 30 September 2013, total assets were SEK 58,914,000 (71,506,000), when equity had decreased to SEK 50,090,000 (63,043,000). The decrease was mainly because of the loss for the period. Intangible assets had increased by SEK 9,941,000 on 30 September 2012, relating to the capitalization of development expenses of SEK 6,077,000, and patents of SEK 3,924,000. The Group's cash position as of 30 September 2013 was SEK 14,955,000 (37,177,000). Most of the change was due to an operating loss and capitalization of development expenses and patents. Short-term liabilities for accounts payable, other liabilities and accrued expenses were SEK 8,824,000, of which SEK 1,248,000 were interest-bearing.

## CASH FLOW

Cash flow from operating activities increased to SEK -8,611,000 (5,033,000) in 2011, mainly relating to operating income. The negative flow in 2010 also related to interest paid on bridge finance. In 2011, cash row from investing activities was negatively affected, mainly because of capitalized development expenses and the acquisition of patents, and then amounted to SEK -6,757,000 (-5,717,000). Cash flow from financing activities was positively affected by SEK 410,000 (35,787,000) due to employees' payments for share warrants while the strong cash flow in 2010 was due to a new share issue. Total cash flow in 2011 was SEK -14,958,000 (25,037,000). Cash and cash equivalents at the end of 2011 were SEK 12,795,000 (27,753,000). Compared to 2011, cash flow from operating activities increased to SEK -12,222,000 in 2012. Primarily, cash flow was affected by a widening operating loss, but also by increasing short-term liabilities. Cash flow from investing activities also increased, amounting to SEK -9,718,000. Mainly, investments were capitalized development expenses but also acquisitions of equipment used in development projects. The new share issue completed in the year increased cash flow by SEK 46,322,000. Total cash flow for 2012 was SEK 24,382,000, and cash and cash equivalents at year-end were SEK 37,177,000.

Consolidated cash flow for the first nine months was SEK -22,227,000 (30,770,000), where the previous year's cash flow was affected by the new share issue of SEK 46,322,000. The change in working capital affected cash flow negatively by SEK -4,066,000 on the previous year, SEK -1,758,000 (2,308,000). The lower cash flow was also affected by increased a widening operating loss of SEK -13,060,000 (-11,146,000). Investments affected cash flow by SEK -7,770,000 (-7,220,000) in 2013. Cash flow was positively affected by milestone payments received.

# Equity, liabilities and other financial information

## FINANCIAL RESOURCES AND FINANCIAL STRUCTURE

Cash and cash equivalents on 30 November 2013 were SEK 8,408,000, consisting of bank balances of SEK 8,408,000. The absence of loans and a high cash position resulted in negative net debt of SEK 7,231,000. The Board of Directors judges that NeuroVive's short-term solvency is good, but to consider long-term solvency as good, NeuroVive needs to raise capital through a new share issue. The cash and cash equivalents the Company will raise through the current new issue will be used for current development projects. As far as the Board of Directors of NeuroVive is aware, there are no limitations to the usage of capital.

## INTANGIBLE ASSETS

Consolidated intangible assets amount to SEK 45,484,000 as of 30 November, and mainly consist of capitalized development expenses and patents.

## PROPERTY, PLANT AND EQUIPMENT

The Group holds no current and/or planned property, plant and equipment or leased assets of material significance. As of 30 November 2013, consolidated property, plant and equipment was SEK 459,000, being wholly equipment. The Company does not have any mortgages or charges on its property, plant and equipment. In this context, there are no relevant environmental factors that could affect the Group's usage of property, plant and equipment.

## CONSOLIDATED EQUITY AND LIABILITIES

The Group's net debt/equity ratio as of 30 November 2013 was -16% due to the Group's high liquidity and the absence of interest-bearing liabilities. As of 30 November 2013 there were no loans, collateral or guarantee commitments nor any indirect liability or contingent liabilities.

## PROVISIONS

There were no provisions or accrued amounts for pensions or similar benefits.

## Working capital

The existing working capital is not sufficient for current needs over the forthcoming 12-month period. Since inception, NeuroVive has conducted research and development and has not yet commercialized a pharmaceutical, and accordingly, not reported any sales. Project and product development within the auspices of NeuroVive's research and development is capital intensive, and accordingly, in future, NeuroVive will also be dependent on being able to secure project finance regularly.

The Company raised SEK 35.0 m before issue expenses of some SEK 1.8 m through the private placement executed in December 2013, after which the Company disposes over cash and cash equivalents of approximately SEK 37.2 m as of the date of this prospectus.

(SEK 000) <b>Equity and indebtedness, 30 Nov 2013</b>		
<b>Short-term liabilities</b>		
(A)	Against security	0
(B)	Against collateral	0
(C)	Unsecured credit	0
(D)	<b>Total short-term liabilities (A)+(B)+(C)</b>	<b>0</b>
<b>Long-term liabilities</b>		
(A)	Against security	0
(B)	Against collateral	0
(C)	Unsecured credit	0
(D)	<b>Total long-term liabilities (A)+(B)+(C)</b>	<b>0</b>
<b>Equity</b>		
(A)	Share capital	958
(B)	Other paid-up capital	98,049
(C)	Accumulated profit or loss	-52,874
(D)	Minority interests	-1,072
(E)	<b>Total equity(A)+(B)+(C)+(D)</b>	<b>45,061</b>
<b>Total equity and liabilities</b>		<b>45,061</b>

(SEK 000) <b>Net indebtedness, 30 Nov 2013</b>		
(A)	Cash	0
(B)	Cash and cash equivalents <sup>1</sup>	8,408
(C)	Readily realizable securities	0
(D)	<b>Total liquidity (A)+(B)+(C)</b>	<b>8,408</b>
(E)	<b>Current receivables</b>	<b>71</b>
(F)	Current bank liabilities	0
(G)	Short-term portion of long-term liabilities	0
(H)	Other short-term liabilities	1,248
(I)	<b>Total short-term liabilities (F)+(G)+(H)</b>	<b>1,248</b>
(J)	<b>Net short-term indebtedness (I)-(E)-(D) <sup>2</sup></b>	<b>-7,231</b>
(K)	Long-term bank borrowings	0
(L)	Bond issues	0
(M)	Other long-term borrowings	0
(N)	<b>Long-term indebtedness (K)+(L)+(M)</b>	<b>0</b>
(O)	<b>Net indebtedness; (J)+(N)</b>	<b>-7,231</b>

<sup>1</sup> Consists of bank balances.

<sup>2</sup> A negative number means the Company has a positive net cash position, which implies available liquidity exceeds current interest-bearing liabilities.

The Board of Directors' plan is to raise requisite working capital to run the Company for the next 12 months through the current rights issue, which on full subscription, would increase liquidity by approximately SEK 75.8 m before deducting for estimated issue expenses of SEK 6.6 m. The Company expects to have received the issue proceeds at the end of February 2014. SEK 50.0 m of the SEK 75.8 m rights issue, or 66.6%, is underwritten. Normally, this is a strong signal to other shareholders and the public to participate in the share issue. However, the Board of Directors cannot definitively judge the prospects that the rights issue will be subscribed above the underwritten level of SEK 50.0 m.

The Company's working capital deficit for the coming 12-month period is estimated at approx. SEK 44.2 m based on the capital needs analysis that has been prepared. A shortfall is expected to arise in June 2014 assuming that the Company does not tillförs/complete the rights issue. The capital needs analysis considers capital needs for a number of projects including investments which may be re-prioritized in ongoing evaluation processes in future. This means that given a decision by the Company, capital needs may be lower than what is stated above, without this causing close-down or other costs. The estimated shortfall of SEK 44.2 m is consistent with what the rights issue is expected to raise after issue expenses, up to the underwritten level.

The purpose of the rights issue is to enable the Company's continued operation and continued strong focus on Europe, as well as evaluation of markets in the USA and Asia. The issue proceeds shall be used to complete ongoing clinical trials on CicloMulsion® and NeuroSTAT®, and assuming positive results from the phase III trial on CicloMulsion®, activities to prepare the market ahead of product launch. Secondly, proceeds will be allocated to R&D projects in hepatitis B/C and new cyclophilin inhibitors for heart cell and neuroprotection, which are the base of the molecules acquired from Biotica Ltd. in 2013.

If the rights issue is not fully subscribed over and above the underwritten level, the Company may need to seek other complementary finance, firstly through raising loans or renegotiating with lenders, and secondly by negotiating with suppliers. Other alternatives to assist in a potential funding shortfall due to insufficient subscription in the share issue would be the Company altering its designated strategy and downscaling planned development projects.

The ultimate consequence of financing not being raised would be the Company being forced to file for chapter 11 proceedings or bankruptcy.

## TENDENCIES AND FUTURE PROSPECTS

To date, the Company's operations have involved, and currently involve, a high proportion of research and development operations, in which there are no known tendencies regarding production, inventories or sales.

As far as the Board of Directors is aware, and over and above general uncertainty related to the research and development operations and delays to clinical trials, there are no known tendencies, uncertainty factors, potential claims or other demands, obligations or events that can be expected to exert a material impact on the Company's future prospects, at least not in the current financial year.

## CAPITAL EXPENDITURE

NeuroVive's primary capital expenditure consists of capitalized development expenses and patents. In 2010, the Company's total capital expenditure was SEK 6,177,000. Capital expenditure on development work intensified in 2011, and the Company's capital expenditure then totaled SEK 7,588,000. In 2012, NeuroVive's total capital expenditure was SEK 13,740,000. In 2013 and until the date of this prospectus, the Company's total capital expenditure was approximately SEK 14,000,000.

(SEK 000)	Development expenses	Patents	Software	Equipment
2010 (12 mth.)	3,913	2,226	-	38
2011 (12 mth.)	6,257	662	400	269
2012 (12 mth.)	12,434	641	-	665
2013 (9 mth.)	6,077	3,924	-	28

Capitalized development expenses consist of external expenses for development and manufacture of NeuroVive's drug candidates, as well as clinical trials and regulatory work. Amortization of patents is from 2010 onwards, based on patent term, which is then included as part of capitalized development expenses. Investments in NeuroVive's patents consist of external expenses to protect and maintain patents. Expenditure for trademarks and brands is expensed from 2010 onwards, directly in the Income Statement.

## CURRENT AND FUTURE CAPITAL EXPENDITURE PLANS

Apart from capitalizing development expenses, expenses associated with patents and the investment agreement with Fresenius Kabi, NeuroVive has no significant ongoing or future capital expenditure that the Board of Directors has any definitive commitments regarding. The Company intends to finance the aforementioned capital expenditure through existing cash and cash equivalents, and the current new share issue.

## SIGNIFICANT CHANGES

The Company raised some SEK 35 m before issue expenses from the private placement executed in December 2013. Apart from the above, no significant changes have occurred to NeuroVive's financial position or position on the market since 30 September 2013.



# Share capital and ownership

## SHARE INFORMATION

Prior to the new share issue, NeuroVive has SEK 1,082,952.30 of share capital, divided between 21,659,046 shares with a quotient value of SEK 0.05 per share. All outstanding shares are fully paid-up. NeuroVive's Articles of Association stipulate that the share capital shall amount to a minimum of SEK 591,000 and a maximum of SEK 2,364,000, and that the number of shares shall be a minimum of 11,820,000 and a maximum of 47,280,000. There are no convertible debentures conferring entitlement to subscribe for shares of the Company.

Each share carries one (1) vote at shareholders' meetings. Normally, shareholders have preferential rights to the subscription for new shares, share warrants and convertible debentures in accordance with the Swedish Companies Act, providing a shareholders' meeting, or the Board of Directors with authorization from a shareholders' meeting, does not decide to waive shareholders' preferential rights.

Each share confers equal rights to participation in the Company's assets and profit. Given a potential liquidation of the Company, shareholders are entitled to a share of surplus in relation to the number of shares that shareholder holds. There are no limitations regarding the transferability of shares. The Shares of NeuroVive are not subject to offerings submitted as a result of mandatory bids, squeeze-out right or sell-out right. Nor has there been any public takeover bid during the current or previous financial years.

The Shares of NeuroVive have been issued in accordance with Swedish legislation and are denominated in Swedish kronor (SEK). The Shares are registered in electronic form in accordance with a CSD clause in the Articles of Association. The share register is maintained by Euroclear, with the address Euroclear Sweden AB, Box 191, SE-101 23 Stockholm, Sweden.

## DIVIDEND

Potential dividends are approved by shareholders' meetings subsequent to proposal by the Board of Directors. Parties entitled to receive dividends are recorded in the share register maintained by Euroclear on the record day designated by a shareholders' meeting. All shares of the Company are entitled to dividends. Dividends are non-cumulative. Investors who are recorded as shareholders of the Company on the record day for dividends are entitled to receive dividends. Potential dividends are managed by Euroclear, or for nominee-registered holdings, in accordance with the processes of the relevant nominee. If the shareholder cannot be reached through Euroclear, the shareholder's claim for the dividend amount remains on the Company, and is only limited by the rules for limitation. Upon limitation, the dividend amount accrues to the Company. No special rules, restrictions or procedures regarding dividends apply to shareholders domiciled outside Sweden. The Company has not paid any dividend to date. Nor can they be any guarantee that any dividend for the Company will be proposed or approved in a specific year.

## SHARE CAPITAL HISTORY

Year	Event	Quotient value	Increase in number of shares	Increase in share capital	Total number of shares	Total share capital
2000	Incorporation	100	1,000	100,000.00	1,000	100,000.00
2003	New share issue	100	25	2,500.00	1,025	102,500.00
2004	New share issue	100	75	7,500.00	1,100	110,000.00
2007	New share issue	100	213	21,300.00	1,313	131,300.00
2007	New share issue	100	120	12,000.00	1,433	143,300.00
2008	Set-off issue	100	60	6,000.00	1,493	149,300.00
2008	New share issue	100	83	8,300.00	1,576	157,600.00
2008	Bonus issue	375	-	433,400.00	1,576	591,000.00
2008	Split	0.05	11,818,424	-	11,820,000	591,000.00
2008	New share issue	0.05	1,255,000	62,750.00	13,075,000	653,750.00
2010	New share issue	0.05	1,867,857	93,392.85	14,942,857	747,142.85
2012	New share issue	0.05	4,216,189	210,809.45	19,159,046	957,952.30
2013	Private placement	0.05	2,500,000	125,000.00	21,659,046	1,082,952.3
2014	Current new issue*	0.05	5,414,761	270,738.05	27,073,807	1,353,690.35
2014	Overalllocation option*	0.05	714,286	35,714.30	27,788,093	1,389,404.65

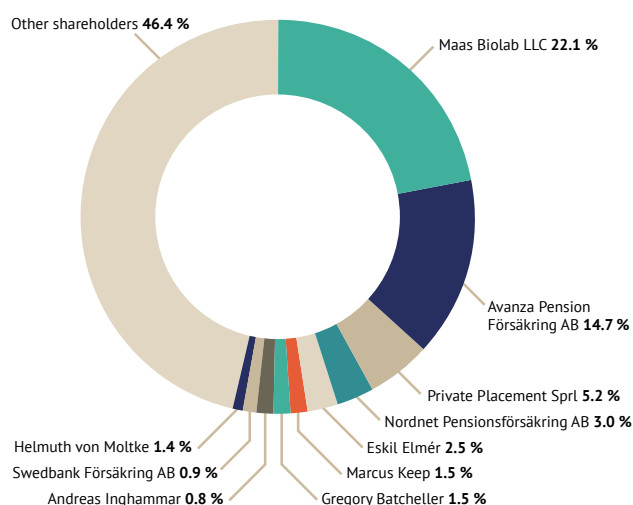
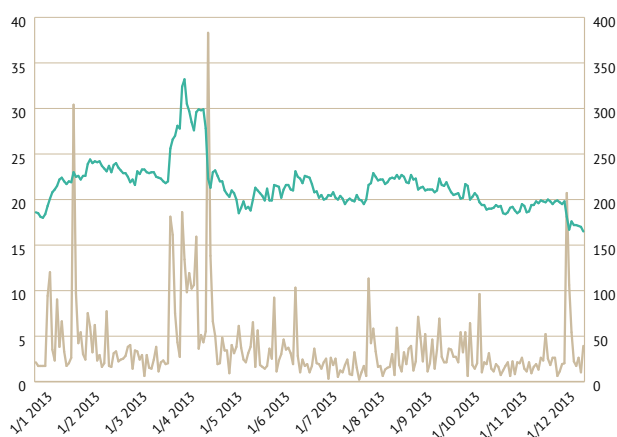
\* Applies on full subscription.



## SHARE WARRANTS

The Annual General Meeting (AGM) 2011 implemented a stock option program for Senior Managers intended to promote the Company's long-term interests. The share warrants confer entitlement to subscribe for a total of 164,000 new shares at an exercise price of SEK 96 per share. The share warrants can be converted into shares during the exercise period, which runs from 10 April 2014 to 10 June 2014, both dates inclusive. If all outstanding share warrants are exercised, based on the Company's current share capital, this currently corresponds to dilution of approximately 0.8% of the Shares and votes.

SHARE PRICE CHART



## TRADING IN SHARES

The Shares of NeuroVive are traded on NASDAQ OMX Stockholm with the stock symbol NVP and ISIN code SE00 0257 5340. The following figure illustrates share price performance from 1 January 2014 to 2 December 2013, both dates inclusive. The market capitalization as of 2 December 2013 was approximately SEK 316 m. The average daily turnover per trading day in this period was 38,873 shares, with the value of approximately SEK 852 million/852,000??.

## OWNERSHIP

NeuroVive has some 2,822 shareholders. The Company's ten largest shareholders as recorded by SiS Ägarservice as of 30 September 2013 and subsequent changes that the Company is aware of are stated in the following table. For information on Board members' and Senior Managers' shareholdings of the Company, see pages 50-56.

As far as the Board of Directors is aware, there are no shareholder agreements between the Company's owners. Nor, as far as the Board is aware, are there any lock-up agreements. However, there is a shareholder agreement in NeuroVive's subsidiary NeuroVive Pharmaceutical Asia Ltd., reviewed in the "legal issues and supplementary information" section under the "significant agreements" heading.

LARGEST SHAREHOLDERS AS OF 30 SEPTEMBER 2013

Name	No. of shares	Votes and capital
Maas Biolab LLC*	4,233,736	22.1 %
Avanza Pension Försäkring AB	2,818,222	14.7 %
Private Placement Sprl	1,000,000	5.2 %
Nordnet Pensionsförsäkring AB	568,164	3.0 %
Eskil Elmér	483,635	2.5 %
Gregory Batcheller	287,626	1.5 %
Marcus Keep	282,311	1.5 %
Helmuth von Moltke	269,000	1.4 %
Swedbank Försäkring AB	170,537	0.9 %
Andreas Inghammar	157,000	0.8 %
<b>Total, ten largest shareholders</b>	<b>10,270,231</b>	<b>53.6 %</b>
<b>Total, other shareholders</b>	<b>8,888,815</b>	<b>46.4 %</b>
<b>Total, all shareholders</b>	<b>19,159,046</b>	<b>100.0 %</b>

\* In turn, Maas Biolab LLC is 49.66% owned by Board member Marcus Keep, 16.96% owned by CSO Eskil Elmér and 5.13% owned by Board member Helmuth von Moltke. At the same date, Chairman of the Board Gregory Batcheller held 1.97% of Maas Biolab LLC.

# Board of Directors, Senior Managers and Auditors

## Board of Directors



Left to right, rear: Arne Ferstad, Gregory Batcheller, Marcus Keep, Helmuth von Moltke.

Left to right, front: Boel Flodgren, Anna Malm Bernsten, Helena Levander.

### SUMMARY—BOARD OF DIRECTORS

Board member	Nationality	Elected	Board of Directors	Audit Committee	Remuneration Committee	Independent of the Company and management	Independent of major shareholders	Fees including committee work (SEK,000)	Shareholding
Gregory Batcheller	Canada	2000	Chairman			No	Yes	0 <sup>1</sup>	288,426 <sup>2</sup>
Arne Ferstad	Norway	2010	Board Member	Board Member		No	Yes	150 + 50	7,999 <sup>3</sup>
Boel Flodgren	Sweden	2013	Board Member			Yes	Yes	150	6,000
Marcus Keep	USA	2000	Board Member			No	No	150	419,572 <sup>4</sup>
Helena Levander	Sweden	2012	Board Member	Chairman	Board Member	Yes	Yes	150 + 100 + 20	5,000
Anna Malm Bernsten	Sweden	2013	Board Member	Board Member	Chairman	Yes	Yes	150 + 50 + 40	0
Helmut von Moltke	Germany	2005	Board Member		Board Member	Yes	Yes	150 + 20	312,000 <sup>5</sup>

<sup>1</sup> Gregory Batcheller declined the Directors' fee of SEK 300,000 the AGM approved in March 2013.

<sup>2</sup> Gregory Batcheller also holds 1.97% of Maas Biolab LLC, which in turn, holds 22.10% of NeuroVive.

<sup>3</sup> Shareholdings, personal and related parties.

<sup>4</sup> Marcus Keep also holds 49.66% of Maas Biolab which in turn, holds 22.10% of NeuroVive.

<sup>5</sup> Helmut von Moltke also holds 5.13% of Maas Biolab LLC, which in turn, holds 22.10% of NeuroVive.

## Gregory Batcheller | Chairman of the Board

Gregory Batcheller, born in 1957, possesses extensive experience of directorships and as an executive in life sciences. Gregory has many years' experience of pharmaceuticals, biotechnology and medical equipment, including serving as CEO of Pulsetten AB, which sold DuoCort Pharma AB to ViroPharma Inc. in 2011, a Director of AcuCort AB, which develops treatments for acute allergic reactions and a partner of PULS (Partners för Utvecklingsinvesteringar inom Life-Science), a virtual pharmaceutical company that supports development and investment in early life science projects through partnerships with research entrepreneurs to develop ideas into commercial products. Greg is also Chairman

of A1M Pharma AB and Preelumina Diagnostics AB, which develop diagnostic methods and therapies for pregnancy toxemia, Chairman of Xintela AB, which develops stem cell therapies for cartilage repair, Chairman of Monocl AB and co-founder of Laccure AB, which develops a treatment for bacterial vaginosis. Gregory has been Chairman of the Board of NeuroVive since 2000, and Executive Chairman since 2008. No. of shares: 28,426 shares personally and 1.97% of Maas Biolab LLC, which holds 22.10% of NeuroVive.

No. of share warrants: 40.000

### CORPORATE ENGAGEMENTS IN THE LAST FIVE YEARS

Company	Position	Dates
AcuCort AB	Board member	2011-
A1M Pharma AB	Chairman of the Board	2008-
Dermafol AB	Board member	2012-
Preelumina Diagnostics AB	Chairman of the Board	2009-
Stanbridge Corporation BVBA (Belgium)	CEO and Chairman of the Board	2007-
Xintela AB	Chairman of the Board	2011-
Maas Biolab LLC (USA)	Board member	2006-2009

### OWNERSHIP INTERESTS OVER 5% IN THE PAST FIVE YEARS

Company	Capital (%)	Votes (%)	Dates
Stanbridge Corporation BVBA (Belgium)	100	100	2007-
Dermafol AB	9.9	9.9	2010-

## Arne Ferstad | Board member

Arne Ferstad, born in 1950, headed up Baxter Healthcare's business in the Nordics and Benelux countries, and was President of Baxter's Renal Division for EMEA. Arne also led Baxter's Bioscience business in Asia, as well as holding senior management R&D positions at Baxter. Most recently, Arne was General Manager and Vice President of Pharmacia Corporation and possesses broad experience of the biotechnology sector including business and pharmaceutical development, as well as marketing

at an international level. Arne is a Director of AroCell AB (publ), Medfield Diagnostics AB (publ), Aggancio research AB and is CEO/Partner of Ankor Consultants BVBA. Arne has been a Board member of NeuroVive since 2010. No. of shares: 3,466 shares personally (including family) and 50% (the remaining 50% being controlled by Arne Ferstad's spouse) of Ankor Consultants BVBA, which holds 4,533 shares of NeuroVive.

No. of share warrants: 0

### CORPORATE ENGAGEMENTS IN THE LAST FIVE YEARS

Company	Position	Dates
Ankor Consultants BVBA (Belgium)	CEO/Director	2000-
AroCell AB (publ)	Board member/Chairman	2010-/2012-
Aggancio Research AB	Chairman of the Board	2010-
Medfield Diagnostics AB (publ)	Board member	2012-
AroCell AB (publ)	Deputy Board member	2003-2010
AroCell AB	CEO	2008-2008

### OWNERSHIP INTERESTS OVER 5% IN THE PAST FIVE YEARS

Company	Capital (%)	Votes (%)	Dates
Ankor Consultants BVBA (Belgium)	50*	50*	2000-
AroCell AB (publ)	8.1	8.1	2003-
Aggancio Research AB	5	5	2010-

\* The remaining 50% is controlled by Arne Ferstad's spouse.

## Boel Flodgren | Board member

Boel Flodgren, born in 1942, is a professor of commercial law and former Vice Chancellor of Lund University. Boel has long-term experience of research and education in business law from domestic and foreign universities, including Stanford and Harvard. Honorary doctorates from the Hanken School of Economics, Helsinki, Finland, McGill University, Montreal, Canada and the University of Oslo, Norway. Boel also possesses broad-based experience of private and public sector directorships, and has

several years' experience as a Board member of AB Industrivärden (publ) and former directorships include Brinova Fastigheter AB, Sparbanken Finn, Lund University, the University of Copenhagen and University of Oslo. Boel has been a Board member of NeuroVive since 2013. No. of shares: 6,000 shares personally (including family).

No. of share warrants: 0

### CORPORATE ENGAGEMENTS IN THE LAST FIVE YEARS

Bolag	Position	Dates
AB Industrivärden (publ)	Board member	2002-
Brinova Fastigheter AB	Board member	2003-2012

## Marcus Keep | Board member

Marcus Keep, born in 1959, Associate Professor of Neurosurgery at Penn State Hershey. Dr. Keep holds the patents, and is a co-founder, of Maas Biolab LLC and NeuroVive Pharmaceutical AB. Dr. Keep is also the CEO of Maas Biolab, LLC. He was formerly Assistant Professor of Neurosurgery at the Universities of Hawaii and New Mexico. In 1989-1990, Dr. Keep was guest researcher at INSERM Unité 106, Hôpital de la Salpêtrière, Paris, France. In 1994-1996, Dr. Keep was a visiting researcher at Lund University, Sweden. Dr. Keep studied at Dartmouth College (BA in religion),

the University of South Carolina (BSc in chemistry), the Medical University of South Carolina (MD), and was trained in neurosurgery at the Montréal Neurological Institute at McGill University. Dr. Keep is also Chief of Neurosurgery at St. Joseph Medical Center, Reading, Pennsylvania. Dr. Keep has been a Board member of NeuroVive since 2000. No. of shares: 419,572 shares personally (including family) and 49.66% of Maas Biolab LLC, which holds 22.10% of NeuroVive.

No. of share warrants: 0

### CORPORATE ENGAGEMENTS IN THE LAST FIVE YEARS

Company	Position	Dates
Maas Biolab LLC (USA)	CEO and Chairman of the Board	1997-

### OWNERSHIP INTERESTS OVER 5% IN THE PAST FIVE YEARS

Company	Capital (%)	Votes (%)	Dates
Maas Biolab LLC (USA)	49.66	49.66	1997-

## Helena Levander | Board member

Helena Levander, born in 1957, is founder and CEO of Nordic Investor Services AB. Helena has long-term experience of the stock market and asset management from SEB, Nordea and Odin Fonder. She also served as CEO of Neonet Securities AB. Board member of companies including Uniflex Bemanning AB, Stampen AB and Collector AB. Previous directorships include Erik Penser

Bankaktiebolag, Allba Holding AB, GANT AB, Bure Equity AB, Mandator AB, SBAB Bank AB, Transatlantic AB, Svensk Exportkredit SEK and GEVEKO AB. Helena has been a Board member of NeuroVive since 2012. No. of shares: 5,000 shares.  
No. of share warrants: 0

### CORPORATE ENGAGEMENTS IN THE LAST FIVE YEARS

Company	Position	Dates
Allba Holding AB	Board member	2011-
Collector AB	Board member	2012-
Collector Credit AB	Board member	2012-
Erik Penser Bankaktiebolag	Board member	2006-
Klöfverön Förvaltnings AB	Board member	2011-
Nordic Investor Services Aktiebolag	CEO and Board member	2006-
Pensare Grande AB	Board member	2010-
SBAB Bank AB (publ)	Board member	2004-
Skäreleja AB	Board member	2011-
Stampen AB	Board member	2007-
Styrelsekollegiet Aktiva Företagsrådgivare ek.för.	Board member	2010-
Tidningsboxen på Soludden AB	Board member	2010-
Uniflex AB (publ)	Board member	2011-
Aktiebolaget Geveko (publ)	Board member	2006-2008
Aktiebolaget Svensk Exportkredit (publ)	Board member	2004-2011
Betting Promotion Sweden AB	Board member	2009-2012
Mandator AB (publ)	Board member	2006-2007
Rederi AB Transatlantic (publ)	Board member	2005-2010
Wiborg Kapitalförvaltning AB	Board member	2007-2012

### OWNERSHIP INTERESTS OVER 5% IN THE PAST FIVE YEARS

Company	Capital (%)	Votes (%)	Dates
Nordic Investor Services AB	43	43	2002-
Pensare Grande AB	100	100	2010-

## Anna Malm Bernstein | Board member

Anna Malm Bernstein, born in 1961, possesses long-term experience of strategic marketing, product launches and business development in the international environment for pharmaceutical and biotech companies such as Medivir, GE Healthcare and Pharmacia&Upjohn. Anna has extensive experience of Directorships of listed companies, and is a Board member of Nolato AB

(publ), Cellavision AB (publ), Birdstep ASA, Medivir AB (publ) and Fagerhult AB (publ). Anna holds a B.Sc. (Eng.) from the Royal Institute of technology, Stockholm, Sweden. She has been a Board member of NeuroVive since 2013. No. of shares: 0.  
No. of share warrants: 0

### CORPORATE ENGAGEMENTS IN THE LAST FIVE YEARS

Company	Position	Dates
Birdstep ASA	Board member	2010-
CellaVision AB (publ)	Board member	2010-
Matrisen AB	Board member	2010-
Nolato AB (publ)	Board member	2010-
Medivir AB (publ)	Board member	2006-
Fagerhult AB (publ)	Board member	2003-
Biophausia AB (publ)	Board member	2010-2011
Artimplant AB (publ)	Board member	2006-2011
DiaGenic ASA	Board member	2005-2009

### OWNERSHIP INTERESTS OVER 5% IN THE PAST FIVE YEARS

Company	Capital (%)	Votes (%)	Dates
Bernsten Konsult AB	100	100	2005-

## Helmuth von Moltke | Board member

Helmuth von Moltke, born in 1937, is a lawyer and venture capitalist with minority holdings in a number of companies in Central and Eastern Europe. He previously held senior management positions in BASF AG and its subsidiaries in the US, Canada, UK and Australia for many years. Helmuth earned his law degree from

Oxford University in the UK. Helmuth has been a Board member of NeuroVive since 2005. No. of shares: 312,000 shares personally (including family) and 5.13% of Maas Biolab LLC, which holds 22.10% of NeuroVive.

No. of share warrants: 0

### CORPORATE ENGAGEMENTS IN THE LAST FIVE YEARS

Company	Position	Dates
Brocard Group GmbH & Co KgaA (Tyskland)	Chairman of the Board	2004-
Maas Biolab LLC (USA)	Board member	1997-2012

### OWNERSHIP INTERESTS OVER 5% IN THE PAST FIVE YEARS

Company	Capital (%)	Votes (%)	Dates
Maas Biolab LLC (USA)	5.13	5.13	1997-

# Senior managers

## Mikael Brönnegård | CEO

Mikael Brönnegård, born in 1956, is a pediatrician, Ph.D. and Associate Professor at the Karolinska Institute. Mikael possesses experience of various international positions in the pharmaceutical industry, including research physician at Eli Lilly's marketing company in Sweden and Vice President and Head of Endocrinology and Metabolism at Pharmacia Corporation in the US. Mikael possesses broad experience of the biotechnology and pharmaceutical sectors. Mikael has also held positions including Investment Director of a venture capital company, where he made a number of early-stage investments in biotechnology and pharmaceutical companies, for which he also served as a Director. Mikael also worked as a business developer for a UK biotech company in Dundee, Scotland, for one year. Mikael Became CEO of NeuroVive in May 2010. No. of shares: 1,500.

No. of share warrants: 40,000

### CORPORATE ENGAGEMENTS IN THE LAST FIVE YEARS

Company	Position	Dates
BioPart Venture AB	Board member	2001-
Gothia Förlag AB	Board member	2006-
Villa Brasil AB	Board member	2006-2010
IDMoS plc (Skottland)	Board member	2006-2007



## Eskil Elmér | CSO

Eskil Elmér, born in 1970, is a physician and Associate Professor of experimental neurology. Eskil is CSO of NeuroVive, and accordingly, has overall responsibility for the Company's research and development. In addition, he works as a researcher and Associate Professor at the Wallenberg Neuroscience Center, Lund, Sweden, in the Clinical Neurophysiology department and as a physician at the Neurophysiological Clinic at Lund University Hospital. Eskil is a co-founder of NeuroVive, and a Board member in 2000-2008 and 2010-2012, as well as serving as CEO of the Company. He has been CSO of NeuroVive since 2000. No. of shares: 486,635 shares personally (including family) and 16.96% of Maas Biolab LLC, which holds 22.10% of NeuroVive.

No. of share warrants: 40,000

### CORPORATE ENGAGEMENTS IN THE LAST FIVE YEARS

Company	Position	Dates
Maas Biolab LLC (USA)	Board member	1997-
Neuropharma i Sverige AB	Board member	2000-2008
NeuroVive Pharmaceutical AB (publ)	CEO	2008-2010
NeuroVive Pharmaceutical AB (publ)	Board member	2010-2012

### OWNERSHIP INTERESTS OVER 5% IN THE PAST FIVE YEARS

Company	Capital (%)	Votes (%)	Dates
Maas Biolab LLC (USA)	16.96	16.96	1997-





## Jan Nilsson | COO

Jan Nilsson, born in 1949, possesses long-term experience of big pharma and biotech enterprises. As Vice President of the Nordic and Baltic Regions for Schering-Plough, Jan had overall responsibility for the Company's business. Jan was also appointed by Schering-Plough to participate in a number of Global Task Forces addressing critical strategic issues for the Group. In his years at Schering-Plough, Jan was involved in many parts of the drug development process, mainly in research and development, business development, marketing and sales. For a number of years, Jan was CEO of listed biotech company Tripep AB, and through his experience of executive positions in larger and smaller pharmaceutical companies, he has accumulated thorough knowledge of drug development and business development. Jan was a Board member of NeuroVive from 2010 up to and including the AGM in March 2013, and has been a NeuroVive employee since February 2013.

No. of shares: 0.

No. of share warrants: 0



### CORPORATE ENGAGEMENTS IN THE LAST FIVE YEARS

Company	Position	Dates
Jan Nilsson Konsult	Proprietor	2010-
Lipopeptide AB	CEO and Board member	2011-
NeuroVive Pharmaceutical AB (publ)	Board member	2010-2013
Tripep AB	CEO and Board member	2004-2009
Kringle Pharma Europe AB	CEO and Board member	2008-2009

## Catharina Jz Johansson | CFO

Catharina Jz Johansson, born in 1967, holds an M.Sc. in Business and Economics with previous experience as interim CFO for medical device company Cellavision, which is listed on NASDAQ OMX Stockholm, and Accounting Manager for Bong AB (publ) and Alfa Laval Europe. Catharina has been a NeuroVive employee since December 2013.

No. of shares: 0.

No. of share warrants: 0



### CORPORATE ENGAGEMENTS IN THE LAST FIVE YEARS

Company	Position	Dates
Visma Software AB	Interim CFO	2007-2009
Cellavision AB (publ)	CFO	2012-2013



## Other disclosures regarding the Board of Directors and Senior Managers

The Board members were elected at the AGM on 8 March 2013 for the period until the AGM 2014. In addition to a Patent and Trademark Transfer Agreement with Maas Biolab, LLC and the two agreements signed with the Research Team in mitochondrial energy regulation and the ToxPhos analysis method (more information in the “legal issues and supplementary information” section under the “significant agreements” heading) there are no special agreements between major shareholders, customers, suppliers or other parties that any Board members or Senior Managers have been elected or appointed to. All board members and Senior Managers can be contacted via the Company.

None of the Company's Board members or Senior Managers have served as representatives of companies that have being declared bankrupt or entered (involuntary) liquidation or been involved in receivership. None of the Company's Board members or Senior Managers have been (i) convicted in cases relating to fraud, (ii) been subject to charges or sanctions according to laws or ordinances by regulatory authorities (including recognized professional societies) or (iii) been disqualified as a member of the Company's administrative, executive management or governing bodies by a court of law, or from serving a senior or supervisory function within a company.

The Company's Board member Marcus Keep is independent of major shareholders, the Company and the Company's Senior Managers because Marcus Keep holds 49.66% of Maas Biolab, LLC, which in turn, holds 22.1% of NeuroVive. Maas Biolab, of which Marcus Keep is also a Board member, holds significant intellectual property jointly with the Company, and should therefore be

considered as a strategic collaboration partner of the Company.

Gregory Batcheller serves as Executive Chairman of the Board of the Company, and accordingly cannot be considered independent of the Company's management.

The Company's Board member Arne Ferstad delivers ongoing consulting services to the Company to a relatively large extent. In addition, Arne Ferstad participates at the Company's strategy events (2-3 days yearly) on a consultancy basis. Consequently, Arne Ferstad is independent of the Company's major shareholders, but dependent on the Company's Senior Managers.

There are no family ties between the Company's Board members and Senior Managers. Nor are there any conflicts of interest, where by Board members' and Senior Managers' personal interests could come into conflict with the Company's interests. Otherwise, there are no benefits due to the Board of Directors or Senior Managers upon termination of assignments or employment.

### AUDITORS

Bengt Ekenberg of MAZARS SET Revisionsbyrå AB is Auditor in Charge. Mr. Ekenberg is an Authorized Public Accountant and member of FAR, the Institute for the Accountancy Profession in Sweden. Up to and including the financial year 2011, Göran Carlsson (c/o Ernst & Young, IDEON, Scheelevägen 17, 223 70 Lund, Sweden) was Auditor. Mr. Carlsson is an Authorized Public Accountant and member of FAR. The change of Auditor was intended to prepare for NeuroVive's listing on NASDAQ OMX Stockholm, Small Cap.

# Advisory Board

*NeuroVive has a Clinical and Scientific Advisory Board, whose members possess long-term and valuable experience of clinical trials and thorough knowledge of trauma. The Company's Advisory Board has the following members:*

## **PER-OLOF GRÄNDE**

Per-Olof Grände is a retired physician and professor. He was formerly head of the Department of Anesthesiology and Intensive Care at Lund University Hospital, Sweden. Professor Grände has received several awards for his innovative research. Jointly with Carl-Henrik Nordström, he developed what is now known as the Lund Concept, whose basis includes preventing brain swelling in cases of traumatic brain injury after road accidents or falls, for example. This model is applied in intensive care in Sweden and foreign countries. Professor Grände has also authored over 100 scientific papers.

## **CARL-HENRIK NORDSTRÖM**

Carl-Henrik Nordström is a retired neurosurgeon, professor and consultant at Lund University and Lund University Hospital, Sweden, and since retirement has been working at Odense University Hospital. Jointly with Per-Olof Grände, Professor Nordström developed what is now known as the Lund Concept, reviewed above. Professor Nordström also participated in preparing a method of cerebral microdialysis, used to evaluate new treatment principles in patients with severe cranial damage, for example. Professor Nordström has received several awards for his research work, and is a frequent guest lecturer at conferences and universities worldwide. Professor Nordström has also authored or co-authored over 200 scientific publications in segments including neurointensive care.

## **HÅKAN WIDNER**

Håkan Widner is a professor and consultant at Lund University Hospital, Sweden. His primary specialism is restorative neurology research with nerve cell transplantation and advanced immunotherapies. Professor Widner has also been an active member of many pharmaceutical company advisory boards and made presentations at a large number of international conferences. Professor Widner was one of the holders of the original patent for neuroprotection using cyclosporine A, and has received many awards for his innovative clinical research. Professor Widner is also a partner of NeuroVive, LLC via Maas Biolab, LLC.

# Legal issues and supplementary information

## GENERAL CORPORATE INFORMATION

NeuroVive Pharmaceutical AB (publ), corp. ID no. 556595-6538, was registered at the Swedish Companies Registration Office on 1 February 2000, and the Company started operations on 16 August 2000. The Company is incorporated as a limited company and its operations are regulated by the Swedish Companies Act (2005:551). The Board of Directors has its registered office, and the Company has its domicile in the Municipality of Lund, the County of Scania, Sweden. The current Articles of Association were approved by the AGM on 8 March 2013. The Company complies with the Swedish Code of Corporate Governance.

## CORPORATE STRUCTURE AND SHAREHOLDINGS

NeuroVive has a subsidiary incorporated in Hong Kong, NeuroVive Pharmaceutical Asia Ltd., with corporate ID no. 1688859, of which the Company holds 70%. The remaining 30% of this subsidiary is

held by Foundation Asia Pacific Limited. NeuroVive has no other shareholdings.

## SIGNIFICANT AGREEMENTS

As a natural part of its operating activities, NeuroVive enters agreements with its collaboration partners such as licensing agreements, collaboration agreements and non-disclosure agreements. Those agreements that can be regarded as being most important to NeuroVive are firstly agreements relating to the acquisition and licensing of intellectual property that is critical to NeuroVive, and secondly, collaboration agreements on research and development. In some cases, agreements with collaboration partners include stipulations regarding the allocation of any future revenues between NeuroVive and the agreement counterparty, as is stated in more detail in the following table, assuming that the relevant terms of the agreement are satisfied.

### SIGNIFICANT AGREEMENTS

Agreement counterparty	NeuroSTAT®	CicloMulsion®	NVP014	Energy regulator	ToxPhos
<b>NeuroVive shares rights to revenues with:</b>					
CicloMulsion AG <sup>1</sup>	Royalty 10%	Royalty 10%	50/50 -> 90/10		
to-BBB <sup>2</sup>					
Forskargruppen					
Lunds universitet <sup>3</sup>				50/50 -> 90/10	50/50 -> 90/10
Mitopharm Ltd <sup>2</sup>				50/50 -> 90/10	
Hospices Civils de Lyon (HCL) <sup>4</sup>		Single-digit minimum royalties with remuneration cap			
<b>NeuroVive receives revenues from:</b>					
Sihuan <sup>5</sup>	Up-front, Milestone, Royalty 10%	Up-front, Milestone, Royalty 10%			
Other					
Foundation Asia Pacific Ltd	See below for information on the shareholders' agreement regarding NeuroVive Asia				

<sup>1</sup> CicloMulsion AG receives 10% royalties on NeuroVive's revenues from products with market approval.

<sup>2</sup> The allocation of, and rights to, future revenues are in a step model based on the parties' individual share of project funding. The division of revenues varies from equal shares (50/50) of revenues to a 90/10 division, with the majority accruing to that party that has assumed the greatest responsibility for development and commercialization. The intention of both these collaborations is for NeuroVive to bear responsibility for the development and commercialization of pharmaceutical products and thus receive a higher share of future revenues.

<sup>3</sup> The allocation of, and rights to, future revenues are in a step model based on how much NeuroVive invests in the development project. The Research Team's share starts at 50% and can fall to 10% of revenues the greater the investment NeuroVive makes in the project.

<sup>4</sup> HCL receives a single-digit minimum royalty that has a remuneration cap based on NeuroVive's net revenues.

<sup>5</sup> NeuroVive Asia Ltd. receives up-front and milestone payments when the project passes agreed milestones and receives a 10% royalties on net revenues in China for a period of 10 years after market approval.

### **Maas Biolab LLC**

Through an agreement with Maas Biolab LLC, NeuroVive has acquired the rights to patents used for NeuroVive's development of the drug candidate CicloMulsion®/NeuroSTAT®. The agreement with Maas Biolab LLC means the relevant patents are jointly owned by the companies, but with the aim of clarifying each company's operational focus, applications have been divided so that NeuroVive holds exclusive rights in acute neuroprotective indications and Maas Biolab LLC the corresponding exclusivity in chronic indications. Registration of the jointly owned patents is with each country's patent office, and at present, processing is still ongoing in a number of countries. All rights to the NeuroSTAT® brand were also acquired through this agreement with Maas Biolab LLC.

### **CicloMulsion AG**

Through an agreement with CicloMulsion AG, NeuroVive has acquired the rights to patents used in NeuroVive's development of the drug candidate CicloMulsion®/NeuroSTAT®. According to this agreement, CicloMulsion AG has the right to receive 10% royalties on the revenues NeuroVive obtains for market approved products (CicloMulsion®/NeuroSTAT®). In March 2013, CicloMulsion AG initiated an arbitration procedure through which it wishes to specify the agreement's implication in terms of NeuroVive's ability to cancel the licensing agreement after 2013, and how CicloMulsion AG's rights to receive royalties would be affected by such cancellation. If the arbitration is found in CicloMulsion AG's favor, the Company may be liable to pay future royalties without being able to cancel the agreement. Accordingly, NeuroVive may be liable to pay royalties for 15 years after product launch. If the arbitration is found in the Company's favor, NeuroVive may be able to cancel the agreement and thus avoid royalty payments after 2013.

### **Fresenius Kabi AG**

NeuroVive has signed an agreement with Fresenius Kabi AG that means that NeuroVive has secured capacity for the full-scale production of NeuroSTAT® and CicloMulsion® in a new production unit that can Fresenius Kabi is building at its production facility in Graz, Austria. Basically, this agreement involves NeuroVive part-funding the production facility that Fresenius Kabi is building in Graz, which guarantees NeuroVive's production capacity. If the forecast production volumes are achieved, this investment will be repaid to NeuroVive. According to this agreement with Fresenius Kabi AG, NeuroVive is not permitted to disclose further details of this agreement.

### **The Research Team at Lund University**

In addition to NeuroVive's research into mitochondrial dysfunction in acute neurological conditions, NeuroVive is also conducting research in a project on mitochondrial energy regulation. Initially,

development was conducted by a group of researchers at the Mitochondrial Pathophysiology Unit at the Faculty of Medicine at Lund University. With the aim of being able to work towards commercialization of the results achieved in this research, an agreement was signed with NeuroVive, through which the Research Team transferred the results achieved to NeuroVive for a predetermined payment, and undertook to work on the project on NeuroVive's behalf to a specific extent. Remuneration to members of the Research Team, several of whom are now employed or otherwise engaged with the Company, is based on the Company's future revenues attributable to this project, and is payable on a stepwise basis, by which the Research Team's share starts at 50% and may fall to 10% of revenues the greater the investment in the project the Company makes. Accordingly, no remuneration will be paid before results from the project generate revenues for the Company.

In its academic work, the Research Team has also developed an analytical method—ToxPhos—to determine mitochondrial function in human blood corpuscles. This analysis method can be applied in diagnostics and preclinical toxicology of drug development. With the aim of commercializing the results achieved in this research, an agreement was signed with NeuroVive in 2012, through which the Research Team transferred the results achieved to NeuroVive for a predetermined payment, and undertook to work on the project on NeuroVive's behalf to a specific extent. Remuneration to members of the former Research Team, several of whom are now employed or otherwise engaged with the Company, is based on the Company's future revenues attributable to this project, and is payable on a stepwise basis, by which the Research Team's share starts at 50% and may fall to 10% of revenues the greater the investment in the project the Company makes. Accordingly, no remuneration will be paid before results from the project generate revenues for the Company.

### **to-BBB Technologies BV and Mitopharm Limited**

NeuroVive collaborates with other companies with the aim of achieving mutual benefit by the combination of NeuroVive's research with its collaboration partner's technology. The collaboration with Dutch biotech enterprise to-BBB Technologies BV is designed to develop a pharmaceutical against stroke and other acute neurodegenerative disorders. Another collaboration agreement with Mitopharm Ltd., a subsidiary of UK research organization Selcia Holding Ltd., has intentions including the development of drug candidates for treating mitochondrial defects and increasing the capacity of the mitochondria to produce energy. Both these agreements contain stipulations regarding revenue sharing on the commercialization of the results of each party's collaboration. The division is based on each party's individual share of funding of the relevant project and varies between equal sharing of revenues to an 80/20 division, with the majority

accruing to that party that has taken the greatest responsibility for development and commercialization. The intention of both these collaborations is for NeuroVive to assume responsibility for the development and commercialization of pharmaceutical products, and thus receive a higher share of future revenues.

NeuroVive has identified the collaboration agreements signed with to-BBB Technologies BV and Mitopharm Ltd. as being particularly important for the Company. Both collaboration partners have specific technology that is critical to the Company's current plans for its operations. If the collaboration works unsatisfactorily or ceases, there are some opportunities to find alternative partners, but this would risk NeuroVive incurring costs and cause delays to the development process.

#### **Sun Moral International (HK) Ltd. (Sihuan)**

Through its subsidiary, the Company has entered a collaboration agreement with Sihuan. According to this agreement, Sihuan is responsible for clinical development, regulatory processes and market approval, launch, marketing, distribution and sale of CicloMulsion® and NeuroSTAT® in China. NeuroVive will provide Sihuan with CicloMulsion® and NeuroSTAT® for clinical trials, and at launch, provide this company with commercial volumes of these pharmaceuticals for distribution and sale by Sihuan in China initially. Sihuan will make up-front and milestone payments to NeuroVive's subsidiary totaling 35 million yuan and 12 million yuan for CicloMulsion® and NeuroSTAT® respectively. In addition, this company shall pay royalties of 10% of net revenues for the two products for ten years after market approval. This agreement is exclusive, which means that the subsidiary cannot enter a corresponding agreement with another party.

NeuroVive has provided a parent company guarantee to Sihuan by which the Company guarantees all group companies' performance according to this agreement, undertakes joint responsibility for all group companies' obligations to Sihuan and guarantees that the Company will take over all rights and obligations pursuant to the agreement in the event of a change of control of the subsidiary so that the Company no longer controls it.

#### **Hospices Civils de Lyon**

The Company has entered an agreement with Lyon Teaching Hospital, Hospices Civils de Lyon (HCL) regarding an external clinical trial (phase III) on its drug candidate CicloMulsion®. This agreement has implications including conferring the Company with entitlement to access to usage of data from the trial with the aim of seeking market approval from the French and other relevant regulatory authorities, for a payment to HCL. Where the data is pivotal, i.e. decisive for registering products, HCL will receive single-digit royalties based on the Company's revenues from these products. The royalty payment HCL receives comprises a yearly minimum remuneration level with a remuneration cap.

#### **Copenhagen University Hospital**

Copenhagen University Hospital is conducting a phase IIa trial on NeuroSTAT®, which is expected to continue until fall 2014. Unlike the phase III trial at HCL, NeuroVive is the sponsor of this phase II trial.

#### **Foundation Asia Pacific Ltd.**

NeuroVive is party to a series of agreements with Foundation Asia Pacific Ltd. regarding NeuroVive's subsidiary NeuroVive Pharmaceutical Asia Ltd. in Hong Kong. This subsidiary is 70% owned by NeuroVive and 30% owned by Foundation Asia Pacific Limited. This subsidiary is administered jointly by the parties through a shareholders' agreement and the subsidiary controls the rights to NeuroVive's prospective future pharmaceuticals in China to enable it to enter collaboration agreements with Chinese pharmaceutical companies on the development and commercialization of prospective pharmaceuticals in China.

#### **Isomerase Therapeutics Ltd.**

On 1 June 2013, the Company entered a collaboration agreement with Isomerase Therapeutics Ltd. involving an average minimum of 160 working-hours each month. All related results accrue to the Company.

#### **Other**

Against the background of the Company's operations involving the development and commercialization of its products, the Company bears product liability regardless of the origin of the technology. In several agreements, NeuroVive has assumed unlimited liability regarding its agreement counterparties for claims based on the infringement of third party intellectual property, as for product liability, which to some extent, exposes the Company to risks that cannot be transferred to agreement counterparties in earlier phases in every respect. These risks have been accepted based on business assessments and are regarded to correspond to industry standards. According to the Company, NeuroVive has no obligations containing terms that materially differ from those generally applied on the market where NeuroVive is active or are unrelated to the operations of the Company.

Most of NeuroVive's research is conducted in collaboration with the Research Team at Lund University, which is led by Associate Professor Eskil Elmér, also NeuroVive's CSO. The Company takes a positive view of its proximity to, and collaboration with, and the University, particularly since a number of services important to the Company have been achieved through this collaboration. However, the Company is conscious of the risks involved for us private-sector player to collaborate with a central government authority. The Company has taken a number of measures to minimize these risks. NeuroVive has prepared agreements with researchers at Lund University on matters including data and patent

rights, as well as non-disclosure. However, there is no formalized collaboration agreement with Lund University at present, and as far as the Board of Directors is aware, none between the University and any other similar company in Lund. Discussions regarding collaboration agreements are ongoing.

There is no currently applicable lock-up agreement where individuals in administrative, executive management or governing bodies or Board members and senior managers with shareholdings have limited their ability to sell shares, decline voting rights or in other ways limit their capability of disposing freely over their shares.

The Company is party to a loan agreement for a maximum of four million Swedish kronor with Baulos Capital Belgium SA as lender. This loan can be drawn down in installments until 7 March 2014 inclusive pursuant to written notification from the Company. This loan accrues no interest but is subject to a 3% charge for each draft. A credit facility commission of SEK 120,000 has also been paid. No collateral is required.

## PATENT PORTFOLIO

### Usage patents

NeuroVive holds approved global patent rights for neuroprotection with cyclosporine for acute neurological damage (usage patents for the usage of the active compound for the specific purpose). This patent covers usage of cyclosporine A, its variants and derivatives, for all acute neurological diseases to prevent nerve cell necrosis. This includes TBI and stroke. NeuroVive jointly holds patents across this whole segment with Maas Biolab LLC, but holds exclusive rights to all acute damage under jointly held patents in this segment (see the "significant agreements" heading). These patents cover 20 European countries, the USA, Canada, Mexico, Russia, Japan and China. The above usage patent protection for treating acute neurological conditions runs until 2016.

### Formulation patents

NeuroVive holds patent rights (formulation patents for ingredient combinations in a pharmaceutical preparation) in a lipid emulsion containing cyclosporine A, which is free from chremophor and ethanol. Accordingly, these patents relate to all the Company's drug candidates that use the relevant composition including cyclosporine A. These patents not only cover intravenous use but also per oral use, i.e. for patients treated orally with capsules or solution. The agreement by which the patent rights were acquired imply royalties of 10% of NeuroVive's revenues that are attributable to non-immunosuppressive pharmaceuticals is in favor of CicloMulsion AG. For the immunosuppressive segment, the royalties are 30%. Both these royalties run for 15 years from product launch, assuming that the aforementioned arbitration procedure is found in favor of CicloMulsion AG. The intravenous patent covers the USA, Japan, the UK, Germany, France and Italy.

## USAGE OF CYCLOSPORINE A AND DERIVATIVES FOR TREATING ACUTE NEUROLOGICAL CONDITIONS

Patent number	Region	Expiry
712974	Australia	2016
2210241	Canada	2016
96192572.8	China	2016
291233	Czech Republic	2016
3643380	Japan	2016
209398	Mexico	2016
300699	New Zealand	2016
2194527	Russia	2016
5972924	USA	2016
0813420	Austria	2016
0813420	Belgium	2016
0813420	Denmark	2016
0813420	Netherlands	2016
0813420	France	2016
0813420	Germany	2016
0813420	Greece	2016
0813420	Ireland	2016
0813420	Italy	2016
0813420	Latvia	2016
0813420	Lithuania	2016
0813420	Luxembourg	2016
0813420	Monaco	2016
0813420	Portugal	2016
0813420	Spain	2016
0813420	Sweden	2016
0813420	Slovenia	2016
0813420	Switzerland	2016
0813420	UK	2016

## PHARMACEUTICAL COMPOSITIONS WITH CYCLOSPORINE FOR INTRAVENOUS TREATMENT

Patent number	Region	Expiry
59310166.9-08	Germany	2013
0570829	France	2013
0570829	Italy	2013
0570829	UK	2013
5622714	USA	2013
5527537	USA	2013
3569534	Japan	2013

## PHARMACEUTICAL COMPOSITIONS WITH CYCLOSPORINE FOR ADMINISTRATION AS ORAL SOLUTION

Patent number	Region	Expiry
594 09 140.3-08	Germany	2014
0651995	France	2014
0651995	Italy	2014
0651995	UK	2014
5529785	USA	2013
5637317	USA	2013

## PHARMACEUTICAL COMPOSITIONS WITH CYCLOSPORINE FOR ADMINISTRATION AS ORAL CAPSULES

Patent number	Region	Expiry
596 08 606.7-08	Germany	2016
0859626	France	2016
0859626	UK	2016
0859626	Italy	2016
6136357	USA	2016

### Patent applications

#### CYCLOSPORINE EMULSION THAT CONTAINS MEDIUM-LENGTH FATTY ACIDS

Application number	Region	Expiry
PCT/EP2011/067117	PCT	2030
61/388,633	USA	
PA201000891	Denmark	

#### TOXPHOS MITOCHONDRIAL TOXICITY TEST

Application number	Region	Expiry
PCT/EP2013/070666	PCT	2032

#### PHARMACEUTICALS FOR MITOCHONDRIAL ENERGY REGULATION

Application number	Region	Expiry
PCT/EP2013/070666	PCT	2032

<sup>1</sup> Patent filed by Mitopharm Ltd. within the collaboration agreement.

In 2010, NeuroVive filed an application for a formulation patent to cover changes to the original formulation.

#### New patent applications acquired from Biotica Ltd.

The acquisition of a portfolio of new cyclophilin inhibitors with the associated intellectual property from Biotica Ltd. in March 2003 also included the rights to global patent applications filed for these molecules. NeuroVive has commenced the work of transferring these patents applications to the Company's name. The acquired assets include molecular composition, knowledge of the production method and its application, primarily medical usage. The filed patent has long duration and broad coverage. The acquisition of intellectual property for the new cyclophilin inhibitors consolidates the Company's patent portfolio and safeguards future commercial rights in the Company's priority business segments.

##### NOVEL GENE CLUSTER

Application number	Filing date	Priority data
PCT/CN2009/074178WO 2010/034243 Published 1 Apr 2010 (P012185PCT1)	24 Sep 2009	CN 200810200388.4 24 Sep 2008

##### SANGLIFEHRIN BASED COMPOUNDS (AMIDE MOTIF)

Application number	Filing date	Priority data
PCT/GB2011/050236 WO 2011/098809 Published 18 Aug 2011 (P012092PCT1)	9 Feb 2011	GB 1002097.2 9 Feb 2010  GB 1006128.1 13 Apr 2010 GB1101085.7 21 Jan 2011

##### SANGLIFEHRIN DERIVATIVES AND METHODS FOR THEIR PRODUCTION (PHENYL MOTIF)

Application number	Filing date	Priority data
PCT/GB2011/052524 WO 2012/085553 Published 28 Jun 2012 (P012127PCT1)	20 Dec 2011	GB 1021522.6 20 Dec 2010  GB 1113626.4 8 Aug 2011

##### MACROCYCLIC COMPOUND AND METHODS FOR ITS PRODUCTION, B C556

Application number	Filing date	Priority data
PCT/GB2012/050700 WO 2012/131371 Published 4 Oct 2012 (P012156PCT1)	29 Mar 2012	GB 1105293.3 29 Mar 2011 GB 1113629.8 8 Aug 2011 GB 1202060.8 7 Feb 2012

##### MACROCYCLIC COMPOUNDS AND METHODS FOR THEIR PRODUCTION (BIOTICA)

Application number	Filing date	Priority data
PCT/GB2012/050707 WO 2012/131377 Published 4 Oct 2012 (P012162PCT1)	29 Mar 2012	GB 1105293.3 29 Mar 2011 GB 1113629.8 8 Aug 2011 GB 1202060.8 7 Feb 2012

##### NOVEL DOSAGE FORM (BIOTICA)

Application number	Filing date	Priority data
PCT/GB2012/052633 WO 2013/061052 Published 2 May 2013 (P012160PCT1)	24 Oct 2012	GB 1118334.0  24 Oct 2011

The filing date is the date the patent application is first received by a patent authority. Priority data is used to determine newness and/or clarity compared to other technology.

#### Patent protection and market exclusivity for each project

NeuroSTAT® for TBI has patent protection through the usage patent (protects usage of the active compound for the specific purpose) until 2016 and through the intravenous formulation patent (covers the ingredients composition in the pharmaceutical preparation) until 2013. Assuming the patent application is granted, when these patents expire, NeuroSTAT® will be covered by the formulation patent filed in 2010, which runs until 2030. Orphan drug designation confers additional market exclusivity on NeuroSTAT® for TBI. Registration of NeuroSTAT® confers ten (10) years' exclusive rights on the market in Europe, and seven (7) years in the USA from the registration date, and the cover also continues even if patents expire before the period for orphan drug designation has expired.

CicloMulsion® for heart cell protection has patent protection until 2013 through intravenous preparation patents. Assuming patent applications are approved, when these patents expire, CicloMulsion® will be covered by the formulation patent filed in 2010, which runs until 2030. The product will enjoy some legal data protection in future registration. This is legal cover is in place to provide third parties that have undertaken an extensive cost-intensive trial exclusive rights to utilize the results to register a pharmaceutical. This means that a competitor must either repeat the clinical trials that NeuroVive's registration is based on or wait until the period of the data protection has expired.

NVP014 is a new chemical composition that includes some protection through to-BBB Technologies BV's existing patent platform and will also be covered by new patent applications that are planned for filing as soon as the development process has generated sufficient data and patent examples, covering design, the production process and application. Assuming they are approved, these new patents will run for 20 years from the date the application is filed and will be jointly owned by NeuroVive and to-BBB Technologies BV. Commercial rights are stated under the "significant agreements" heading.

The Company is also developing a new family of mitochondrial energy regulation pharmaceuticals. The first patent application was filed through Mitopharm Ltd. in 2012 covering the chemical design, production process and application. Assuming they are approved, these new patents run for 20 years from the date the application is filed and will be owned by NeuroVive from the start of preclinical trials. Commercial rights are stated under the "significant agreements" heading.

NICAMs and NCCIMs are new druggable compounds intended for protection via new patent applications, planned for filing as soon as the development process has generated sufficient data and patent examples, which will cover the design, production process and application. Assuming they are approved, these new patents will run for 20 years from the date the patent is filed and the Board of Directors expects them to be owned and commercialized according to the same principles as the energy regulation of mitochondria. Commercial rights are stated under the "significant agreements" heading.



### The extent of patent protection

NeuroVive's patent portfolio is an important asset to the Company and an extensive patent portfolio prevents competitors from infringing on the Company's patented segments. However, the Board of Directors judges that NeuroVive is not dependent on its patents to be able to commercialize its drug candidates. Patents confer market exclusivity during the term of the patents.

### Trademark protection

NeuroVive has also secured trademark protection for the names NeuroSTAT®, CicloMulsion®, NeuroVive and the NVP logo in a number of countries, and intends to progressively extend trademark protection to other countries. The actual registration is no guarantee that the regulatory authorities will permit usage of the trademark for the relevant pharmaceutical. The application for permission to use a specific trademark for a pharmaceutical is filed coincident with, or immediately after, an application for approval for sale, and is granted if there is no risk of confusion with the name of an already extant pharmaceutical.

### ORPHAN DRUG DESIGNATION IN THE EU AND USA

In October 2010, the European Commission granted orphan drug designation for NeuroSTAT® for treating patients with moderate and severe TBI. The designation confers NeuroVive market exclusivity in the EU for ten (10) years after marketing authorization is granted and also runs even if patents expire before this ten-year period has expired. Orphan drug designation also confers access to regulatory assistance and reduced filing fees from the European Medicines Agency (EMA) through the development phase.

In December 2010, the US pharmaceutical regulatory authority the FDA, also granted orphan drug designation for treating patients with moderate to severe brain injury with the company's drug candidate NeuroSTAT® (cyclosporine A).

Securing orphan drug designation implies market exclusivity for seven (7) years, and also continues even if patents expire before the seven-year period has passed. Orphan drug designation also grants access to regulatory support from the FDA through the development process.

In itself, the designation does not imply that the drug candidate has demonstrated the efficacy, safety and quality necessary for drug registration in the USA or Europe. These criteria must be satisfied in the pharmaceutical and clinical phases that the regulatory authority will then approve before marketing authorization is granted for the drug candidate.

### TAX

As of 30 September 2013, the Company reported an accumulated deficit of SEK 62,198,000. However, the Company has not reported any value for this deficit. The Company's prospects of utilizing the accumulated deficit wholly or partly in the future is determined by factors including future changes of ownership of the Company, which the Company has no control over.

### INCENTIVE PROGRAM—SHARE WARRANTS

The shareholders' meeting on 10 July 2011 approved a share-related incentive program for senior managers and/or other employees through the issuance of a maximum of 164,000 share warrants.

#### PERSONER SOM VALDE ATT TECKNA TECKNINGSOPTIONER HÄNFÖRLIGA TILL INCITAMENTSPROGRAMMET

Name	No. of share warrants
Mikael Brönnegård	40,000
Gregory Batcheller	40,000
Eskil Elmér	40,000
Andreas Inghammar	16,000
Christian Svensson	16,000
Fredrik Sjövall	4,000
Eleonor Åsander-Frostner	4,000
Magnus Hansson	4,000
<b>Total</b>	<b>164,000</b>

The warrants were subscribed at a price of SEK 2.50 per share warrant. NeuroVive paid net salary compensation with the additional tax and social security contributions to the Board of Directors and Senior Managers with the aim of part-funding option subscription. The net salary paid out was SEK 50,000 to Gregory Batcheller, SEK 50,000 to Mikael Brönnegård, SEK 50,000 to Eskil Elmér, SEK 20,000 to Andreas Inghammar and SEK 20,000 to Christian Svensson. In the period 10 April 2014 to 10 June 2014, holders of share warrants are entitled to subscribe for one new share of the Company for each share warrants at a subscription price of SEK 96.00 per share. If all share warrants are exercised, the Company's share capital would increase by SEK

#### REMUNERATION TO THE BOARD OF DIRECTORS AND SENIOR MANAGERS IN 2012

Remuneration (SEK 000)	Directors' fees*	Basic salary	Variable salary	Pension expense	Consulting fees	Other remuneration	Social security contributions	Total
Gregory Batcheller (Chairman of the Board)	-	-	-	-	1,206	168	-	1,374
Arne Ferstad (Board member)	250	-	-	-	272	43	-	565
Marcus Keep (Board member)	230	-	-	-	-	-	-	230
Helena Levander (Board member)	250	-	-	-	-	-	79	329
Helmuth von Moltke (Board member)	230	-	-	-	-	-	-	230
Jan Nilsson (Board member)	270	-	-	-	213	43	85	425
Mikael Brönnegård (CEO)	-	1,140	240	160	-	5	434	1,979
Eskil Elmér (CSO)	-	188	-	-	-	-	59	247
Andreas Inghammar (Manager, Corp. Affairs)	-	101	-	-	-	-	32	167
Christian Svensson (former CFO)	-	72	-	9	551	2	23	657
<b>Total</b>	<b>1,230</b>	<b>1,501</b>	<b>240</b>	<b>169</b>	<b>2,242</b>	<b>261</b>	<b>712</b>	<b>6,355</b>

\* There are no bonus agreements, contracted severance pay or corresponding compensation for Board members and Senior Managers. Nor is there any conditional or deferred compensation or emoluments to report, nor any reserved or accrued amounts for pensions or similar benefits after termination of service.



8,200, and the Company would raise SEK 15,744,000.

## TRANSACTIONS WITH RELATED PARTIES

### Consulting fees and reimbursement

Consulting fees and reimbursement for travel expenses has been payable on an arm's length basis to Gregory Batcheller (via Stanbridge Corporation BVBA), Arne Ferstad (via the company Ankor Consultant BVBA), Jan Nilsson (via Jan Nilsson Konsult), Mikael Brönnegård (via Bio&IT Partners AB prior to becoming CEO in May 2010) and Christian Svensson as CFO (via the company Christian Svensson och Verum Consulting AB) according to the following statement (total amounts for each period excluding Directors' fees). Consulting fees for work in legal services, patents, strategy, business development, market start-ups, and as CFO.

#### CONSULTING FEES AND REIMBURSEMENT

(SEK 000)	2013	2012	2011	2010
	(9 mth.)	(12 mth.)	(12 mth.)	(12 mth.)
Gregory Batcheller (via company)	1,030	1,374	664	456
Arne Ferstad (via company)	298	315	358	29
Jan Nilsson (via company)	46	255	395	-
Mikael Brönnegård (via company)	0	-	-	71
Christian Svensson (the Company's former CFO) (via company)	120	553	169	168

### Intellectual property and remuneration—the Research Team

As stated under “significant agreements”, NeuroVive is in agreement with a research team at the Mitochondrial Pathophysiology Unit at the Faculty of Medicine at Lund University, called the “Research Team,” which includes the CSO Eskil Elmér and Chairman of the Board Gregory Batcheller, regarding the rights to, and remuneration for, products that may be developed in a project in mitochondrial energy regulation in future. This is an externally developed academic project, which is the base to one of the sub-projects in the collaboration with Mitopharm Ltd. NeuroVive's Board of Directors judges that potential remuneration payable on the successful sale or out-licensing of products spawned from this project are on market terms and that the agreement provides significant opportunities for NeuroVive in the mitochondrial energy regulation segment.

The agreement between members of the Research Team and NeuroVive partly formalizes the exclusive transfer of future intellectual property within the project from the authors to the Company, but also compensation to the authors. The compensation is based exclusively on future revenues such as sales, license revenue, down-payments, milestone payments, etc. Compensation is on a step-wise bases, whereby taking responsibility for product development, NeuroVive progressively increases its financial interest vis à vis individuals in the Research Team. The out-licensing or sale in an early stage when the Company's development expenses are less than SEK ten (10) m confer the authors with 50% of the Company's revenues from the specific project. Subsequently, the compensation

levels progressively step down in relation to the Company's increased development expenses until the authors' compensation is ten (10)% of NeuroVive's revenues from the specific project, when the Company's development expenses exceed SEK 50 m.

The transaction of intellectual property was conducted in 2011, although there has been no monetary transactions to date. This will not become relevant until the out-licensing or sale of drug candidates associated with this specific project.

In its academic work, the Research Team has also developed an analytical method to determine mitochondrial function in human blood corpuscles. This analysis method can be applied in diagnostics and preclinical toxicology of drug development. With the aim of commercializing the results achieved in this research, an agreement was signed with NeuroVive in 2012, through which the Research Team transferred the results achieved to NeuroVive for a predetermined payment, and undertook to work on the project on NeuroVive's behalf to a specific extent. Remuneration to members of the Research Team is based on the Company's future revenues attributable to this project, and is payable on a stepwise basis, by which the Research Team's share starts at 50% and may fall to 10% of revenues the greater the investment in the project the Company makes. Accordingly, no remuneration will be paid before results from the project generate revenues for the Company.

### Other transactions with related parties

Apart from the aforementioned transactions with related parties and the incentive program reviewed above, there have not been any transactions between NeuroVive and related parties of the Company.

## STAKEHOLDING IN NEUROVIVE

NeuroVive's Board of Directors and Senior Managers hold shares (directly and indirectly) and share warrants in the Company. Share and share warrant holdings for each individual are reviewed in more detail in the “Board of Directors, Senior Managers and Auditors” section of this prospectus.

Since 2009, NeuroVive has been purchasing consulting services on an arm's length basis from companies controlled by Board members. For more information see the “transactions with related parties” heading. This implies a potential conflict of interest. Before NeuroVive pays invoices, they must be approved pursuant to the Company's guidelines for approving invoices.

NeuroVive and principal owner Maas Biolab LLC (which is part owned by Board members) entered a Patent and Trademark Transfer Agreement on 29 May 2008. In 2011 and 2012, NeuroVive entered agreements with the Research Team at the Mitochondrial Pathophysiology Unit at the Faculty of Medicine at Lund University (including the CSO Eskil Elmér and chairman of the Board Gregory Batcheller). These agreements formalize rights and compensation in the mitochondrial energy regulation and ToxPhos segments, the latter being an analysis method for determining mitochondrial

function in human blood corpuscles. For more information, see the "significant agreements" section above. To ensure there is no conflict of interest relating to these agreements, members of the Board and management affected by these agreements do not participate in the decisions or discussions that lead to potential decisions.

Apart from this, there is no conflict of interest in administrative, executive management or governing bodies or with other individuals in senior positions of NeuroVive, nor is there any other physical or legal person associated with the share issue with financial or other relevant interests in the Company.

Erik Penser Bankaktiebolag is the financial advisor to the Company that is serving as issuing house for the new share issue. Advokatfirman Lindahl is the legal advisor to the Company for the new share issue. Erik Penser Bankaktiebolag and Advokatfirman Lindahl will receive pre-arranged remuneration for services rendered in connection with the forthcoming new issue. Apart from what is stated above, Erik Penser Bankaktiebolag and Advokatfirman Lindahl have no financial or other interests in the new share issue.

No conflict of interest between the parties, which in accordance with the above, have financial or other interests in the new issue, is considered to exist.

## LEGAL PROCEEDINGS AND DISPUTES

In March 2013, CicloMulsion AG initiated an arbitration procedure whereby CicloMulsion AG is seeking to determine the significance of the agreement entered into between CicloMulsion AG and NeuroVive. CicloMulsion AG wants to determine whether NeuroVive has the right to cancel the agreement between the parties, and how CicloMulsion AG's right to receive royalty would be affected by such cancellation. CicloMulsion AG also wants to obtain information regarding NeuroVive's agreement with Sihuan for reasons including computing royalties. If the arbitration is ruled in NeuroVive's favor, NeuroVive could avoid royalty payments the Company would otherwise have been liable to have paid for a period of 15 years after products are launched. If the arbitration is ruled in CicloMulsion AG's favor, NeuroVive may be obliged to pay future royalties without being able

to cancel the agreement. There is a risk that CicloMulsion AG decides to have the arbitration procedure cover other agreement areas.

## SUBSCRIPTION UNDERTAKINGS AND UNDERWRITING GUARANTEES

The rights issue is underwritten up to approximately SEK 50 m through an underwriting guarantee agreement, which corresponds to approximately 66% of the rights issue. The following table on this page indicates those parties that have made subscription undertakings and entered agreements on underwriting guarantees with the Company regarding the rights issue. Cash commission is payable at 8% of the underwritten amount under the underwriting guarantee agreement. The total guarantee commission SEK 4,000,000 SEK 000. The underwriting guarantee agreement was entered on 20 November 2013.

## DOCUMENTATION INCORPORATED BY REFERENCE

In addition to this document, the prospectus consists of the following documentation, which accordingly, is incorporated by reference:

- NeuroVive's Interim Report for the period January-September 2013. This Interim Report has been subject to a summary review by the Company's Auditor.
- NeuroVive's Annual Accounts for the financial years 2012, 2011 and 2010. The Annual Accounts have been reviewed by the Company's Auditor. The reference only relates to historical information including statutory administration reports, notes to financial statements and audit reports.

This prospectus and the documentation incorporated by reference as stated above will be available in electronic form from the Company's website [www.neurovive.se](http://www.neurovive.se) for the term of the prospectus. The website also has audited Annual Accounts for previous financial years and Interim Reports available, as well as documentation on corporate governance, etc.

The above information incorporated by reference should be read as part of this prospectus. The level of information in this prospectus stands in reasonable proportion to the relevant type of share issue (rights issue).

## UNDERWRITING GUARANTEES

Shareholder/external guarantor	Subscription undertaking, SEK	Issue Guaranty, SEK	Total subscription commitment, SEK	Compensation, SEK
SSE Opportunities Ltd. <sup>1</sup>	0	15,000,000	15,000,000	1,200,000
Grenspecialisten Förvaltning AB <sup>2</sup>	0	5,000,000	5,000,000	400,000
LMK Ventures AB <sup>3</sup>	0	5,000,000	5,000,000	400,000
Göran Källebo <sup>4</sup>	0	5,000,000	5,000,000	400,000
Råsunda förvaltning aktiebolag <sup>5</sup>	0	3,500,000	3,500,000	280,000
Mats H Nilsson <sup>6</sup>	0	3,500,000	3,500,000	280,000
Gryningskust Holding AB <sup>7</sup>	0	3,000,000	3,000,000	240,000
Fårö Capital AB <sup>8</sup>	0	3,000,000	3,000,000	240,000
Falvir International Ltd. <sup>9</sup>	0	1,500,000	1,500,000	120,000
LR Johansson Aktier AB <sup>10</sup>	0	1,000,000	1,000,000	80,000
Chrilotte AB <sup>11</sup>	0	1,000,000	1,000,000	80,000
Belmondo AB <sup>12</sup>	0	1,000,000	1,000,000	80,000
Ulti AB <sup>13</sup>	0	1,000,000	1,000,000	80,000
Falvir AB <sup>14</sup>	0	500,000	500,000	40,000
Creocasus AB <sup>15</sup>	0	500,000	500,000	40,000
Lagoras AB <sup>16</sup>	0	500,000	500,000	40,000

<sup>1</sup>Templar House, Don Road, JE1 2TR St Helier, JERSEY

<sup>2</sup>Box 4042, 203 11, MALMÖ, Sweden

<sup>3</sup>c/o LMK Industri AB, Stortorget 6, 222 23, LUND, Sweden

<sup>4</sup>Karlavägen 77, 114 49 STOCKHOLM, Sweden

<sup>5</sup>adress c/o Nilsson-Sjöblom, Skogsbacken 20, plan 4, 172 41, SUNDBYBERG, Sweden

<sup>6</sup>Via Della Brima 15b, 6612 Ascona, Switzerland

<sup>7</sup>c/o Thorell, Baldersuddevägen 26, 134 38, GUSTAVSBERG, Sweden

<sup>8</sup>Norra Villavägen 19 B, 237 34 BJÄRRED, Sweden

<sup>9</sup>Koumashon street 45, Villa 3, 8560 Peyia, Cyprus

<sup>10</sup>Trädlyckevägen 84, 432 34, VARBERG, Sweden

<sup>11</sup>Glasvingevägen 2, 311 72, FALKENBERG, Sweden

<sup>12</sup>Bobergs Kustväg 31, 311 92, FALKENBERG, Sweden

<sup>13</sup>Floragatan 14, 114 31 STOCKHOLM, Sweden

<sup>14</sup>Metallgatan 21 B, 262 72 ÄNGELHOLM, Sweden

<sup>15</sup>c/o Falvir AB, Framtidsgatan 3, 262 73, ÄNGELHOLM, Sweden

<sup>16</sup>Box 21, 311 21, FALKENBERG, Sweden

# Corporate governance

NeuroVive's internal controls and corporate governance are based on applicable laws, rules and regulations and sector-specific parameters considered important for the Company. The control system not only covers applicable rules and regulations but also the specific standards NeuroVive applies to its operations.

Internal controls and corporate governance confer overall control over all important phases for the Company. Thereby, the Company's Board and management have good prospects of being able to control and manage operations in the manner required to satisfy the high standards set by the Company, market, stock exchange, shareholders and regulatory authorities.

Laws/rules and regulations including the following, as well as the Company's own control documentation, are the foundation of NeuroVive's corporate governance:

## EXTERNAL RULES AND REGULATIONS

- The Swedish Companies Act,
- Relevant accounting legislation,
- IFRS,
- The Swedish Code of Corporate Governance.

Effective from NeuroVive's listing on NASDAQ OMX Stockholm, Small Cap, the Company is also subject to NASDAQ OMX Stockholm's rules for issuers.

## INTERNAL CONTROL DOCUMENTS

- Articles of Association,
- Instructions and rules of procedure for the Board of Directors, Committees and CEO,
- Remuneration guidelines to senior managers,
- Corporate Communication Policy
- Ethical Guidelines, Accounting Handbook.

## APPLICATION OF, AND NON-COMPLIANCE WITH, THE SWEDISH CODE OF CORPORATE GOVERNANCE

NeuroVive has applied the Swedish Code of Corporate Governance (called the "Code" below) effective 8 June 2012, coincident with the Company's AGM. The Corporate Governance Report for 2012 is available from the Company's website, [www.neurovive.se](http://www.neurovive.se)

According to code stipulation 9.8, share-related incentive programs may not run for less than three years from entering the agreement until the Share can be acquired. Senior managers and/or employees were party to a share-related incentive program in July 2011 where shares could be acquired in the period April - June 2014. The agreed period is three months less than the three years stipulated by the Code. According to the Code, nor may the

incentive program be addressed to Board members that are not simultaneously employed by the Company. Chairman of the Board Gregory Batcheller has subscribed for options in the incentive program. However, it should be noted that the incentive program was entered before NeuroVive started to apply the Code. The Company intends to comply with the Code in any future share-related incentive programs.

## ANNUAL GENERAL MEETING (AGM)

The AGM is the ultimate decision-making body of a limited company and shareholders exercise their rights to decide over the Company's affairs at the AGM. The AGM is planned and executed for the shareholders to be able to exercise their influence over the Company in the best manner possible. Invitations and other information is designed for shareholders to be able to reach well-founded decisions on those matters arising at the AGM. Resolutions by AGMs should be reached in accordance with the Swedish Companies Act's rules on majority requirements.

## Entitlement to attend AGMs

All shareholders directly registered in the share register maintained by Euroclear Sweden AB five days prior to the AGM and that have notified NeuroVive of their intention to participate by no later than the date stated in the invitation to the AGM are entitled to attend the AGM and vote for the number of shares they hold.

## Initiatives from shareholders

Shareholders that desire to have a matter considered at the AGM must send a written request to the Board of Directors no later than seven weeks prior to the AGM.

Considering the composition of the Company's ownership base, it is not considered justifiable or defensible to offer simultaneous interpretation to other languages and translation of all or parts of AGM documentation, considering the Company's financial circumstances.

NeuroVive's website has information on the Company's previous AGMs and information on shareholders' rights to have matters considered at the Meeting, and when the Company must have received shareholders' requests for such matters.

## AGM 2013

The AGM was held on 8 March 2013 at Scheelevägen 2, Lund, Sweden. The invitation was published in the Swedish Official Gazette and on the Company's website. An announcement that the invitation has been advertised is published in Swedish daily newspaper Svenska Dagbladet. Proposals for resolution are stated in the invitation to provide the Company's shareholders with a

good overview of the matters to be considered by the Meeting. The Annual Accounts and Audit Reports as well as complete proposals for resolution are available at the Company's office and on the Company's website the requisite time before the AGM. Material from the Meeting, such as the invitation, minutes and decision-support data, is available at NeuroVive's website [www.neurovive.se](http://www.neurovive.se).

The AGM 2013 reached the following resolutions:

- Adoption of the Balance Sheet and Income Statement, as well as the Consolidated Balance Sheet and Consolidated Income Statement,
- Resolution on discharging the Board members and Chief Executive Officer from liability,
- Determining the number of Board members,
- Approving fees for the Board of Directors and Auditors,
- Electing the Board of Directors,
- Resolution on remuneration guidelines for Senior Managers,
- Resolution on guidelines for the Nomination Committee

## NOMINATION COMMITTEE

The Company shall have a Nomination Committee that shall consist of one member for each of the three largest shareholders in terms of the number of votes based on the ownership statistics obtained from Euroclear Sweden AB. The Chairman of the Board is convener and co-opted to the Nomination Committee. The Chief Executive Officer or other member of management may not be a member of the Nomination Committee, nor may Board members constitute a majority of Nomination Committee members. If a shareholder does not exercise its right to appoint a member, that shareholder that is next largest in terms of the number of votes shall be entitled to appoint a member of the Nomination Committee. The majority of the Nomination Committee's members should be independent of the Company and management, if more than one Board member is a member of the Nomination Committee, a maximum of one of them may be dependent on the Company's major shareholders. At least one of the members of the Nomination Committee should be independent of the largest shareholder of the Company in terms of the number of votes or group of shareholders that cooperate on the Company's administration. No compensation is payable to any members of the Nomination Committee for their work.

The Nomination Committee commences its work on reviewing the appraisal conducted of the incumbent Board of Directors. This work should feature openness in discussions with the aim of achieving a well-balanced Board of Directors. Subsequently, the Nomination Committee nominates members of NeuroVive's Board of Directors for the forthcoming term of office, which are then proposed at the AGM. The duty of the Nomination Committee is to propose the Chairman of the AGM, Chairman of the Board and Board members, number of Board members, remuneration of Board members and Committee members, as well as the election

and remuneration of Auditors. The Nomination Committee also has the duty of proposing guidelines for appointing members of the Nomination Committee, and for the Nomination Committee's assignments.

Until a new Nomination Committee for the AGM 2014 has been appointed, the Nomination Committee has the following members:

Michael Vickers (Chairman of the Nomination Committee), member for Maas Biolab LLC,  
Anders Ermén, member for Private Placement SPRL, and  
Tomas Hagström, member for Eskil Elmér.

## BOARD OF DIRECTORS

### Composition of the Board of Directors

the Board of Directors should consist of a minimum of three and a maximum of eight members. Board members are appointed yearly by the AGM and elected for a period until the end of the next AGM. NeuroVive's AGM on 8 March 2013 re-elected Gregory Batcheller, Arne Ferstad, Marcus Keep, Helena Levander and Helmuth von Moltke as Board members. Boel Flodgren and Anna Malm Bernsten were elected as Board members. Gregory Batcheller was re-elected Chairman of the Board. No Board member is employed in the Company's management, although Gregory Batcheller serves in the Company's management on a consultancy basis via Stanbridge Corporation BVBA. Each Board member's independence of the Company, the Company's management and the Company's major shareholders is stated in the table on page 50.

### Chairman of the Board

The Chairman of the Board is appointed by the AGM. The Chairman of the Board represents the Board of Directors externally and internally. The Chairman of the Board should lead the work of the Board of Directors, monitor and be responsible for the Board of Directors performing its duties in accordance with law, the Articles of Association, the Swedish Code of Corporate Governance and the rules of procedure of the Board of Directors.

Through contacts with the Chief Executive Officer, the Chairman of the Board should monitor the Company's progress, consult with the Chief Executive Officer on strategic matters and monitor and ensure that the Board of Directors follows and addresses strategic matters. The Chairman of the Board should also ensure that through the Chief Executive Officer, the Board of Directors receives regular information on the Company for analysis of the Company's position.

Because Gregory Batcheller has a permanent position for the Company in addition to Chairmanship, the division of responsibility between the Chairman and Chief Executive Officer has been clarified in the rules of procedure of the Board of Directors and the instructions for the Chief Executive Officer.

## THE WORK AND RESPONSIBILITIES OF THE BOARD OF

## DIRECTORS

The Board of Directors is the Company's chief decision-making body below the AGM. The work of NeuroVive's Board of Directors is controlled by applicable laws and recommendations, and by the rules of procedure of the Board of Directors, which are adopted yearly. The rules of procedure include rules for the division of responsibility between the Board of Directors and CEO, financial reporting and audit issues. The Board of Directors also considers relevant rules of procedure, policies and guidelines that are the foundation of the Company's internal regulatory system at the Board meeting following election.

Primarily, the Board of Directors should attend to overall and long-term matters and matters that are of unusual significance to the Company. The Board of Directors bears overall responsibility for the Company's operations and management and for accounting and the management of assets being controlled satisfactorily. The Board of Directors is responsible for the Company's compliance with applicable laws, ordinances and the Swedish Code of Corporate Governance, and for the Company having good internal controls and formalized processes that ensure compliance with the adopted principles for financial reporting and internal controls.

## REMUNERATION COMMITTEE

To support the Board of Directors on salary and compensation issues, the Board of Directors has established a Remuneration Committee, whose duties include

- Consulting on the Board of Directors' decisions on matters regarding remuneration principles, remuneration and other employment terms for management,
- Monitoring and continuously evaluating programs that conclude in the year for variable salary for management, and
- Monitoring and evaluating the application of remuneration guidelines that senior managers at the AGM should resolve on according to law, and the applicable remuneration structures and remuneration levels in the Company.

After consultation by the Committee, decisions on remuneration issues shall be ratified by the Board of Directors.

The Remuneration Committee members are: Helena Levander, Anna Malm Bernsten (Chairman) and Helmuth von Moltke.

## AUDIT COMMITTEE

The members of the Audit Committee are appointed by the Company's Board of Directors at its Board meeting following election, and shall consist of a minimum of three Board members. The Board of Directors appoints the Chairman of the Committee, who may not be the Chairman of the Board. The majority of Committee members should be independent of the Company and management. At least one of the members that is independent of the Company and management should also be independent of the Company's major shareholders.

The Audit Committee has been established with the aim of facilitating fulfillment of the Board of Directors' supervisory responsibilities. As a sub-committee of the Board of Directors, the Committee has limited rights to make decisions. The rules of procedure of the Committee are adopted annually by the Board of Directors during the Board meeting following election. Minutes from the Committee's meetings are presented at this Board meeting, and there is a verbal report on Committee work.

The Committee should contribute to good financial reporting that maintains the market's confidence in the Company by specially monitoring and verifying the Company's accounting policies, accounting management, risk management and the structure, resources, ongoing work and yearly reporting of internal controls. The Audit Committee also verifies the Auditor's independence to the Company.

The Committee should consult on issues relating to the election of Auditors and the fees to external Auditors, and maintain close contact with the Nomination Committee for its proposal to the AGM on the election of Auditors and determining audit fees. The Audit Committee's contact with the Nomination Committee is conducted and maintained by the Chairman of the Committee.

The members of the Audit Committee are Arne Ferstad, Helena Levander (Chairman) and Anna Malm Bernsten.

## CEO AND OTHER SENIOR MANAGERS

The Chief Executive Officer is appointed by the Board of Directors. The work of the Chief Executive Officer complies with the written instructions the Board of Directors adopt yearly at the Board meeting following election.

The instructions for the Chief Executive Officer formalize the customary areas and the Chief Executive Officer's obligations toward the Company and the Board of Directors including responsibility for providing the Board of Directors with expedient reports that are relevant for performing the Board of Directors' duty of judgment regarding the Company. The Chief Executive Officer should ensure that ongoing planning, including business planning and budgets, are prepared and provided to the Board of Directors for the Board of Directors' decisions. With good leadership, the Chief Executive Officer should lead operations in the best manner so the Company progresses according to predetermined plans, adopted strategies and policies. In instances of feared departure from plans and significant events, the Chief Executive Officer should immediately inform the Board of Directors through the Chairman. The Chief Executive Officer should ensure that the Company's operations including its administration, is organized so that they satisfy market standards and ensure that control of operations is organized and functions effectively and securely.

Within the auspices of directives issued by the Board of Directors, management deals with management of the Company's operations, preparation and follow-up of strategies and budgets,

the allocation of resources, monitoring operating activities and preparations for Board meetings.

## **REMUNERATION OF BOARD MEMBERS AND SENIOR MANAGERS**

### **Remuneration of Board members**

The AGM 2013 resolved that Directors' fees of SEK 300,000 should be payable to the Chairman of the Board and SEK 150,000 to each of the other Board members.

The AGM 2013 resolved that fees of SEK 100,000 should be paid to the Chairman of the Audit Committee and SEK 50,000 to each of the other members. The Meeting also resolved that SEK 40,000 should be paid to the Chairman of the Remuneration Committee, and SEK 20,000 to each of the other members of the Remuneration Committee.

### **Remuneration of Senior Managers**

Subsequent to a proposal by the Board of Directors, the AGM 2013 resolved on remuneration guidelines for Senior Managers.

Guidelines for remuneration and other employment terms for management mainly imply that the Company shall offer its Senior Managers market compensation, that compensation shall be consulted by a dedicated Remuneration Committee within the Board of Directors, that the relevant criteria shall consist of senior managers' responsibilities, roles, competence and position.

Remuneration to Senior Managers is decided by the Board of Directors excluding any Board members who are in a position of dependence on the Company and management. The guidelines shall be applied to new agreements or amendments to existing agreements reached with Senior Managers after the guidelines have been adopted, and until new or revised guidelines are adopted.

Senior Managers shall be provided with a basic salary that is on market terms and based on the Senior Manager's responsibility, role, competence and position. Salary shall be set per calendar year.

From time to time, Senior Managers may be offered variable pay. Such variable salary should be on market terms and shall be based on the achievement of predetermined financial and individual targets. The terms, conditions and computation bases of variable salary shall be determined for each financial year. Variable salary is settled the year after accrual and can be paid either as salary or as a lump-sum pension contribution. Upon payment as a lump-sum pension contribution, there is some indexation so the total cost to NeuroVive is neutral. The basic principle is that the yearly variable salary portion can amount to a maximum of 30% of basic annual salary. The total of variable salary for senior managers may amount to an aggregate maximum of SEK 1,200,000.

When setting variable salary to management that is payable in

cash, the Board of Directors should consider introducing clauses that:

- Make payment of a certain portion of such remuneration conditional on the performance on which accrual is based being demonstrably sustainable over time, and
- Enable the Company to reclaim such remuneration paid on the basis of information that later proves obviously inaccurate.

Senior Managers are entitled to market pension solutions according to collective bargaining agreement and/or agreements with NeuroVive. All pension obligations should be defined contribution. It is permitted to waive salary to increase pension provisions through lump-sum pension contributions, assuming the total cost is neutral for NeuroVive.

Notification of termination from NeuroVive's side shall be a maximum of six months for the Chief Executive Officer and a maximum of six months for other Senior Managers. The notice period from the Chief Executive Officer's side shall be a minimum of six months and a minimum of three months for other Senior Managers.

The Board of Directors should be entitled to depart from the above guidelines if the Board of Directors judges that there are circumstances justifying this in an individual case.

Variable salary of SEK 240,000 was paid to Senior Managers in 2012, which is within the guidelines.

At the AGM 2013, the Auditor made a statement regarding whether the Board of Directors complied with the predetermined guidelines for remunerating Senior Managers in 2012. The Auditor stated that the guidelines were complied with.

### **Share-related incentive program**

The AGM 2011 introduced a warrant program for Senior Managers intended to promote the Company's long-term interests.

The share warrants confer entitlement to subscribe for a total of 164,000 new shares at an exercise price of SEK 96 per share. The share warrants can be converted to shares during the exercise period, which runs from 10 April 2014 to 10 June 2014, both dates inclusive. If all outstanding share warrants are exercised, based on the Company's current share capital, this would correspond to a dilution of approximately 0.8% of the Shares and votes at present.

### **AUDITOR**

The Auditor shall review the Company's Annual Accounts and accounting records and the Board of Directors' and CEO's administration. The Auditors should submit an Audit Report and a Consolidated Audit Report to the AGM after each financial year. The Company's Auditors are appointed by the shareholders' at the AGM every fourth year.

Mazars SET Revisionsbyrå was elected as audit firm at the AGM 2012. The Auditor in Charge is Bengt Ekenberg.

To ensure compliance with the communication and control



standards applying to the Board of Directors, the Auditors provide regular reports to the Audit Committee regarding audit issues and regarding potential misstatements or suspected impropriety. In addition, the Auditors participate at most Audit Committee meetings, and where necessary, Board meetings. The Auditor's report to the Board of Directors at least once a year without the Chief Executive Officer or any other member of the Company's operational management being present at the meeting.

#### **Remuneration of Auditors**

The AGM 2013 resolved that audit fees should be payable in accordance with approved account in accordance with the customary charging standards.

SEK 430,000 of audit fees were payable in 2012 for the audit provided. Audit assignments means audits of the Annual Accounts and accounting records and the Board of Directors' and CEO's administration, other duties appropriate to the Company's Auditor and advisory or other services caused by observations from such audit of the performance of other such duties. Upon inspection, the Audit Committee has judged that the Auditors are not dependent on the Company.

#### **INTERNAL CONTROLS OVER FINANCIAL REPORTING**

The overall purpose of internal controls is to provide reasonable assurance that the Company's operational strategies and targets are monitored and that shareholder investments are protected. In addition, internal controls should provide reasonable assurance that external financial reporting is reliable and prepared in accordance with generally accepted accounting practice, that applicable laws and ordinances are followed and the standards applying to listed companies are complied with. The internal control environment mainly consists of the following five components: control environment, risk assessment, control activities, information and communication and monitoring.

#### **Control environment**

NeuroVive's control environment includes its organizational structure, decision paths, responsibilities and authorization, which are clearly defined in a number of control documents. Control documents have been adopted by the Board of Directors to constitute a well-functioning control environment.

The Company's control environment consists of cooperation between the Board of Directors, the Remuneration and Audit Committees, the CEO, CFO, internally appointed staff and the Company's Auditor. Additionally, controls are effected by the accounting manual's predetermined reporting processes, which contain items including monthly financial reporting to the Board of Directors and yearly reporting to the Board of Directors regarding internal controls conducted.

#### **Risk assessment**

Risk assessment includes identifying risks that may arise if the fundamental standards applying to financial reporting of the Group are not satisfied. A review is conducted so the Company has an infrastructure to enable effective and expedient control and the evaluation of the Company's accounting circumstances and significant financial, legal and operational risks.

#### **Control activities**

Control activities limit identified risks and ensure accurate and reliable financial reporting. The Audit Committee and Board of Directors are responsible for internal controls and monitoring by management. This is achieved through internal and external control activities and through reviews of the Company's control documents that relate to risk management. Yearly compilation and reporting of internal controls are provided to the Board of Directors and Audit Committee.

#### **Information and communication**

The Company has information and communication paths designed to promote the accuracy of financial reporting and enable reporting and feedback from operations to the Board of Directors and management, through channels including control documents in the form of internal policies, guidelines and instructions regarding financial reports being made available and known to affected staff.

#### **Monitoring**

NeuroVive monitors compliance with the Company's control documents and internal control processes. At each meeting, the Company's Audit Committee receives reports from management on internal controls. The Board of Directors is regularly updated on the Company's financial position and results of operations against budget and reporting of development projects against each project budget. The CEO provides the Board of Directors with written reports on monitoring and status of the Company's current projects and drug candidates quarterly, or when a specific need arises.

#### **SPECIAL ASSESSMENT OF THE NEED FOR AN INTERNAL AUDIT**

NeuroVive does not conduct internal audits. The Board of Directors evaluates the need for such a function yearly, and judges that considering the Company's size, relatively small number of employees and scale of transactions, there is no reason to establish a formal internal audit function.

# Articles of Association

**NeuroVive Pharmaceutical AB (publ)**

**Corporate identity no: 556595-6538**

**Adopted by the Annual General Meeting (AGM) on 8 June 2012**

## **§ 1 Corporate name**

The Company's corporate name is NeuroVive Pharmaceutical AB. The Company is a public limited company (publ).

## **§ 2 Registered office**

The Board of Directors shall have its registered office in the Municipality of Lund, Sweden.

## **§ 3 Operations**

Directly or indirectly through subsidiaries, the Company shall conduct research, development, sale and licensing of pharmaceuticals and associated business. The Company shall also be able to manage real estate and chattels.

## **§ 4 Share capital**

The share capital shall be a minimum of SEK 591,000 and a maximum of SEK 2,364,000.

## **§ 5 Number of shares**

There shall be a minimum of 11,820,000 shares and a maximum of 47,280,000 shares.

## **§ 6 Board of Directors**

The Board of Directors shall consist of a minimum of three and a maximum of eight members.

## **§ 7 Auditors**

For auditing the Company's Annual Accounts and the Board of Directors' and Chief Executive Officer's administration, one or two Auditors with or without deputies shall be appointed, or one registered public accounting firm.

The assignment of Auditor shall apply until the end of the AGM held in the fourth financial year after the Auditor is appointed.

## **§ 8 Invitation to AGM**

Invitations to the AGM shall always be through an announcement in the Swedish Official Gazette and the Company's website. There shall be an announcement in Swedish daily newspaper Svenska Dagbladet that the invitation has been published. If the publication of Svenska Dagbladet is discontinued, there shall be an announcement in Swedish daily newspaper Dagens Industri instead.



#### **§ 9 Notification of attendance at shareholders' meetings**

Shareholders registered in the share register in the manner stipulated in chap. 7 § 28 para. 3 of the Swedish Companies Act, and have notified the Company of their intention to attend by no later than the day stated in the invitation to the meeting are entitled to participate at shareholders' meetings. Such day may not be a Sunday, other public holiday, Saturday, Midsummer's Eve, Christmas Eve or New Year's Eve, and may not fall earlier than the fifth weekday prior to the meeting.

#### **§ 10 AGM**

The AGM shall be held yearly within six (6) months after the end of the financial year.

The following matters shall be considered at the AGM:

1. Election of a Chairman of the Meeting;
2. Preparation and approval of the voting list;
3. Approval of the agenda;
4. Appointment of one or two people to verify the minutes;
5. Consideration of whether the Meeting has been duly convened;
6. Submission of the Annual Accounts and Audit Report, and where applicable, the Consolidated Accounts and Consolidated Audit Report;
7. Resolutions
  - a) on adoption of the Income Statement and Balance Sheet, and where applicable, the Consolidated Income Statement and Consolidated Balance Sheet,
  - b) on appropriation of the Company's profit or loss according to the adopted Balance Sheet,
  - c) on discharging the Board members and Chief Executive Officer from liability;
8. Determination of the number of Board members, and where applicable, the number of Auditors and Deputy Auditors;
9. Determination of fees for the Board of Directors and Auditors;
10. Election of the Board of Directors, and where applicable, Auditors, audit firm, and potential Deputy Auditors;
11. Other matters appropriate to the Meeting as stipulated by the Swedish Companies Act or the Articles of Association.

#### **§ 11 Financial year**

The Company's financial year shall be the period 1 January - 31 December.

#### **§ 12 CSD clause**

Such shareholder or nominee that is registered in the share register and noted in a CSD register in accordance with chap. 4 of the Swedish Financial Instruments (Accounts) Act (1998:1479), or that party recorded in a CSD account pursuant to chap. 4 §18 first paragraph 6-8 of the aforementioned Act should be considered authorized to exercise the rights stipulated by chap. 4 § 39 of the Swedish Companies Act (2005:551).

# Tax issues in Sweden

*Certain Swedish tax issues that become topical for shareholders in the context of the new share issue, and the holders of subscription rights and BTAs, who have unlimited tax liability in Sweden (unless otherwise stated) are summarized below. This summary is based on current legislation and is intended only as general information for the period when shares, subscription rights and BTAs are listed for trading on NASDAQ OMX Stockholm. This summary does not consider:*

- *situations where securities are held as inventory items in a business operation,*
- *situations where securities are held by limited partnerships or general partnerships,*
- *situations where securities are managed in an investment savings account,*
- *those specific regulations governing tax-free capital gains (including the prohibition on deduction for capital losses) and dividends in the corporate sector that may be applicable when the investor holds securities of the Company that are considered business-related (for tax purposes),*
- *foreign companies that conduct operations from a permanent establishment in Sweden, or*
- *foreign companies that have been Swedish companies.*

*Additionally, special tax rules apply for certain types of company. The fiscal consideration of each individual holder of securities depends partly on their individual situation. Each shareholder and holder of subscription rights and BTAs should consult with an independent tax adviser on the tax consequences that the new share issue may imply a for such party, including the applicability and efficacy of foreign regulations and double taxation treaties.*

## GENERAL

### Physical persons

For physical persons with unlimited tax liability in Sweden, investment income such as interest, dividends and capital gains is taxed under the income tax schedule of capital. The tax rate in the income tax schedule of capital is 30%.

Capital gains or capital losses on the sale of shares and other part-ownership rights are computed as the difference between the payment on sale after deducting for selling expenses and the cost amount. The cost amount for all shares of the same class and type is aggregated and computed jointly with the application of the average method. Accordingly, BTAs are not considered of the same class and type as the existing shares of the Company prior to the decision on the new share issue being registered with the Swedish Companies Registration Office. Alternatively, when selling shares of the Company, the standardized method may be applied. This method means that the cost amount may be determined at 20% of the payment on sale after deducting for selling expenses.

Capital losses on shares and other listed part-ownership rights of the Company (e.g. subscription rights and BTAs) may be fully deducted against taxable capital gains that arise in the same year, firstly on shares, and secondly on other listed part-ownership rights (although not units in investment funds that contain only Swedish claims, known as fixed-income funds). Deductions of 70% of capital losses not deducted through the above offset facility are permitted in the capital income tax schedule.

If there is a deficit in the capital income tax schedule, and reduction of tax on income from employment and business

activity is permitted, as well as property tax and municipal property charges. This tax reduction is 30% of that portion of the deficit that does not exceed SEK 100,000, and 21% of the remaining deficit. The deficit cannot be carried forward to subsequent years of assessment.

For physical persons with unlimited tax liability in Sweden, 30% preliminary tax is withheld on dividends. The preliminary tax is normally held by Euroclear, or for nominee-registered shares, by the nominee.

### Limited companies

For limited companies, all income, including taxable capital gains and dividends are taxed in the income from business activity income tax schedule. The tax rate is 20%. Computation of capital gains and capital losses is in the same manner as for physical persons in accordance with the above.

Deductions for deductible capital losses on shares and other part-ownership rights is permitted only against taxable capital gains on shares and other part-ownership rights. If a capital loss can not be deducted by the Company that has incurred the loss, it can be deducted against taxable capital gains on shares and other part-ownership rights in another company of the same group in the same year if there is entitlement to make group contributions between these companies and both companies request this for a year of assessment with the same tax return date, or that would have had if any of the companies' requirement to maintain accounting records had not ceased. The capital loss on shares and other part-ownership rights that have not been usable in a specific

year may be saved (within the limited company that incurred the loss) and deducted against taxable capital gains on shares and other part-ownership rights in a subsequent year of assessment without any limitation in time. Special tax rules may be applicable on certain types of company or certain legal entities, such as holding companies.

## **EXERCISE AND SALE OF SUBSCRIPTION RIGHTS**

### **Exercise of subscription rights**

If the shareholder of the Company exercises subscription rights allotted for the purchase of acquisition of new shares, this triggers no taxation.

### **Sale of subscription rights**

Shareholders that do not wish to exercise their preferential rights to participate in the new share issue may sell their subscription rights. Subscription rights will be subject to trading on NASDAQ OMX Stockholm for a limited period coincident with the consummation of the share issue. Taxable capital gains should be computed on the sale of subscription rights. Subscription rights based on shareholdings of the Company are regarded as being acquired for SEK 0. The standardized method may not be applied to compute the cost amount in this case. Accordingly, the full payment on sale after deducting for selling expenses is considered for taxation. The cost amount for the original shares is not affected. A subscription right that is neither exercised nor sold, and accordingly expires, is considered as sold for SEK 0. Because subscription rights acquired in this manner are considered as acquired for SEK 0, neither a capital gain nor a capital loss arises.

For parties that purchase or acquire subscription rights of the Company in another similar manner, remuneration is the cost amount for them. Exercise of subscription rights for the subscription of shares does not trigger any taxation. A portion of the cost amount or subscription rights should be included when computing the cost amount of shares. If, instead, the subscription rights are sold, capital gains taxation is triggered. The cost amount for subscription rights is computed according to the average method. The standardized method may be used for listed subscription rights acquired in this manner. A subscription right that is neither exercised nor sold and thus expires is considered sold for SEK 0.

### **Sale of BTAs**

The sale of BTAs triggers capital gains taxation as stated above.

### **Foreign shareholders**

Withholding tax is normally deducted for shareholders with limited tax liability in Sweden that receive dividends on shares in a Swedish limited company. The same applies to payment from a Swedish limited company coincident with events including the redemption of shares and re-purchases of treasury shares through a take-over bid to all shareholders or all owners of shares of a specific class. The tax rate is 30%. However, the withholding tax rate is generally reduced by double taxation treaties. In Sweden, Euroclear, or for nominee-registered shares, the nominee, usually makes the deduction for withholding tax.

Shareholders and holders of the other part-ownership rights that have limited tax liability in Sweden—and do not conduct business from a permanent establishment in Sweden—are not normally subject to capital gains taxation in Sweden on the sale of shares or other part-ownership rights. However, shareholders and holders of other part-ownership rights may be subject to taxation in their country of domicile. However, according to a special rule, physical persons with limited tax liability in Sweden are subject to capital gains taxation in Sweden on the sale of shares and other part-ownership rights of the Company, if at any time during the calendar year when the sale occurs, or the preceding ten calendar years, they have been domiciled or permanently resident in Sweden. However, in several cases, the application of this rule is limited through double taxation treaties.

# Glossary

## **ADME**

Absorption, Distribution, Metabolism, Excretion. Describes the processing of a pharmaceutical in an organism.

## **Active compound**

A pharmaceutical active ingredient in a pharmaceutical product.

## **Animal model**

A disease or other injury is brought about in animals to resemble a similar condition or disease in humans.

## **Apoptosis**

Programmed cell death. Slow cell death in the body that requires functional energy supply.

## **Bioequivalent**

Equal efficacy in the body of two comparative pharmaceuticals with the same active compound.

## **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 blood-borne substances to access brain tissue (nerve cells).

## **Carrier medium**

In pharmaceutical terms, the inactive portion of a pharmaceutical, used for transporting active compound in the body.

## **Clinical trial**

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)".

## **Cremophor**

Polyoxyethylene castor oil. Cremophor is an ingredient of products including Novartis's intravenous pharmaceutical Sandimmune® that contains cyclosporine A, which has been reported to cause hypersensitivity reactions, anaphylaxis in a small number of treated patients.

## **CRO**

Clinical research organization.

## **CsA**

Cyclosporine A.

## **Cyclophilin D**

The recipient mitochondria that cyclosporine A and other cyclosporines bind to in all cells of the body.

## **Cyclosporine A**

A natural active compound (cyclical molecule) produced by the fungus *Tolypocladium inflatum*. Cyclosporine A is now produced by artificial or chemical methods. Cyclosporine A is a well-known clinically applied cyclosporine that has been demonstrated as potentially protective of the brain in animal models of brain injury, where cyclosporine A has transited the blood-brain barrier and entered the brain.

## **Drug candidate**

A specific compound designated during the preclinical phase. The drug candidate is the compound that is then studied on humans in clinical trials.

## **EMA**

The European Medicines Agency.

## **Eureka Eurostars**

European research and development collaboration designed to stimulate small and medium-sized enterprises to undertake international research work and innovation projects through access to support and funding. An agreement with the Commission formalizes the funding terms.

## **Eurostars consortium agreement**

A separate agreement between the participants in a project funded by Eureka Eurostars. This agreement formalizes how the project should be managed, the resolution of issues on non-disclosure and publication and how to manage the rights to results, etc.

## **FDA**

The US Food and Drug Administration.

## **GMP**

Good Manufacturing Practice rules produced by regulatory authorities and the pharmaceutical industry to define how the pharmaceutical industry should produce medicines so that the patient can always be sure that they receive the right product, and with high quality. These rules control production including packaging pharmaceuticals foods and health foods.

**IFRS**

Stands for International Financial Reporting Standards.

NeuroVive implemented IFRS in 2012, which means from this year onwards, its Consolidated Accounts are produced in accordance with IFRS, and that accordingly, reporting at parent company level is in accordance with RFR 2 Accounting for Legal Entities/ÅRL the Swedish Annual Accounts Act.

**Immunosuppression**

Suppression of the immune system. Pharmaceuticals that work to inhibit or suppressed the activity of the immune system are primarily used when it is necessary to lower the body's natural defenses to a foreign agent—such as after organ transplantation.

**IND**

Investigational New Drug. An IND means permission to commence clinical trials on humans. The application for an IND is filed with the US regulatory authority.

**Indication**

A disease condition that requires treatment, such as traumatic brain injury, reperfusion injury after myocardial infarction and stroke.

**In vivo**

Scientific experiments or clinical trials on living humans or animals. This, in contrast to analysis and experiments conducted outside the living body, in test tubes, for example.

**Leigh's syndrome**

Leigh's 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 spinal cord).

**Lipid emulsion**

The carrier medium of drug candidate NeuroSTAT® is a lipid emulsion that consists of small fat globules. It is a version of the well-known lipid emulsion Intralipid® that is administered intravenously in patients that require nutrition and is used as a carrier medium for common pharmaceuticals such as the anesthetic Propofol.

**Melas**

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

**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.

**Pharmaceuticals that protect the mitochondria**

Pharmaceuticals that protect mitochondrial function and thus promote cell survival.

**Mitochondrial medicine**

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

**NCCIM**

Non Cyclosporine Cyclophilin Inhibiting Molecules. Non-cyclosporine-based compounds (third-generation cyclophilin inhibitor).

**Necrosis**

Non-programmed cell death. Cell death occurring from severe injury to the central nervous system (and other organs). May occur coincident with injury (primary necrosis) but also delayed (secondary necrosis).

**Neuroprotection**

Synonymous with nerve cell protection. Treatment intended to prevent cell death in the central nervous system.

**NICAM**

Non Immunosuppressive Cyclosporine Analogue Molecules. Versions of cyclosporine A, with the immunosuppressant effect removed.

**NIH**

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

**Pathophysiology**

The study of disease mechanisms, on how the function of various physiological systems are affected by disease and can be affected by various treatments.

**Percutaneous coronary intervention (PCI)**

PCI is the collective term for procedures in the coronary arteries conducted using a catheter, which is introduced into a major blood vessel, usually via the groin. Angioplasty is often conducted during PCI, a treatment method used when coronary arteries have become obstructed by hardening of the arteries. Coincident with angioplasty, a stent is then introduced to restore the diameter of the vessel after angioplasty. The stent is a pipe-shaped metallic mesh made of various alloys.

**Per oral**

Intake of a substance via the mouth.

**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. In phase IIa, which is open, different doses of the pharmaceutical are tested without comparison against placebo and focusing on the pharmaceutical's metabolism in the body, as well as safety. Then in phase IIb, studies of efficacy of a selected dose(es) against placebo is studied, which is then termed "blind."

**Preclinical**

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

**R&D**

Research & development.

**Reperfusion injury**

The removal of blood clots in heart vessels is one type of treatment for myocardial infarction. This involves the restoration of blood flow in the vessel, but coincident with this procedure, there is a risk of further tissue damage and a larger myocardial infarction, known as reperfusion injury.

**Spinal cord injury**

The cells of the spinal cord are damaged in a spinal cord injury in a manner similar to cells of the brain in traumatic brain injury.

**Status epilepticus**

Long-term epileptic fit. A life-threatening indication that requires immediate treatment. The definitions of this indication vary, but the usual definition is an epileptic fit that continues for more than 5-10 minutes. Causes cell death in the brain

**Stroke**

There are two types of stroke; ischemic and hemorrhagic (bleeding). In this prospectus, "stroke" means ischemic stroke. Ischemic stroke is caused by an obstruction to one of the blood vessels of the brain with the resulting oxygen deprivation in the surrounding tissue.

**Traumatic brain injury (TBI)**

TBI is an injury to the brain where the nerve cells are subjected to immediate damage. The injury then continues to exacerbate several days after the incident, which often significantly impacts on the overall damage.

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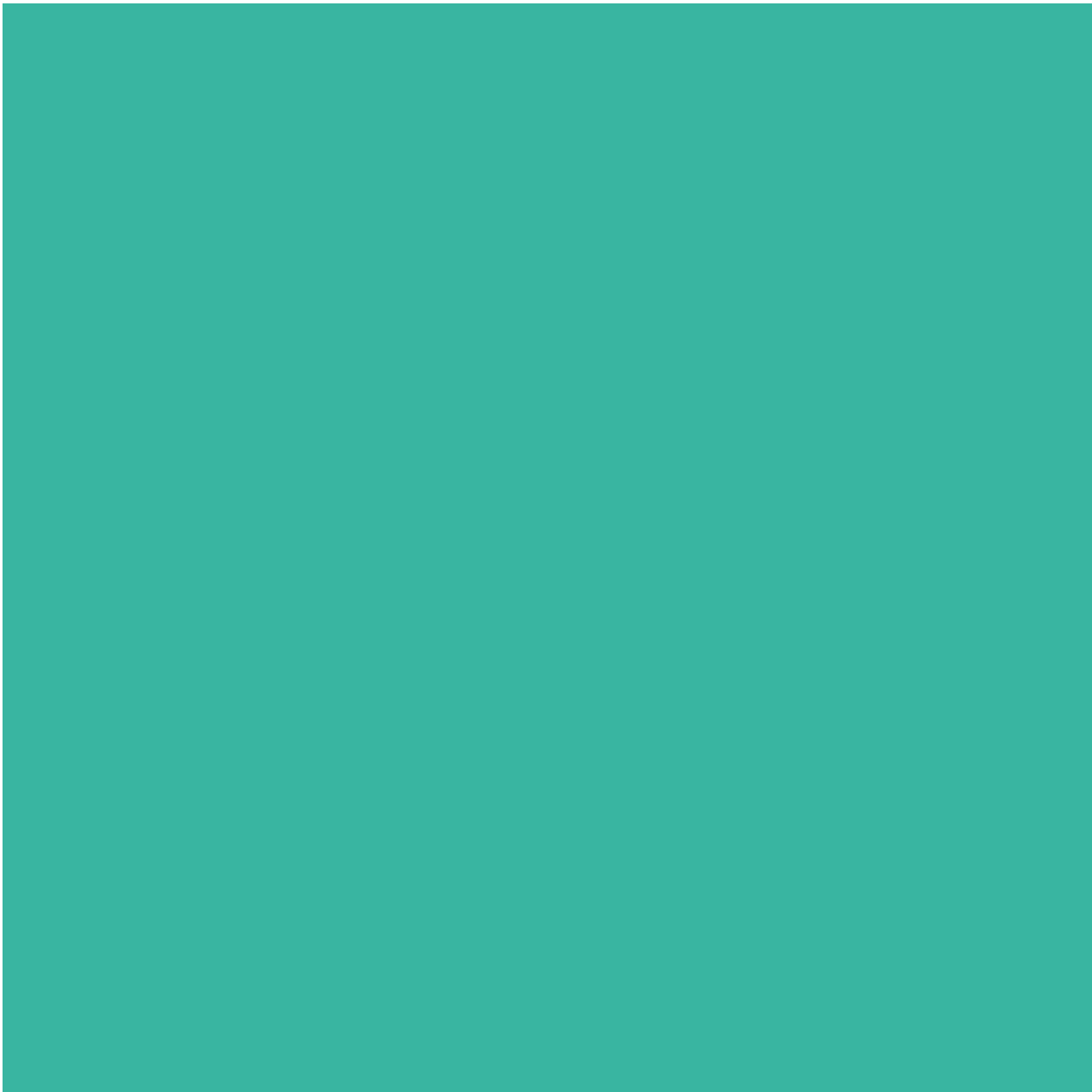
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