

NEUROVIVE PHARMACEUTICAL

Fast track for NeuroSTAT

The FDA has granted Neurovive's traumatic brain injury (TBI) asset, NeuroSTAT (cyclosporine), fast-track designation. As there is no treatment available that can protect brain cells from damage during TBI, a significant unmet medical need exists. However, previous randomised controlled trials evaluating cyclosporine demonstrated that it is not better than placebo in improving neurological outcomes in TBI patients; therefore we continue to apply a likelihood of approval rate of 10% on NeuroSTAT. We reiterate our fair value of SEK1.55–4.46 on the stock.

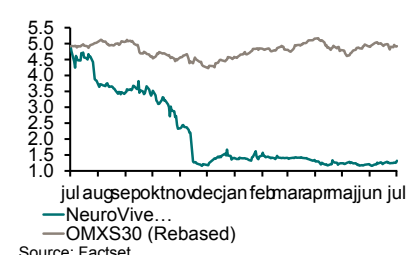
How does it work? NeuroSTAT is a formulation based on the active product ingredient cyclosporine, which binds and inhibits cyclophilin D. Cyclophilin D plays an essential role in the opening of pores in mitochondria and thereby regulates mitochondrial permeability transition (mPT). During traumatic brain injury (TBI), neurons experience an overload of Ca²⁺ influx in the mitochondria. The Ca²⁺ influx causes imbalance in the mPT that subsequently triggers the release of death ligands, signalling apoptosis, which is programmed cell death. The theory behind the drug is that by binding cyclophilin D, NeuroSTAT indirectly inhibits the opening of Ca²⁺ ion channels and thereby protects mitochondria from Ca²⁺ overload and could thereby potentially help cells to avoid cell death.

Other randomised controlled trials have demonstrated that cyclosporine is not better than placebo in improving neurological outcomes. A 2009 study carried out by Mazzeo A et al. evaluated cyclosporine in 50 adult patients with TBI. It was a randomised double-blinded and placebo-controlled study where patients received 5mg/kg of cyclosporine over 24 hours or placebo within 12 hours of injury. Mazzeo A et al. (2009) concluded cyclosporine demonstrated a good safety and tolerability profile in these patients; however, there were no significant differences in neurological outcomes or adverse events between placebo and the dose group at any time point. A more recent study, by Aminmansour et al. (2014), assessed the impact of cyclosporine on cognitive function and consciousness in 100 patients who suffered from diffuse axonal injury after TBI. Outcome measurements included in the study were Glasgow outcome scale-extended (GOS-E) and mini-mental state examination (MMSE), three and six months after injury. In conclusion, Aminmansour et al. suggest that administration of cyclosporine is not effective in improving cognitive function or consciousness in these patients.

Year-end Dec	2015	2016	2017	2018	2019e	2020e	2021e
Revenue (SEKm)	3	0	0	nm	nm	nm	nm
EBITDA adj (SEKm)	-91	-72	-71	-76	-104	-122	-176
EBIT adj (SEKm)	-91	-72	-71	-73	-103	-120	-175
PTP (SEKm)	-91	-72	-71	-73	-103	-120	-175
EPS rep (SEK)	-3.01	-1.67	-1.33	-0.94	-0.62	-0.40	-0.58
Revenue growth (%)	-63.7	-96.1	133.1	nm	nm	nm	nm
EV/Sales adj (x)	65.41	nm	nm	nm	nm	nm	nm

Source: Company (historical figures), DNB Markets (estimates)

NVP versus OMXS30 (12m)



Source: Factset

SUMMARY

Share price (SEK)	1.32
Tickers	NVP SS, NVP.ST

CAPITAL STRUCTURE

No. of shares fully dil. (m)	186.0
NIBD adj end-2019e (SEKm)	0

Source: Company, DNB Markets (estimates)

Note: Unless otherwise stated, the share prices in this note are the last closing price.

NEXT EVENT

Q2 2019 report	21/08/2019
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ESTIMATE CHANGES (SEK)

Year-end Dec	2019e	2020e	2021e
Sales (old)	0.00	0.00	0.00
Sales (new)	0.00	0.00	0.00
Change (%)	nm	nm	nm
Change (%)	nm	nm	nm

Source: DNB Markets,

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ANALYSTS

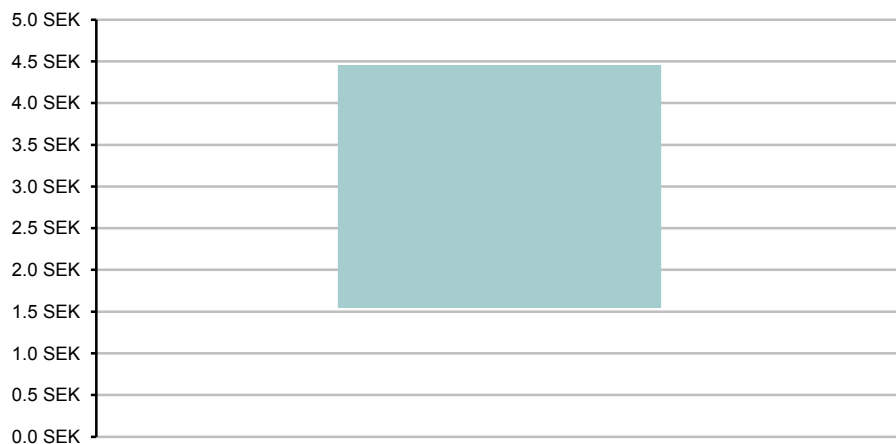
Patrik Ling

Jon Berggren

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Overview

Valuation – fair value range per share SEK1.55–4.46



Source: DNB Markets

Downside risks to our fair value

- We believe the key risks are the outcomes of future efficacy trials. Today, there is very limited clinical data supporting the efficacy of either NeuroSTAT or KL1333.
- Delays in clinical development could have a major share price impact.
- There is a high execution risk in both scenarios since all of the company's assets are in early-stage development.

Source: DNB Markets

DNB Markets estimates

- For KL1333 we assume a price per patient per year of USD50,000 in the EU and USD100,000 in the US. We assume the same price for a one-time treatment with NeuroSTAT.
- In our bull case, we estimate a peak penetration of 50% in both the US and the EU for MELAS. We estimate off-label usage of 15% and 35%, respectively, in other target indications.
- In our bear case, we estimate a peak penetration of 35% in both the US and the EU for MELAS. We estimate off-label usage of 15% and 35%, respectively, in other target indications.

Source: DNB Markets

Valuation methodology

- We continue to use a risk-adjusted DCF approach with a bull-case and a bear-case scenario. We discount the value with a WACC of 10% and apply a tax rate of 22% on all future sales.
- In our bull case, we assume an LOA of 15% for KL1333 in MELAS and 5% in other target indications.
- In our bear case, we assume an LOA of 10% for KL1333 in MELAS and 5% in other target indications.

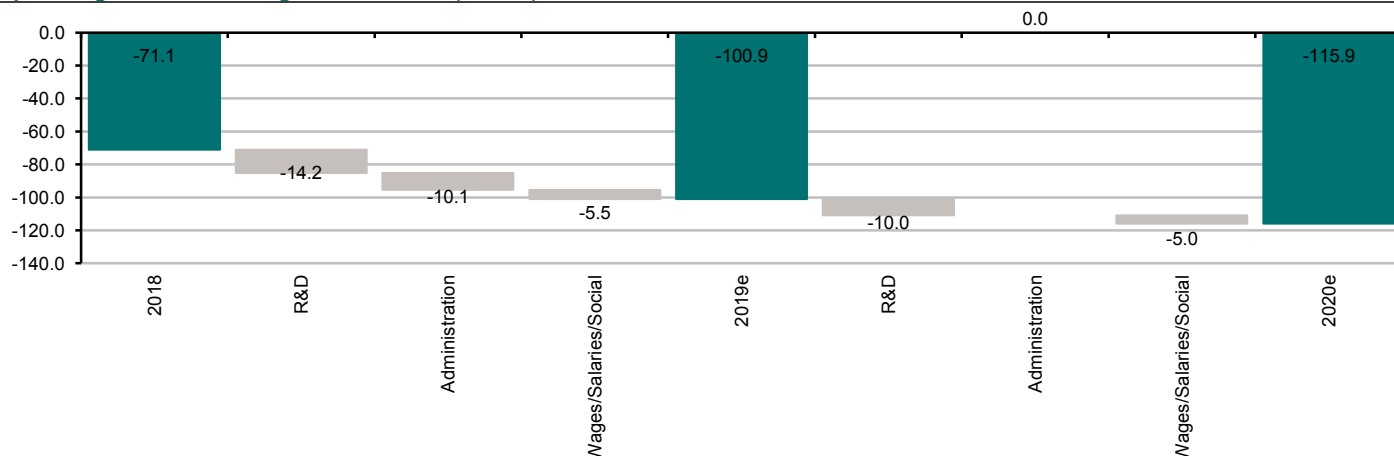
Source: DNB Markets

Upside risks to our fair value

- Higher sales of KL1333 and/or NeuroSTAT due to a higher price being charged if promising outcomes are shown in pivotal trials.
- Clinical development can accelerate if patients can be recruited to trials faster than anticipated or due to a potential breakthrough designation.
- The company, or one of its assets, is acquired by a large pharma company.

Source: DNB Markets

Operating cost base bridge 2018–2020e (SEKm)



Source: DNB Markets (forecasts), company (historical data)

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Forecast changes – P&L

(SEKm)	New			Old			Change		
	2019e	2020e	2021e	2019e	2020e	2021e	2019e	2020e	2021e
Revenues	0	0	0	0	0	0	0	0	0
Cost of sales	0	0	1	0	0	1	0	0	0
Gross profit	0	0	1	0	0	1	0	0	0
Operating expenses	-101	-116	-171	-101	-116	-171	0	0	0
EBITDA	-104	-122	-177	-104	-122	-177	0	0	0
EBITDA adj	-104	-122	-176	-104	-122	-176	0	0	0
EBITDA margin (%)	nm	nm	nm	high	high	high	nm	nm	nm
Depreciation	-3	-6	-6	-3	-6	-6	0	0	0
EBITA	-107	-128	-183	-107	-128	-183	0	0	0
Amortisation	0	0	1	0	0	1	0	0	0
EBIT	-103	-120	-175	-103	-120	-175	0	0	0
EBIT adj	-103	-120	-175	-103	-120	-175	0	0	0
Net interest	0	0	0	0	0	0	0	0	0
Net financial items	0	0	0	0	0	0	0	0	0
PBT	-103	-120	-175	-103	-120	-175	0	0	0
Taxes	0	0	0	0	0	0	0	0	0
Net profit	-103	-120	-175	-103	-120	-175	0	0	0
Adjustments to net profit	0	0	1	0	0	1	0	0	0
Net profit adj	-103	-120	-175	-103	-120	-175	0	0	0
<i>Per share data (SEK)</i>									
EPS	-0.62	-0.40	-0.58	-0.62	-0.40	-0.58	0.00	0.00	0.00
<i>Other key metrics (%)</i>									
Revenue growth	nm	nm	nm	nm	nm	nm	nm	nm	nm
EBIT adj growth	nm	nm	nm	40.0	17.3	45.6	nm	nm	nm
EPS adj growth	nm	nm	nm	nm	nm	nm	nm	nm	nm
OpFCF	-104	-122	-176	-104	-122	-176	0	0	0
Working capital	0	3	0	0	3	0	0	0	0
NIBD adj	0	0	0	0	0	0	0	0	0

Source: DNB Markets

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Annual P&L

(SEKm)	2012	2013	2014	2015	2016	2017	2018	2019e	2020e	2021e
Revenues	1	7	8	3	0	0	0	0	0	0
Cost of sales	0	0	0	0	0	0	0	0	0	1
Gross profit	1	7	8	3	0	0	0	0	0	1
Operating expenses	-18	-29	-53	-93	-71	-70	-71	-101	-116	-171
EBITDA	-16	-22	-45	-91	-72	-71	-76	-104	-122	-177
Depreciation	0	0	0	-1	-1	-2	-5	-3	-6	-6
EBITA	-17	-22	-46	-93	-73	-73	-81	-107	-128	-183
Amortisation		0	0	0	0	0	0	0	0	1
EBIT	-16	-22	-45	-91	-72	-71	-73	-103	-120	-175
Net interest	0	0	0	0	0	0	0	0	0	0
Net financial items	0	0	0	0	0	0	0	0	0	0
PBT	-16	-22	-45	-91	-72	-71	-73	-103	-120	-175
Taxes	0	0	0	0	0	0	0	0	0	0
Effective tax rate (%)	0	0	0	0	0	0	0	0	0	0
Net profit	-16	-22	-45	-91	-72	-71	-73	-103	-120	-175
Adjustments to net profit	0	0	0	-1	2	0	0	0	0	1
Net profit adj	-16	-22	-46	-92	-70	-71	-73	-103	-120	-175
<i>Per share data (SEK)</i>										
EPS	-0.85	-1.17	-1.53	-3.01	-1.67	-1.33	-0.94	-0.62	-0.40	-0.58
<i>Growth and margins (%)</i>										
Revenue growth	-76.3	422.1	20.2	-63.7	-96.1	133.1	nm	nm	nm	nm
EPS adj growth	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm
Gross margin	100.0	100.0	100.0	100.0	100.0	100.0	nm	nm	nm	nm
EBITDA margin	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm
EBITDA adj margin	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm
Depreciation/revenues	-9.6	-2.1	-5.3	-39.7	-950.0	-580.0	nm	nm	nm	nm
EBIT margin	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm
EBIT adj margin	-1242.4	-322.3	-543.1	-3024.7	nm	nm	nm	nm	nm	nm
PBT margin	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm
Net profit margin	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm

Source: Company (historical figures), DNB Markets (estimates)

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Adjustments to annual P&L

(SEKm)	2012	2013	2014	2015	2016	2017	2018	2019e	2020e	2021e
EBITDA	-16	-22	-45	-91	-72	-71	-76	-104	-122	-177
Other EBITDA adjustments						0	0	0	0	1
EBITDA adj	-16	-22	-45	-91	-72	-71	-76	-104	-122	-176
EBITA	-17	-22	-46	-93	-73	-73	-81	-107	-128	-183
Other EBITA adjustments						0	0	0	0	1
EBITA adj	-17	-22	-46	-93	-73	-73	-81	-107	-128	-182
EBIT	-16	-22	-45	-91	-72	-71	-73	-103	-120	-175
Other EBIT adjustments		0	0	0	0	0	0	0	0	1
EBIT adj	-16	-22	-45	-91	-72	-71	-73	-103	-120	-175
Net profit	-16	-22	-45	-91	-72	-71	-73	-103	-120	-175
Other EBIT adjustments		0	0	0	0	0	0	0	0	1
Tax adjustments		0	0	0	0	0	0	0	0	0
Other adjustments	0	0	0	-1	2	0				
Net profit adj	-16	-22	-46	-92	-70	-71	-73	-103	-120	-175
<i>Per share data (SEK)</i>										
EPS	-0.85	-1.17	-1.53	-3.01	-1.67	-1.33	-0.94	-0.62	-0.40	-0.58

Source: Company (historical figures), DNB Markets (estimates)

Cash flow

(SEKm)	2012	2013	2014	2015	2016	2017	2018	2019e	2020e	2021e
Net profit	-16	-22	-45	-91	-72	-71	-73	-103	-120	-175
Depreciation and amortisation		0	0	1	1	2	5	3	6	5
Other non-cash adjustments	1	1	0	29	28	11	11	0	0	1
Cash flow from operations (CFO)	-16	-21	-45	-61	-43	-59	-64	-101	-119	-174
Cash flow from investing (CFI)	-10	-80	-201	-23	-25	-15	-4	0	0	0
Free cash flow (FCF)	-26	-101	-246	-85	-68	-74	-68	-101	-119	-174
Cash flow from financing (CFF)	46	34	77	120	77	9	65	121	119	174
Total cash flow (CFO+CFI+CFF)	24	3	10	47	-3	-64	-3	20	0	0
<i>FCFF calculation</i>										
Free cash flow	-26	-101	-246	-85	-68	-74	-68	-101	-119	-174
Less: net interest	0	0	0	0	0	0	0	0	0	0
Growth (%)										
CFO	-53.7	-32.8	-112.5	-37.6	30.5	-37.5	-8.9	-58.4	-17.6	-46.3
CFI	-43.3	-719.3	-152.8	88.4	-6.8	39.0	74.7	100.0	nm	nm
FCF	-49.6	-294.3	-144.4	65.5	20.2	-9.2	8.4	-49.3	-17.6	-46.3
CFF	11198.0	-27.5	128.0	56.1	-35.3	-88.3	615.9	87.2	-1.8	46.3
FCFF	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm

Source: Company (historical figures), DNB Markets (estimates)

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Balance sheet

(SEKm)	2012	2013	2014	2015	2016	2017	2018	2019e	2020e	2021e
Assets	72	89	131	175	181	120	115	152	165	187
Other receivables	1	1	1	2	2	2	1	0	3	0
Cash and cash equivalents	37	40	50	97	93	29	26	46	46	46
Current assets	38	42	51	100	96	33	27	46	49	46
Property, plant and equipment	1	0	0	0	0	0	0	0	0	0
Other intangible assets	33	47	80	75	71	74	73	92	102	127
Non-current financial assets	0	0	0	0	13	13	0	0	0	1
Non-current assets	33	48	80	75	85	88	74	93	103	129
Total assets	72	89	131	175	181	120	115	152	165	187
Equity and liabilities	72	89	131	175	181	120	115	152	165	187
Total equity to the parent	64	75	103	141	155	101	97	132	152	154
Minority interests	-1	-1	5	14	13	5				
Total equity	63	75	108	155	168	106	97	132	152	154
Short-term debt	8	15	23	20	12	14	0	0	0	0
Total current liabilities	8	15	23	20	12	14	0	0	0	0
Total non-current liabilities	0	0	0	0	0	0	0	0	0	0
Total liabilities	8	15	23	20	12	14	0	0	0	0
Total equity and liabilities	72	89	131	175	181	120	115	152	165	187

Key metrics

Source: Company (historical figures), DNB Markets (estimates)

Valuation ratios

(SEKm)	2012	2013	2014	2015	2016	2017	2018	2019e	2020e	2021e
<i>Enterprise value</i>										
Share price (SEK)		12.35	36.13	6.80	2.70	2.41	1.25	1.32	1.32	1.32
Number of shares (m)	19.16	21.66	27.79	29.09	49.46	52.33	78.18	165.1	300.0	301.0
Market capitalisation		267	1,004	198	133	126	98	218	395	397
Net interest bearing debt adj	0	0	0	0	0	0	0	0	0	0
EV adj		267	1,004	198	133	126	98	218	395	397
<i>Valuation</i>										
EPS	-0.85	-1.17	-1.53	-3.01	-1.67	-1.33	-0.94	-0.62	-0.40	-0.58
P/E		-10.6	-23.6	-2.3	-1.6	-1.8	-1.3	-2.1	-3.3	-2.3
Average ROE	-34.5%	-32.5%	-49.6%	-69.7%	-44.6%	-51.9%	-72.3%	-89.5%	-84.6%	-114.3%
Earnings yield adj		-9.5%	-4.2%	-44.3%	-61.9%	-55.1%	-75.3%	-47.2%	-30.5%	-44.2%
EV/SALES adj		38.58	120.47	65.41	1129.96	459.05				
EV/EBITDA adj		-12.0	-22.2	-2.2	-1.8	-1.8	-1.3	-2.1	-3.2	-2.3
EV/EBIT adj		-12.0	-22.2	-2.2	-1.8	-1.8	-1.3	-2.1	-3.3	-2.3

Source: Company (historical figures), DNB Markets (estimates)

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Key accounting ratios

	2012	2013	2014	2015	2016	2017	2018	2019e	2020e	2021e
<i>Profitability (%)</i>										
ROA	-31.2	-27.8	-41.1	-59.7	-40.6	-47.3	-62.3	-77.0	-76.3	-100.0
<i>Return on invested capital (%)</i>										
Net PPE/revenues	50.1	6.6	4.1	10.4	232.2	58.9				
Working capital/revenues	55.3	15.8	13.5	78.3	1398.3	570.2				
<i>Cash flow ratios (%)</i>										
FCF/revenues	-1920.7	-1450.8	-2949.8	-2802.8	-57352.5	-26872.4				
FCF/market capitalisation		-37.6	-24.5	-42.8	-50.8	-58.5	-69.4	-46.5	-30.1	-43.8
CFO/revenues	-1188.9	-302.4	-534.6	-2027.5	-36136.4	-21316.4				
CFO/market capitalisation		-7.8	-4.4	-31.0	-32.0	-46.4	-65.4	-46.5	-30.1	-43.8
CFO/current liabilities	-186.6	-144.3	-190.2	-304.3	-343.5	-411.1				
Cash conversion ratio	154.6	450.1	543.2	92.7	93.9	104.0	92.3	98.4	98.7	99.1
OpFCF margin	-1242.4	-322.3	-543.1	-3024.7	-61110.2	-25850.2				
<i>Leverage and solvency (x)</i>										

Source: Company (historical figures), DNB Markets (estimates)

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Important Information

Company: NeuroVive Pharmaceutical
 Coverage by Analyst: Patrik Ling
 Date: 29/07/2019

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Number of shares	0	0	0	29/07/2019

*The analyst or any close associates. **Share positions include people involved in the production of credit and equity research, including people that could reasonably be expected to have access to it before distribution.

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	Buy	Hold	Sell	No_rec	Total
Number	136	63	38	12	249
% of total	55%	25%	15%	5%	
DNB Markets client	27%	8%	3%	2%	101

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