NeuroVive Pharmaceutical AB

(Nasdaq Stockholm: NVP.ST, OTCQX: NEVPF

Target Price: SEK 8.50 / USD $1.30)

Based in Lund, Sweden, NeuroVive Pharmaceutical AB (Nasdaq Stockholm: NVP, OTCQX: NEVPF, "NeuroVive") is a clinical stage biotechnology company focused on the discovery and development of compounds that protect and enhance mitochondrial function. NeuroVive has several intriguing assets, which leverage the company's domain expertise regarding mitochondria – including multiple projects focused on genetic mitochondria disease and an ongoing clinical trial program for traumatic brain injury. The company's programs include Phase 2 NeuroSTAT® for the prevention of traumatic brain injury (TBI), and pre-clinical programs targeting mitochondrial disease and NASH. NeuroVive reported positive data from its early Phase 2 clinical study and pre-clinical study of NeuroSTAT® for TBI and is expected to continue clinical development for this program. NeuroVive also recently announced what management views as a highly attractive in-licensing deal with South Korea's Yungjin Pharm Corp for KL1333 for rare genetic mitochondrial disorders.

Investment Highlights

Yungjin deal, Swelife award raise NeuroVive's growing presence in genetic mitochondrial diseases

NeuroVive recently announced that it would in-license **KL1333** from Yungjin Pharm Corp. KL1333 is a compound that is being developed for the treatment of rare genetic mitochondrial disorders, and should drive the company's expanding franchise in genetic mitochondrial disease. Deal terms include a $3mn fee for a candidate with an estimated risk-adjusted NPV (rNPV) of $180mn. NeuroVive also reported that it was awarded a prestigious Swelife grant of SEK 1mn from Swedish innovation agency Vinnova for development of new treatments for mitochondrial disease, which NeuroVive will put towards developing NVP015 for genetic mitochondrial disorders; Swelife is a national innovation program funded by the Swedish government. Clearly KL1333 enhances NeuroVive's business model, as it complements NVP015 in that both are targeted towards mitochondrial disease, but KL1333 is a disease modifier for chronic use, while NVP015 is for acute energy crisis management.

Encouraging data for NeuroSTAT® program

NeuroVive also continues to advance its lead candidate NeuroSTAT® for neuro-protective properties in moderate to severe TBI. The company announced data from two key studies underway, a pre-clinical efficacy study at the University of Pennsylvania ("Penn") in the US, and the CHIC Phase 2a clinical trial at Copenhagen University Hospital in Denmark. NeuroVive reported that the Phase 2a open label trial was able to meet its main objectives of demonstrating safety and characterizing the pharmacokinetic profile of two dosing regimens of NeuroSTAT in severe Traumatic Brain Injury (TBI) patients (5 and 10 mg/kg/day). Additionally, NeuroVive reported that the studies with Penn showed a significantly reduced volume of brain injury (a 35% decrease) in MRI scans and experimental TBI studies following NeuroSTAT® treatment. Considering the results, NeuroVive management stated that it will advance the program, and will begin planning a Phase 2b clinical trial to test the efficacy of NeuroSTAT® in TBI patients.

Price increases to SEK 8.50 for NeuroVive

We are increasing our price target to SEK 8.50 ($0.98) for NeuroVive following the significant addition of KL1333. We remain attracted to NeuroVive's pipeline and look forward to learning about plans for a Phase 2b trial for NeuroSTAT® and further developments in its growing genetic mitochondrial disease.

Stock Details (6/29/17)

Nasdaq Stockholm	NVP
OTCQX:	NEVPF
Sector / Industry	Healthcare / Biotechnology
Price target	**SEK 8.50 / USD $1.00**
Recent share price	SEK 6.75 / USD $0.80
Shares o/s (mn)	49.5
Market cap (mn)	SEK 338mn / USD $39.4mn
52-week high/low	SEK 7.90 / 2.90

Source: Thomson Reuters, SeeThruEquity Research

Key Financial (SEK, unless specified)

	FY15	FY16	FY17E
Revenues (mn)	3.0	0.1	21.3
EBITDA	(90.3)	(71.0)	(31.3)
EBIT	(91.5)	(72.1)	(32.2)
Net income	(90.8)	(71.8)	(32.2)
EPS (SEK)	(3.01)	(1.67)	(0.76)

Source: SeeThruEquity Research

Key Ratios

	FY15	FY16	FY17E
Operating Margin (%)	(3,024.7)	(61,110.2)	(151.7)
EBITDA margin (%)	(2,985.0)	(61,110.2)	(147.3)
Net margin (%)	(3,002.7)	(60,885.6)	(151.7)
P/ Revenue (x)	110.4	2,829.2	15.7
EV/Revenue (x)	88.1	2258.9	12.5

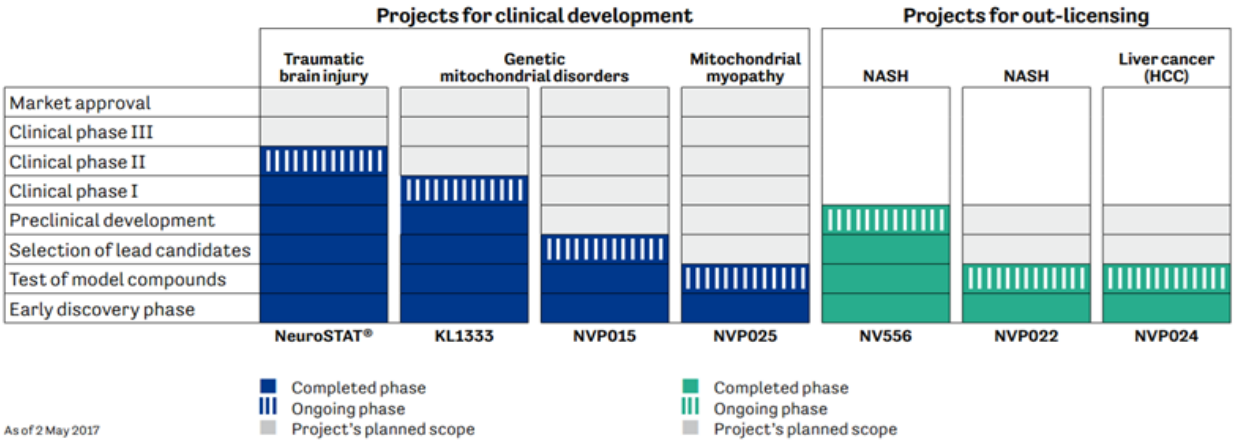
Source: SeeThruEquity Research

Share Price Performance (SEK, LTM)

Source: Thomson Reuters

NeuroVive increases focus and expands domain expertise on genetic mitochondrial diseases with acquisition of KL1333 from South Korea's Yungjin Pharm

- **In-Licensing of KL1333 for orphan genetic mitochondrial disorders:** NeuroVive recently announced a key new strategic deal with the in-licensing of candidate **KL1333** for rare genetic mitochondrial disorders from South Korean pharmaceutical company Yungjin Pharm Corp.
- KL1333 is a regulator of cellular NAD levels+, which is a coenzyme central to cellular metabolism. KL1333 modulates NAD+ levels and to rectify mitochondrial defects. In pre-clinical studies KL1333 has been shown to increase mitochondrial energy output and reduce lactate accumulation, with signs of long term beneficial effects on energy metabolism. Clearly KL1333 enhances NeuroVive's business model for mitochondrial disease, as it complements NVP015. Both candidates are targeted towards mitochondrial disease, but KL1333 is a disease modifier, while NVP015 is for acute energy crisis management.
- **Ready for Clinical Trials:** In the announcement NeuroVive stated that KL1333 was ready for Phase 1 clinical development. Yungjin began a Phase 1 clinical trial on June 27, 2017, at the Seoul National University College of Medicine. The trial will be a double-blind, placebo-controlled, single-dose, dose-escalation phase I clinical study to investigate the pharmacokinetics and safety/tolerability of KL1333 in healthy subjects, and is planned to include 60 healthy volunteers.
- The move expands NeuroVive's presence in genetic mitochondrial disease, while offering attractive risk-adjusted returns. Indeed, terms of the agreement include a $3mn licensing fee for a clinical trial-ready compound, which NeuroVive management has calculated is a project that offers a $180mn risk-adjusted NPV. We are eager to hear more for the company about next steps on this intriguing project. Initially we have assumed KL1333 can reach commercialization by 2023E, with a potential patient pool in excess of 30,000 and an average annual cost of treatment of $80,000.
- **NeuroVive awarded SEK 1mn grant for NVP015 for genetic mitochondrial disorders**: On June 1, 2017, the company reported that it had received a Swelife grant of SEK 1mn from Swedish innovation agency Vinnova for the development of new treatments for mitochondrial disease. The grant is an honor for NeuroVive and will help fund development - Swelife is a national innovation program funded by the Swedish government.
- NeuroVive company plans to deploy the grant monies towards pre-clinical candidate NVP015, which explores energy metabolism and disease progression in mitochondrial complex I dysfunction. The news follows another favorable development for NVP015 this year, including a preclinical collaboration with the Children's Hospital of Philadelphia (CHOP) under genetic mitochondrial disorder researcher Marni J. Falk, M.D.
- With recent developments in NVP015 and the in-licensing of KL1333, it is clear that NeuroVive is increasing its focus on mitochondrial disease and particularly in the strategic area of genetic mitochondrial disorders. We note that management has stated that NVP015 and KL1333 are complementary, as NVP015 is intended to alleviate acute episodes of energy crisis in genetic mitochondrial disorders. We have included an update of the company's pipeline below.



Source: Company investor materials

NeuroVive announces positive clinical update, will continue clinical development for NeuroSTAT

- **Positive data from NeuroSTAT® studies:** On May 23, 2017, NeuroVive announced positive results from clinical and pre-clinical studies with its lead candidate NeuroSTAT® for prevention of moderate to severe traumatic brain injury (TBI).

- **Phase 2a CHIC Study reaches primary objective:** The company's most advanced study, the Phase 2a open label Copenhagen Head Injury Cyclosporine (CHIC) study, was conducted at Rigshospitalet in Copenhagen, Denmark, at two different dose levels (5 and 10 mg/kg/day) in patients with severe TBI.

- According to the announcement, the CHIC study reached its primary objective of demonstrating safety and characterizing the pharmacokinetic profile of NeuroSTAT®. The company stated that the CHIC study showed that appropriate dose-dependent concentration levels can be measured in the blood, and that NeuroSTAT® reached the central nervous system (CNS) with no unexpected safety signals detected. Further analysis is being conducted to better evaluate the efficacy of NeuroSTAT® at the mitochondrial level, and study how NeuroSTAT® affects various biochemical processes after a brain injury.

- NeuroVive also reported encouraging data from preclinical studies conducted at the University of Pennsylvania. With researchers at the University of Pennsylvania, NeuroVive conducted three pre-clinical sub-studies with an aim to establish the pharmacokinetic profile of NeuroSTAT® in blood, Cerebrospinal Fluid, and brain in the disease model, while showing that NeuroSTAT® dose-dependently crosses the blood-brain barrier. The third study focused on evaluating different efficacy parameters related to mitochondrial function and metabolism.

- Importantly, according to the announcement, the studies at Penn showed a significantly reduced volume of brain injury (35% decrease) after NeuroSTAT® treatment.

- **To Move Forward with Clinical Development:** NeuroVive CEO Erik Kinnman stated that the company would move forward with clinical development of NeuroSTAT® for TBI. According to Kinnman, the company is planning discussions with regulatory authorities in the US and Europe to review the findings in the clinical and experimental studies, as well as for the design of the next clinical study, which is anticipated to be a Phase 2b clinical study to test the efficacy of NeuroSTAT® in TBI patients.

- **TBI represents a significant opportunity**. TBI is a disruption in the normal function of the brain that can be caused by a bump, blow, or jolt to the head, or penetrating head injury. According to the US Center for Disease Control and prevention, in 2013, approximately 2.8mn TBI-related emergency department (ED) visits, hospitalizations, and deaths occurred in the United States. In the US, TBI results in 50,000 deaths annually and accounts for direct and indirect costs of $60 billion each year.

- **Positive preclinical data for NV556 for NASH:** We were also pleased to see news that NeuroVive reported positive anti-fibrotic pre-clinical results for NV556 for NASH in April. NASH is a chronic liver disease which affects approximately 15mn Americans, and has been an area of focus for the company. NeuroVive reported that NV556 was well-tolerated and shown to reduce liver weight gain, an indicator of reduced tumor burden.

QUARTERLY FINANCIAL SUMMARY

Figure 1. Income Statement Summary

Figures in SEK 000 unless specified	Mar-17	Mar-16	FY2016
Net Sales	27	0	14
Other Operating Income	63	46	104
Total	90	46	118
Personnel cost	3,377	3,269	15,276
Other external expenses	6,733	7,379	34,168
D&A, Write-down of Intangibles	204	259	1121
Other Expenses	11,009	77	21,663
Operating Expenses	21,322	10,984	72,228
Operating Income	-21,232	-10,938	-72,110
Gain (Loss) from financial Items	-158	22	265
PreTax Income	-21,390	-10,916	-71,845
Taxes	0	0	0
Profit (loss) in period	-21,390	-10,916	-71,845
Translation	18	-264	0
Comprehensive Income	-21,372	-11,180	-71,845
EPS	-0.4	-0.35	-1.67

Source: Company Filings Release, SeeThruEquity Research

ADDITIONAL NOTES

- NeuroVive reported FY1Q17 results on May 18, 2017. As expected for a clinical stage biotechnology company, NeuroVive did not report material revenues. The company's most advanced program is Phase 2, and we would not expect it to reach regulatory approval for several years.
- **1Q17 Net loss per share of SEK 0.40:** In 1Q17, NeuroVive reported a net loss of SEK 21.5mn, or 0.40 per share.
- **Balance Sheet update:** NeuroVive ended the quarter with cash on hand of SEK 67.3mn. The company had total assets of SEK 154.9mn. NeuroVive had SEK 7.9mn in liabilities at the end of the quarter and no financial debt. Operating cash outflows were SEK 10.1mn during the quarter.
- We still see liquidity as a key area to watch, as NeuroVive does not have operating revenues, and the cost to fund clinical trials is substantial.
- We continue expect NeuroVive to seek to strike license agreements with industry participants as a path to monetization, rather than to fund development from early stage through the regulatory decision process and commercialization. Management has indicated that its business model will be focused on out-licensing programs for common indications, as well as to pursue development of orphan indication projects.

Price target rises to SEK 8.50 after addition of KL1333, data in 1H17

- Our price target for NeuroVive increases to SEK 8.50 following 1Q17 results and an encouraging clinical update, as well as optimistic commentary on the company's new move to in-license KL1333 for orphan genetic mitochondrial diseases.
- Our target considers the clean balance sheet at the company as well as NeuroVive's pipeline targeting traumatic brain injury, mitochondrial diseases, and NASH.

Management Team

Erik Kinnman, Chief Executive Officer

Erik Kinnman, born 1958, is a seasoned life science executive with broad experience and understanding from the industry across a variety of businesses and functions. He has held a number of senior leadership positions in biopharmaceutical companies such as AstraZeneca and Sobi. His expertise and experience includes clinical development, business strategy, business development, and investor relations. Erik Kinnman also has experience from the financial sector. In addition, he holds an Executive MBA from the Stockholm School of Economics and has comprehensive scientific qualifications from the Karolinska Institutet, which has rendered him a Ph.D. and an Associate Professor. Moreover, Erik Kinnman is an M.D., board certified in Neurology and Pain Management. Employed since 2016.

Catharina Jz Johansson, Chief Financial Officer

Catharina Jz Johansson, born 1967, possesses experience from work on medtech growth enterprises with multinational operations. Catharina Johansson holds a M.Sc. in Business and Economics. Her previous experience includes serving as interim CFO for medical device company Cellavision, which is listed on Nasdaq Stockholm, and Accounting Manager for Bong and Alfa Laval Europe. Employed since 2013.

Eskil Elmér, CSO

Eskil Elmér, born 1970, is associate professor of experimental neurology at Lund University (Sweden) and group leader of the Mitochondrial Medicine lab at the department of Clinical Neurophysiology. Dr Elmér is patentee and co-founder of both Maas Biolab, LLC and NeuroVive Pharmaceutical AB, and CSO of NeuroVive, with overall charge of the company's pre-clinical research. In addition, Eskil Elmér is a practising physician in the department of clinical neurophysiology at Skåne University Hospital in Lund, Sweden. Employed since 2000.

Magnus Hansson, CMO

Magnus Hansson, born 1976, has extensive experience in the area of Mitochondrial Medicine. He has previously been serving as a Senior Scientist in NeuroVive since 2008 and as a consultant physician and associate professor in medical imaging and physiology at Skåne University Hospital, Sweden. Dr Hansson has overall charge of the company's pre-clinical and clinical development programs. He holds a PhD in Experimental brain research from Lund University, Sweden and has authored more than 30 scientific publications and 10 patent applications. Employed since 2008.

Cecilia Hofvander, IR & Communications Director

Cecilia Hofvander, born 1967, has long experience from IR (Investor Relations) and international business development. She has also worked with financial transactions, early drug development and global clinical trials of candidate drugs. She joins NeuroVive from a position at Active Biotech AB (publ) where she worked for 15 years, the last eight years as responsible for IR and communication. Cecilia holds a B.Sc degree in chemistry and molecular biology from Lund University and a Communications Executive Program diploma from Stockholm School of Economics. Employed since 2016.

About NeuroVive Pharmaceutical AB

NeuroVive Pharmaceutical AB is a leader in mitochondrial medicine, with one project in clinical phase II development for the prevention of moderate to severe traumatic brain injury (NeuroSTAT) and one project in clinical phase I (KL1333) for genetic mitochondrial diseases. The R&D portfolio consists of several late stage research programs in areas ranging from genetic mitochondrial disorders to cancer and metabolic diseases such as NASH. The company's strategy is to advance drugs for rare diseases through clinical development and into the market. The strategy for projects within larger indications outside the core focus area is out-licensing in the preclinical phase. NeuroVive is listed on Nasdaq Stockholm, Sweden (ticker: NVP). The share is also traded on the OTCQX Best Market in the US (OTC: NEVPF).

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