

# NeuroVive Pharmaceutical AB

(Nasdag Stockholm: NVP.ST, OTCQX: NEVPF

Target Price: SEK 11.05 / USD \$1.30)

We initiate coverage on NeuroVive Pharmaceutical AB (Nasdag Stockholm: NVP, OTCQX: NEVPF, "NeuroVive") with a price target of SEK 11.05 Based in Lund, Sweden, NeuroVive is a clinical stage (US\$1.30). 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 two ongoing clinical trials and multiple research projects in late-stage discovery. NeuroVive's pipeline is anchored by two Phase 2 clinical programs bringing a novel approach to large potential therapeutic opportunities: CicloMulsion® for preventative treatment of acute kidney injury (AKI) and NeuroSTAT® for the prevention of traumatic brain injury (TBI). We are expecting results from these two studies and pre-clinical data in programs for stroke and mitochondrial disorders over the next twelve months, as well as potential partnership / business development discussions, which could set the stage for a series of key events through the end of 2017E.

# **INVESTMENT HIGHLIGHTS**

### Large opportunity from two ongoing Phase 2 trials

NeuroVive expects to release results from its ongoing CiPRICS (Cyclosporine to Protect Renal Function In Cardiac Surgery) Phase 2 clinical study of CicloMulsion® for prevention of acute kidney injury in connection with major surgery by the end of 2016E. With the support of NeuroVive, the Department of Cardiothoracic Surgery at Skane University Source: See Thru Equity Research Hospital in Lund, Sweden completed enrollment of this 150 patient, randomized, double-blind, placebo-controlled trial in June. should have a significant opportunity for CicloMulsion®, if results are positive, given that more than 400,000 people undergo coronary artery bypass surgery each year, and AKI is a frequent and serious complication from the procedure. In addition to patient care benefits, there would likely be a strong economic benefit for the administration of CicloMulsion® as a protective measure to reduce risk of AKI from coronary artery bypass surgery, given that studies have shown that postoperative AKI develops in 5% to 40% of patients following coronary artery bypass, and the average annual cost of kidney insufficiency treatment by an organ transplant / dialysis is \$70,000 per patient.

NeuroVive has also made significant progress in its Phase 2 clinical study of NeuroSTAT® for traumatic brain injury (TBI). TBI occurs in more than 3mn patients in the US and Europe each year, with approximately 15% of those suffering moderate to severe injuries. In the US, TBI results in 50,000 deaths annually and accounts for direct and indirect costs of \$60 billion each year. NeuroVive's ongoing Copenhagen Head Injury Cyclosporine (CHIC) study had enrolled 16 patients in July 2016 and is expected to be fully enrolled in early 2017, with results available later in the year.

### Initiate coverage with a price target of SEK 11.05 / USD\$1.30

We see NeuroVive as an intriguing company in the biotechnology sector Source: Bloomberg pursuing a focused strategy targeted towards discovery and development in

# Equity | Healthcare / Biotechnology

mitochondrial medicine. We are attracted to NeuroVive's short balance sheet, which included cash on hand of SEK 132.3mn (\$15.6mn) as of June 30, 2016, and should support investments in clinical development through the end of its ongoing Phase 2 trials for AKI and TBI. If achieved, the price target of SEK 11.05 suggests upside potential of 66.2% from the recent price of SEK 6.65 on September 13, 2016.

### Stock Details (9/13/2016)

Nasdaq Stockholm	NVP
OTCQX:	NEVPF
Sector / Industry	Healthcare / Biotechnology
Price target	SEK 11.05 / USD \$1.30
Recent share price	SEK 6.65 / USD \$0.78
Shares o/s (mn)	49.5
Market cap (mn)	SEK 328.9mn / USD \$38.7mn
52-week high/low	SEK 17.90 / SEK 4.29

### Key Financials (SEK unless specified)

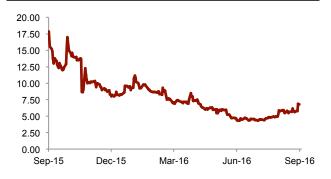
	FY15	FY16E	FY17E
Revenues (mn)	3.0	0.1	21.3
EBITDA	(90.3)	(48.6)	(31.3)
EBIT	(91.5)	(49.8)	(32.2)
Net income	(90.8)	(49.6)	(32.2)
EPS (SEK)	(3.01)	(1.16)	(0.76)

### **Key Ratios**

	FY15	FY16E	FY17E
Operating Margin (%)	(3,024.7)	(53,004.3)	(25.9)
EBITDA margin (%)	(2,985.0)	(51,727.7)	(23.7)
Net margin (%)	(3,002.7)	(52,725.5)	(25.9)
P/ Revenue (x)	108.8	3,498.9	15.5
EV/Revenue (x)	65.0	2091.7	9.3

Source: SeeThruEquity Research

### Share Price Performance (SEK, LTM)



# **SUMMARY TABLE**

Figure 1. Summary Table (	As of September 13	2016)			
Share data		Balance Si	heet data	Key personnel:	
Recent price (SEK / USD):	SEK 6.65 / \$0.78	Total assets:	SEK 226.2mn	CEO	Erik Kinnman
Price target (SEK / USD):	SEK 11.05 / \$1.30	Total debt:	0.0mn	CFO:	Catharina Jz Johansson
52-week range (SEK):	17.50 / 4.06	Equity:	SEK 215.9mn	CSC:	Eskil Elmér
Average volume:*	209,340	W/C:	SEK 126.3mn	CMO:	Magnus Hansson
Market cap*:	SEK 328.9mn	ROE:	-22%		
Book value/share:	SEK 4.37	ROA:	-21%		
Cash/share	SEK 2.67	Current ratio:	13.3		
Dividend yield:	0.00%	Asset turnover:	0.0		
Risk profile:	High / Speculative	Debt/Cap:	0.0%		

<sup>\*</sup> three month average volume (number of shares); Company data in SEK unless noted

SEK		Estimates*			Valuation	
FY December	Rev (mn)	EBITDA (mn)	EPS (SEK)	P/Rev (x)	EV/Rev (x)	P/E (x)
2014	3.0	(90.3)	(3.01)	108.8x	65.0x	NM
2015	0.1	(48.6)	(1.16)	3498.9x	2091.7x	NM
1Q16	0.0	(10.7)	(0.30)	1787.5x	1068.6x	NM
2Q16	0.0	(11.8)	(0.34)	2936.6x	1755.5x	NM
3Q16E	0.0	(11.8)	(0.24)	4111.2x	2457.7x	NM
4Q16E	0.0	(14.3)	(0.30)	#DIV/0!	#DIV/0!	NM
2016E	0.1	(48.6)	(1.16)	3498.9x	2091.7x	NM
2017E	21.3	(31.3)	(0.76)	15.5x	9.3x	NM
2018E	29.8	(28.3)	(0.52)	11.1x	6.6x	NM

Source: SeeThruEquity Research
\*Company data in SEK unless noted

# **INVESTMENT THESIS**

We initiate coverage on NeuroVive Pharmaceutical AB (Nasdaq Stockholm: NVP, OTCQX: NEVPF, "NeuroVive") - with a price target of SEK 11.05 (US\$1.30). Based in Lund, Sweden, NeuroVive is a clinical stage pharmaceutical 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 two ongoing Phase 2 clinical trials and multiple preclinical research projects in late-stage discovery. The company's pipeline is anchored by two Phase 2 clinical programs: CicloMulsion® for preventative treatment of acute kidney injury (AKI) and NeuroSTAT® for the preventative treatment of traumatic brain injury (TBI). NeuroVive is also optimistic with respect to preclinical asset NVP015 for mitochondrial disorders, which was recently highlighted in Nature Communications, a well-regarded scientific journal.



We see several key events on the horizon at NeuroVive over the next six to 12 months. NeuroVive recently completed a fully subscribed preferred rights issue of SEK 77mn (\$9.1mn), after deduction of costs for the rights issue, which should fund development efforts in the near term, and the company was uplisted to the OTCQX Best Market. On the clinical front, we are expecting the completion of the company's Phase 2 clinical trials for AKI and TBI, which would position the company to engage in strategic partnership and/or licensing discussions in 2017. In addition to data from these two Phase 2 programs, NeuroVive recently presented positive data for NVP015 for mitochondrial metabolic disorders in *Nature Communications*, and management has indicated that it will be expanding on its plans to develop treatment for stroke and NVP019, which is also being investigated as a possible therapeutic for AKI, by the end of the year.



### NeuroVive pursuing specialist pharma model focused on mitochondrial medicine

We are intrigued by the corporate strategy at NeuroVive to define itself as a leader in the area of mitochondrial medicine research and development. Mitochondria play a central role in human health and development, but NeuroVive notes that there are no approved drugs in the US that target mitochondria to treat mitochondrial dysfunction. NeuroVive's drug candidates are focused on treating and maintaining mitochondrial integrity, while improving mitochondrial function. The company's research and development in these programs is supported by a broad Intellectual Property (IP) position. This IP includes ten patent families relating to cyclosporins, succinate prodrugs, mitochondrial toxicity tests, and cyclophilin inhibitors. The company continues to look for new opportunities to expand this leadership, as evidenced by its August 15, 2016, move to increase its stake in Isomerase Therapeutics Ltd., a British drug discovery and



development company, to 10%. In our view, NeuroVive's focus on achieving a leading position in mitochondrial medicine is a prudent strategy offering the potential to generate value as a domain specialist.

### Large opportunity for initial Phase 2 programs

NeuroVive's two initial clinical programs are **CicloMulsion®** for prevention of acute kidney injury (AKI) in major surgery and **NeuroSTAT®** for moderate to severe Traumatic Brain Injury (TBI). In June, NeuroVive announced that it completed enrollment of 150 patients in its CiPRICS (Cyclosporine to Protect Renal Function In Cardiac Surgery) Phase 2 study for CicloMulsion®. The CiPRICS study is a randomized, double-blind, placebo-controlled Phase 2 study for CicloMulsion® as a preventative treatment for acute kidney injury (AKI). In the study, CicloMulsion® is being administered in conjunction with coronary artery bypass surgery by the Department of Cardiothoracic Surgery at Skane University Hospital in Lund, Sweden, with support from NeuroVive. In their August 30, 2016, press release NeuroVive management stated that the company expected the trial to be completed and to have results available by mid-October 2016. NeuroVive should have a significant opportunity for CicloMulsion®, if results are positive, given that more than 400,000 people undergo coronary artery bypass surgery each year, and AKI is a frequent and serious complication from the procedure. In addition to patient benefits, there would likely be a strong economic benefit to use CicloMulsion® as a protective measure to reduce risk of AKI from coronary artery bypass



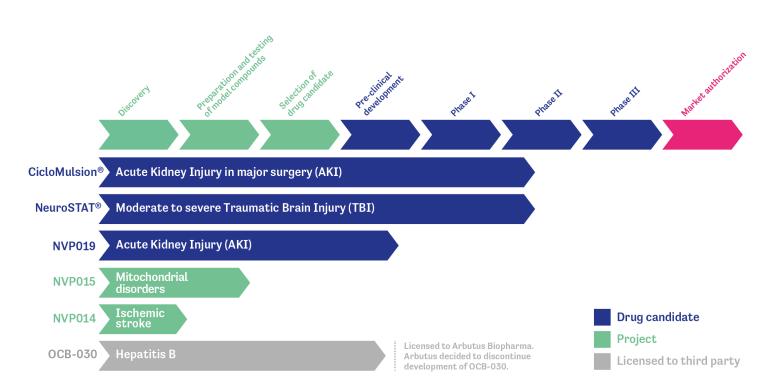
surgery, given that studies have shown that postoperative AKI develops in more than 10% of patients following coronary artery bypass, and the average annual cost of kidney insufficiency treatment by an organ transplant / dialysis is \$70,000 per patient.

NeuroVive has also made significant progress in its Phase 2 clinical study of **NeuroSTAT®** for preventative treatment of traumatic brain injury (TBI). TBI is caused by external violence to the head resulting in immediate damage to nerve cells. TBI occurs in more than 3mn patients in the US and Europe each year, with approximately 15% of those suffering moderate to severe injuries. In the US, TBI accounts for 50,000 deaths annually and accounts for direct and indirect costs of \$60 billion each year.

NeuroVive has an ongoing Open Phase 2 study for NeuroSTAT: Copenhagen Head Injury Cyclosporine (CHIC) study. The CHIC study had enrolled 16 patients in July 2016 and is expected to be fully enrolled by 1Q17E, with results expected to be available in 2017. In April 2016 the company also recently began a supplementary preclinical study at the University of Pennsylvania, which will evaluate NeuroSTAT's neuroprotective properties in an advanced experimental TBI model. Importantly, NeuroSTAT® has an Orphan Drug Designation in the EU and the US for moderate-to-severe TBI, which could hasten the regulatory approval process and provide extended exclusivity.

In addition to its ongoing Phase 2 studies, NeuroVive has multiple preclinical programs in place, which leverage the company's expertise in therapeutic approaches to mitochondria. These include **NVP019** for organ protection, **NVP014** for ischemic stroke, and **NVP015** for mitochondrial energy regulation, as illustrated in the following graphic representation of the company's project pipeline.

Figure 2. NeuroVive Project Pipeline Overview



Source: Company data





NeuroVive management has indicated that it will release results from ongoing preclinical studies for next generation cyclophilin inhibitor NVP019 and NVP015 during 2H16, which would likely be significant events for the company. We expect NeuroVive to follow this data with plans for Phase 1/ Phase 2 clinical trials. NVP015 is being developed as an energy regulating preparation for specific intravenous acute treatment of conditions involving cellular energy crisis. Management has stated that it expects to initially explore NVP015 for a series of relatively unusual childhood diseases, such as pediatric mitochondrial disease, Leigh syndrome, and MELAS, which enable the application for an Orphan Drug Designation. Importantly, NVP015 was featured in *Nature Communications*, a well-regarded scientific journal, for its potential in combatting mitochondrial metabolic disorders.



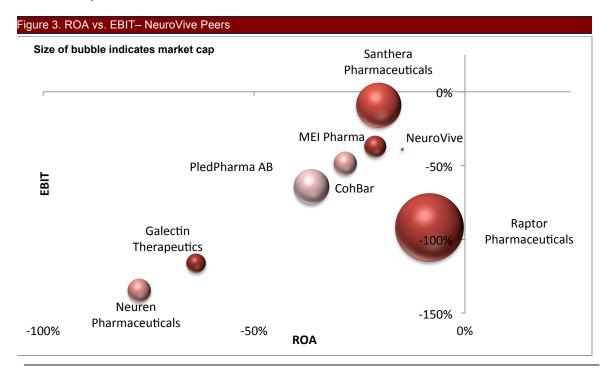
# COMPETITIVE LANDSCAPE

NeuroVive operates in the biotechnology industry, which is a large and highly competitive industry characterized by significant capital requirements, a high degree of regulation, and rapid technology change. The company faces competition from both established pharmaceutical corporations and emerging biotechnology companies focused on developing new therapeutics for traumatic brain injury (TBI) acute kidney injury (AKI), and mitochondrial disorders.

NeuroVive seeks to define itself in the market by pursuing a focused strategy of being a mitochondrial medicine specialist. By carving out a niche for itself as a mitochondrial medicine specialist, the company aims to differentiate itself through domain expertise, which should allow it to source attractive early-stage clinical candidates and generate value from its pipeline that is outsized relative to the company's position in the overall biotechnology market.

In AKI, management sees Stealth BioTherapeutics and its candidate Bendavia<sup>™</sup> (MPT-131) as the most direct mitochondrial competition. For TBI, the company's competition includes privately held Remedy Pharmaceuticals and Neuren Pharmaceuticals (NEU.AX), among others. The company faces several Phase 2 competitors developing therapeutics for mitochondrial disorders, including Raptor Pharmaceuticals (RPTP) candidate *RP103*, Edison Pharmaceuticals' *Vinverinone*, (*EPI743*), Ocuvia from stealth Biotherapeutics, and Raxone from Santhera Pharmaceuticals (SWX: SANN).

In the following graphic we compare NeuroVive to a number of peer companies and competitors in the biotechnology industry on the basis of size and profitability. We selected small and micro capitalization companies with products / candidates that compete with NeuroVive or have exposure to mitochondrial medicine. As shown below, given that the majority of these companies are pre-revenue or have only recently achieved commercial approval from regulators, margins are negative for the group, reflecting investments in clinical development with no revenues.



Source: Thompson Financial, Company filings, SeeThruEquity Research



# FINANCIALS AND FUTURE OUTLOOK

### Clinical stage biotechnology company

NeuroVive is a clinical stage biotechnology company, which does not have products approved for commercialization in the US or Europe at this time. This analysis assumes that the company is able to advance its clinical programs through to regulatory approval and commercialization, through strategic licensing agreements. Readers of this analysis should be aware that it is difficult to estimate future sales, pricing and margins of products which have not completed the clinical trial / regulatory approval process. Our valuation accounts for the uncertainty of future results and regulatory approval by using discount rate to reflect risk, and a probability discount factor, which reflects the reality that regulatory approvals are inherently uncertain.

### **Key Assumptions**

Partner Strategy. Our model assumes that NeuroVive's expertise is identifying and validating new mitochondrial medicines, and adding value by showing their safety and efficacy in clinical trials. We have assumed that the company will pursue a partner-based commercialization strategy, rather than raising the substantial capital that would be required to plan and complete Phase 3 trials on its own, and to fund initial sales and marketing efforts and working capital required for a commercial launch.

Given that the company's most advanced programs are its Phase 2 clinical studies of CicloMulsion® for AKI and NeuroSTAT® for TBI, these programs represent the majority of our forecast. We believe the company will seek to form strategic partnerships for these programs between 2017E – 2020E, following the release of Phase 2 results and end of trial meetings with the FDA. We have assumed total license / milestone fees of \$30mn (SEK 255mn) for these programs, plus 10% royalty rate from partner revenues, which are estimated to begin in FY21E for CicloMulsion® and FY23E for NeuroSTAT®. We also assumed modest revenues from NVP019 beginning in 20124E and did not include the preclinical program for stroke in our model at this time. We would likely revisit these programs in the future as they begin clinical trials.

Readers of this analysis should be aware that the company has not announced / completed strategic licensing deals in either the US or Europe for NeuroSTAT®, CicloMulsion®, or NVP019. Our model's assumptions are based on: 1) management commentary that it would increase business development / deal conversations over the next 12 months; and 2) our estimate of partnership terms that might be available assuming strong clinical results, which may or may not occur.

Figure 4. NeuroVive Assumptions Overview (000)

CicloMulsion®	FY16	FY17E	FY18E	FY19E	FY20E	FY21E	FY22E
Clinical Phase	Phase 2	Phase 2/3	Phase 3	Phase 3	FDA	Market	Market
License / Milestone Fees (\$)	0	2,500	0	3,250	0	7,000	0
Partner Sales (\$)	0	0	0	0	0	25,646	65,079
Royalties (\$)	0	0	0	3,250	0	2,565	6,508
Total Revenues (\$)	0	2,500	0	6,500	0	9,565	6,508
Total Revenues (SEK)	0	21,250	0	55,250	0	81,299	55,317

Source: STE Estimates



NeuroSTAT®	FY16E	FY17E	FY18E	FY19E	FY20E	FY21E	FY22E	FY23E	FY24E
Clinical Phase	Phase 2	Phase 2	Phase 2	Phase 3	Phase 3	Phase 3	FDA	Market	Market
License Fees (\$)	0	0	3,500	0	0	4,500	7,500	0	0
Partner Sales (\$)	0	0	0	0	0	0	0	83,239	171,802
Royalties (\$)	0	0	0	3,250	0	0	0	8,324	17,180
Total Revenue (\$)	0	0	3,500	3,250	0	4,500	7,500	15,824	17,180
Total Revenues (SEK)	0	0	29,750	27,625	0	38,250	63,750	134,503	146,032

Source: STE Estimates

### **Balance Sheet & Financial Liquidity**

NeuroVive closed a significant capital raise in May 2016, which we believe should support development of its clinical program over the next twelve months. The company ended 2Q16 with cash on hand of SEK 132.3mn (\$15.6mn) with current liabilities of SEK 10.3mn (\$1.2mn). The company expects this capital position to be sufficient to fund its operations and development plans for approximately the next twelve months. We do expect the company to continue to require new capital to advance its clinical portfolio. Our model assumes the company structures partnership deals with upfront license payments, which would provide cash that could be deployed for this purpose; however, while management plans to explore strategic partnerships that could include licensing deals, the company has not yet announced deals in this area. In the absence of upfront licensing payments we would expect the company to issue new equity to fund its clinical portfolio, beginning in 2H17.



# **VALUATION**

We valued NeuroVive using the discounted cash flow ("DCF") method. We have also included a Peer Group analysis comprised of select NeuroVive peers and competitors for informative purposes; however, given that NeuroVive – and a majority of the selected peer companies – is a clinical stage company with no drug products approved by regulators at this time, classic peer valuation measures such as P/E and EV/Revenue do not generate sufficient data to calculate a price target.

### **DCF**

Our valuation considers the possibility that NeuroVive is successful in advancing three products to commercial stage through research & development, clinical trials, and regulatory approval. We have assumed the company pursues a partner-based commercialization strategy, partnering with larger pharmaceutical corporations after the Phase 2 results, with deals structured to include license and milestone payments, as well as royalties on future product sales. We outlined these assumptions in further detail in the Financials & Future Outlook section of this report.

We do not expect NeuroVive to have commercial products form 2016E – 2020E. We have forecast initial commercialization for CicloMulsion® to begin in FY21E, and NeuroSTAT to begin in FY23E. We have not forecast large working capital / capital spending commitments for the company, due to our assumption of a partner-based approach to commercialization. We included our assumption of by programs and associated license / milestone fees, as shown in the table below. We assumed a 45% probability factor, discounted future cash flows by a weighted average cost of capital of 13.9%, and assumed a terminal growth rate of 5% at the end of FY2027E, to determine a price target of SEK 11.05 / \$1.30 per share.

000	FY16E	FY17E	FY18E	FY19E	FY20E	FY21E	FY22E	FY23E	FY24E	FY25E	FY26E	FY27
CicloMulsion® (AKI)	Phase 2	Phase 2	Phase 3	Phase 3	FDA	Market	Market	Market	Market	Market	Market	Marke
NeuroSTAT (TBI)	Phase 2	Phase 2	Phase 2	Phase 3	Phase 3	Phase 3	FDA	Market	Market	Market	Market	Mark
NVP019	Preclinical	Phase 1	Phase 1	Phase 2	Phase 2	Phase 3	Phase 3	FDA	Market	Market	Market	Mark
Est License Fees (SEK)	0	21,250	29,750	38,250	0	102,000	63,750	0	0	0	0	
EBIT	(26,767)	(32,245)	(29,274)	(26,728)	(67,601)	49,638	37,693	38,221	131,921	174,253	312,189	450,46
Less: Tax	0	0	0	0	0	5,460	7,162	8,409	36,938	59,246	106,144	153,1
NOPLAT	(26,767)	(32,245)	(29,274)	(26,728)	(67,601)	44,178	30,532	29,812	94,983	115,007	206,045	297,3
Working capital	(837)	66	153	251	815	(104)	1,447	(486)	(965)	975	782	8
D&A	670	1,200	1,200	929	945	980	1,039	1,129	1,202	1,262	1,311	1,3
Capex	0	(250)	(250)	(250)	(250)	(350)	(490)	(686)	(700)	(714)	(728)	(74
FCFF	(26,934)	(31,229)	(28,171)	(25,799)	(66,091)	44,704	32,528	29,770	94,520	116,529	207,409	298,7
Discount factor	0.96	0.84	0.74	0.65	0.57	0.50	0.44	0.39	0.34	0.30	0.26	0.
Probability factor	0.45	0.45	0.45	0.45	0.45	0.45	0.45	0.45	0.45	0.45	0.45	0.
PV of FCFF	(11,662)	(11,872)	(9,402)	(7,560)	(17,003)	10,098	6,451	5,183	14,449	15,639	24,439	30,9
Sum of PV of FCF	F											49,6
Terminal cash flow	N											3,524,9
PV: Terminal cash	n flow											364,6
Enterprise value	(SEK)											414,3
Less: Debt												
Add: Cash (SEK)												132,2
Equity value												546,5
		_		-							_	49
Avg. Shares (mn)												
Avg. Shares (mn) Fair value per sh												11.



Summary conclusions		Key assumptions	
DCF FV (SEK per share)	11.05	Beta	1.5
Recent price (\$ per share)	6.65	Cost of equity	13.9%
Upside (downside)	66.2%	Probability factor	45.0%
WACC	13.9%	Terminal Growth Rate	5.0%

Source: SeeThruEquity Research

Figure 5. Sensitivi	gure 5. Sensitivity of Valuation – WACC vs. Terminal Growth Rate								
		WAC	C (%)						
rate		13.700%	13.800%	13.9%	14.0%	14.1%			
_	4.00%	10.54	10.39	10.24	10.17	9.96			
growth (%)	4.50%	10.95	10.79	10.63	10.55	10.32			
alg (%)	5.00%	11.40	11.23	11.05	10.97	10.72			
Terminal	5.50%	11.91	11.72	11.53	11.43	11.16			
Ţ	6.00%	12.49	12.27	12.06	11.96	11.67			

Source: SeeThruEquity Research



### **Peer Group Analysis**

As noted earlier in this analysis, we did not use a Peer Group Analysis to determine a price target for NeuroVive given that the company is a Phase 2 clinical stage business, and classic fundamental multiple analyses such as P/S, P/E would not produce actionable information. Indeed, there are many company-specific factors that can affect the valuation of biotechnology companies whose products have not yet been approved for commercial sale, which may include: the reputation of the management team, the market opportunity for lead candidates, and the persuasiveness of clinical trial data. These factors have a significant impact on the potential growth, profitability, and strategic importance of companies in the biotechnology sector but are not readily apparent in classic comparative valuation measures. Nevertheless, we felt it would be informative to include a comparison of NeuroVive to peer companies in the sector.

Our peer group includes a range of small capitalization and microcap companies in the biotechnology sector, which either have competing therapeutic candidates to NeuroVive's pipeline, or in some way use mitochondrial science in their clinical research and development. We considered other companies focused on mitochondrial therapeutics, such as CohBar, Inc., as well as commercial stage companies like Raptor Pharmaceuticals and Santhera Pharmaceuticals, among others, as shown in the graphic below. One point of interest in the comparable valuation table is the dramatic increase in market capitalization for those companies with a product approved for commercial sale by the FDA.

Figure 6. Comp	arable Valuatio	on *			
Company	Mkt cap (\$USD mn)	Clinical Stage	Clinical / Preclinical Area of Focus	Price / Book	EV/ Revenue FY16E
Galectin Therapeutics	50	Phase 2	NASH	7.0x	N/A
Raptor Pharmaceuticals	636	Commercial	Mitochondrial disorders, NASH / NAFLD, Leigh's Disease	9.4x	4.7x
MEI Pharma	62	Phase 2	AML, MDS, mitochondrial inhibitors	1.3x	N/A
Galmed Pharmaceuticals	42	Phase 2a	NASH / NAFLD	2.9x	N/A
Santhera Pharmaceuticals	273	Commercial	Mitochondrial Disorders	2.9x	N/A
Neuren Pharmaceuticals	72	Phase 2	Traumatic Brain Injury (TBI)	NM	N/A
CohBar, Inc.	70	Pre-clinical	Mitochondria based therapeutics for diabetes, neurodegenerative disorders & cancer	8.1x	N/A
PledPharma AB	165	Phase 2	Reperfusion injuries caused by myocardial infarction	34.1x	N/A
Average	_	_		9.4x	4.7x
NeuroVive	40	Phase 2	Mitochondrial disorders, TBI, AKI	1.7x	N/A
Premium (discount)				(82.3%)	NM

Source: Bloomberg, SeeThruEquity Research, \*Data as of Sept 9, 2016;



# **RISK CONSIDERATIONS**

### **Financial Liquidity**

We see continued access to capital as a key risk for NeuroVive. Although in the short run the company has recently competed a rights offering, which provided existing investors the opportunity to invest additional capital into the company without large dilution, we do expect that NeuroVive will require additional capital in 2017-2018, to fund its development pipeline. This capital could be provided in the form of a strategic partnership / license deal, through the issuance of new shares, through research grants, or, more likely, a combination of these sources. The biotechnology industry requires substantial capital intensity to bring new products to market, given the high cost of clinical trials required for regulatory approval.

#### Competition

NeuroVive is seeking to develop new therapeutics using mitochondrial medicine. Although the company seeks to differentiate itself by focusing on this segment of the biotechnology industry, it nevertheless faces stiff competition from other industry participants. Indeed, the global biotechnology industry is characterized by intense competition, with a relatively small selection of large global corporations having significant advantages of scale, sales distribution, research & development labs, and financial resources when compared to the many smaller companies in the industry. This dynamic could place NeuroVive at a competitive disadvantage as it seeks to source promising mitochondrial medicine candidates and when it seeks to strike strategic distribution / licensing partnerships after having proven the safety and efficacy of its existing portfolio through clinical trials.

### **Regulatory Risks**

NeuroVive operates in a highly regulated industry, which is structured to be advantageous for large pharmaceutical companies with deep resources to fund time-consuming and expensive clinical trials in order to gain regulatory approval. The process of achieving regulatory approval for new therapies is highly uncertain and difficult to predict.

### **Lack of Commercial Products**

NeuroVive has no commercial products and will be unable to sell its mitochondrial medicines without approval by a regulatory body. This analysis assumes that NeuroVive is able to commercialize and/or license several programs in its portfolio. However, company's ongoing trials and future trials / studies may not support the safety and efficacy of its products, which would require the company to raise new capital or cease operations.

### Dilution

Small companies in the biotechnology are especially susceptible to risk of dilution, given the significant costs associated with funding clinical studies required for regulatory approval. If NeuroVive requires more capital than expected, or faces a more challenging capital raising environment, or if its clinical pipeline takes longer to develop than anticipated, the company maybe forced to raise capital at prices / terms which are unfavorable to existing equity holders. This may include the issuance of new shares and dilutive instruments such as warrants, convertible debt and preferred stock. Dilution reduces the proportionate ownership of shareholders.



# **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 different financial positions in the medical device company Cellavision, which is listed on Nasdag Stockholm, and 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.



# **FINANCIAL SUMMARY**

Figure 7. Income Statement					
Figures in SEK mn unless specified	FY14A	FY15A	FY16E	FY17E	FY18E
Revenue	8.3	3.0	0.1	21.3	29.8
YoY growth	NM	(63.7%)	(96.9%)	22506.4%	40.0%
Operating expenses	53.6	94.5	49.9	53.5	59.0
EBIT	(45.3)	(91.5)	(49.8)	(32.2)	(29.3)
Margin	(543.1%)	(3024.7%)	(53004.3%)	(151.7%)	(98.4%)
EBITDA	(44.8)	(90.3)	(48.6)	(31.3)	(28.3)
Margin	NM	NM	NM	NM	(95.1%)
Other income/ (expense)	0.6	0.7	0.3	0.0	0.0
Profit before tax	(44.7)	(90.8)	(49.6)	(32.2)	(29.3)
Tax	0.0	0.0	0.0	0.0	0.0
Net income to Common	(44.7)	(90.8)	(49.6)	(32.2)	(29.3)
Margin	NM	NM	NM	NM	(98.4%)
EPS (per share)	(1.53)	(3.01)	(1.16)	(0.76)	(0.52)

Source: SeeThruEquity Research

Figure 8. Balance Sheet							
Figures in SEK mn, unless specified	FY14A	FY15A	FY16E	FY17E	FY18E		
Current assets	51.3	99.6	109.7	76.9	149.9		
Other assets	79.9	75.4	88.9	88.0	87.0		
Total assets	131.3	174.9	198.6	164.9	236.9		
Current liabilities	23.4	20.1	10.0	10.0	10.8		
Other liabilities	0.0	0.0	0.0	0.0	0.0		
Shareholders' equity	107.8	154.8	188.6	188.6	226.2		
Total liab and shareholder equity	131.3	174.9	198.6	198.7	236.9		

Source: SeeThruEquity Research

Figure 9. Cash Flow Statement					
Figures in SEK mn, unless specified	FY14A	FY15A	FY16E	FY17E	FY18E
Cash from operating activities	(43.6)	(67.2)	(61.9)	(30.5)	(27.4)
Cash from investing activities	(23.4)	(23.4)	(5.0)	(2.3)	(0.3)
Cash from financing activities	76.6	138.4	77.3	0.0	100.0
Net inc/(dec) in cash	9.5	47.7	10.5	(32.7)	72.4
Cash at beginning of the year	40.0	49.7	96.7	104.8	72.1
Cash at the end of the year	49.7	96.7	104.8	72.1	144.5

Source: SeeThruEquity Research



# **About NeuroVive Pharmaceutical AB**

NeuroVive Pharmaceutical AB (Nasdaq Stockholm: NVP, OTCQX: NEVPF) is a pioneer in mitochondrial medicine and a company committed to the discovery and development of highly targeted candidates that preserve mitochondrial integrity and function in areas of significant therapeutic need. NeuroVive's business approach is driven by value-adding partnerships with mitochondrial research institutions and commercial partners across the globe.

NeuroVive's portfolio consists of two clinical projects, one in acute kidney injury (CicloMulsion®) and one in traumatic brain injury (NeuroSTAT®). The candidate drug NeuroSTAT has orphan drug designation in Europe and in the US for treatment of moderate to severe traumatic brain injury and is currently being evaluated in the CHIC study. CicloMulsion is being evaluated in an on-going study, CiPRICS, in acute kidney injury during major surgery. Furthermore, the R&D portfolio consists of two late stage discovery programs and one compound in preclinical development.

NeuroVive is listed on Nasdaq Stockholm, Sweden, Small Cap, under the ticker symbol NVP. The share is also traded on the OTC Markets Group Inc. market in the US. NeuroVive Pharmaceutical (OTC: NEVPF) trades on the OTCQX Best Market.



### Contact

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