EDISON

NeuroVive Pharmaceutical

R&D update

Several R&D events within cash reach

Pharma & biotech

The combined net proceeds of SEK108m from a rights issue and direct placement completed in Q119 ensure NeuroVive Pharmaceutical's operations will be funded well into 2020. Potential near-term share price catalysts include initial results from the KL1333 Phase Ia/b, a non-dilutive financing solution to enable the start of the NeuroSTAT Phase II clinical trial, the publication of *in vivo* data for NV354 and the an out-licensing of NV556. Our updated valuation is slightly higher at SEK1.55bn or SEK8.3/share.

Year end	Revenue (SEKm)	PBT* (SEKm)	EPS* (SEK)	DPS (SEK)	P/E (x)	Yield (%)
12/17	0.6	(70.1)	(1.49)	0.0	N/A	N/A
12/18	2.5	(68.8)	(0.94)	0.0	N/A	N/A
12/19e	1.5	(92.0)	(0.64)	0.0	N/A	N/A
12/20e	1.5	(115.0)	(0.65)	0.0	N/A	N/A

Note: *PBT and EPS are normalised, excluding amortisation of acquired intangibles and exceptional items.

KL1333 trial to drive R&D costs; funded into 2020

The company reported a Q119 operating loss of SEK13.8m versus SEK13.0m a year ago and in line with our expectations. Q119 R&D costs were SEK6.1m, but we expect this to increase now that the KL1333 Phase Ia/b trial is underway. Q119 personnel costs of SEK3.5m were in line with Q118. Following the rights issue (SEK82.0m net) completed in February 2019 and the direct issue (SEK26.0m net) in March 2019, NeuroVive's cash position was SEK113.3m at the end of Q119, which should fund the company's operations well into 2020.

Expected near-term newsflow

The initial results from the Phase Ia/b study testing KL1333, in development for mitochondrial diseases, should be the key catalyst achievable with the new funds. The trial has already enrolled the first healthy volunteer and initial data are expected in H219. In addition, following the FDA's approval of an investigation new drug application (IND) for NeuroSTAT, NeuroVive plans to initiate a proof-of-concept Phase II trial in traumatic brain injury (TBI), where there is no specific, approved therapeutic treatment. The company will require additional funding to initiate the trial and this could come from non-dilutive funding or a partnership. NV354 (selected compound from the NVP015 programme) is one of the preclinical projects also gaining pace and could enter the clinic in 2020.

Valuation: SEK1.55bn or SEK8.3/share

Our updated, risk-adjusted NPV valuation of NeuroVive is marginally higher at SEK1.55bn or SEK8.3/share. This is due to rolling our model forward and a positive forex effect. We leave our financial forecasts and R&D assumptions virtually unchanged, as described in our initiation report and last outlook note.

12 June 2019

Price	**SEK1.21**
Market cap	**SEK225m**
	SEK9.40/US$
Net cash (SEKm) at end-Q119	113.3
Shares in issue	186.0m
Free float	95%
Code	NVP
Primary exchange	Nasdaq Stockholm
Secondary exchange	OTCQX

Share price performance

%	1m	3m	12m
Abs	2.7	(13.3)	(58.1)
Rel (local)	1.8	(16.2)	(59.7)
52-week high/low	SEK5.06	SEK1.16	

Business description

NeuroVive Pharmaceutical is a Swedish biopharmaceutical company with deep expertise in mitochondrial medicine. It has a diversified portfolio in terms of indications and employs a dual strategy: it develops a core portfolio of assets for orphan diseases and seeks to out-license proprietary products for non-orphan indications. NeuroSTAT (neurotrauma, Phase IIb ready) and KL1333 (genetic mitochondrial diseases) are the most advanced assets.

Next events

Initial results from Phase Ia/b with KL1333	H219
Initiation of NeuroSTAT Phase II	2019
NV354 in vivo data	2019

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Edison profile page

Highlights of the most advanced products in R&D

KL1333 – Phase Ia/b has started

The funds raised in Q119 allowed NeuroVive to initiate the next steps in the clinical development of its lead clinical assets, KL1333 and NeuroSTAT, and the preclinical asset NV354. In March 2019, the first healthy volunteer was enrolled in the Phase Ia/b study testing KL1333 for mitochondrial diseases, such as MELAS, PEO, KSS and Pearson's syndrome. KL1333, a small molecule NAD+ modulator, is intended for oral use in a variety of mitochondrial diseases. The drug was tested in healthy volunteers in a Phase I trial (single ascending dose) by NeuroVive's partner (licensor) Yungjin Pharm in South Korea and positive safety and tolerability results were reported in May 2018. We believe this diminishes the likelihood of negative surprises from NeuroVive's own Phase Ia/b trial with KL1333, although additional interesting early efficacy insights could be obtained from patient data. NeuroVive's own trial will include multiple ascending doses in healthy volunteers and patients. Initial data from healthy volunteers are expected by end-2019 and hence are achievable with current funding.

KL1333 is a novel NAD+ modulator, which interacts with NQO1 (NAD(P)H:quinone oxidoreductase 1) as a substrate and regulates the levels of nicotinamide adenine dinucleotide (NAD+) (Kang-Sik Seo et al, 2018). NAD+ is a coenzyme necessary for many cellular metabolism processes including mitochondrial biogenesis and function, as well as the production of ATP in the electron transport chain. The ability to increase the level of NAD+ in patients could therefore improve mitochondrial function in various mitochondrial diseases.

NeuroSTAT – IND approved

NeuroSTAT is another of NeuroVive's leading clinical-stage drug candidates. NeuroSTAT is an innovative, patent-protected formulation of ciclosporin without the use of Cremophor or ethanol. There is still no neuroprotective treatment available for TBI. The most advanced dataset with this drug was generated in the Phase IIa Copenhagen Head Injury Ciclosporin (CHIC) study (n=20). In October 2018, NeuroVive, in collaboration with researchers at the University of Florida released a biomarker analysis from this study, which included four novel biomarkers from cerebrospinal fluid samples: GFAP (Glial fibrillary acidic protein), UCH-L1 (Ubiquitin carboxy-terminal hydrolase L1), NF-L (Neurofilament Light) and Tau. The administration of NeuroSTAT had a positive longitudinal effect on the levels of these biomarkers potentially alleviating secondary brain injury. The CHIC study was complemented by an experimental large animal (piglets) study, which showed a 35% reduction of brain injury volume in TBI. The study was conducted in collaboration with the University of Pennsylvania, US (published Karlsson et al, 2018).

The CHIC study was open-label and non-controlled, therefore the next step is a proof-of-concept Phase II clinical trial. To this end, in May 2019 NeuroVive announced that the FDA had approved an investigational new drug application, which enables the initiation of clinical studies with NeuroSTAT in the US. Study design details have not been announced yet. Additional funding will be required to initiate the Phase II efficacy trial, which management indicated could be carried out via non-dilutive funding or a partnership.

NV354 – external validation from BridgeBio

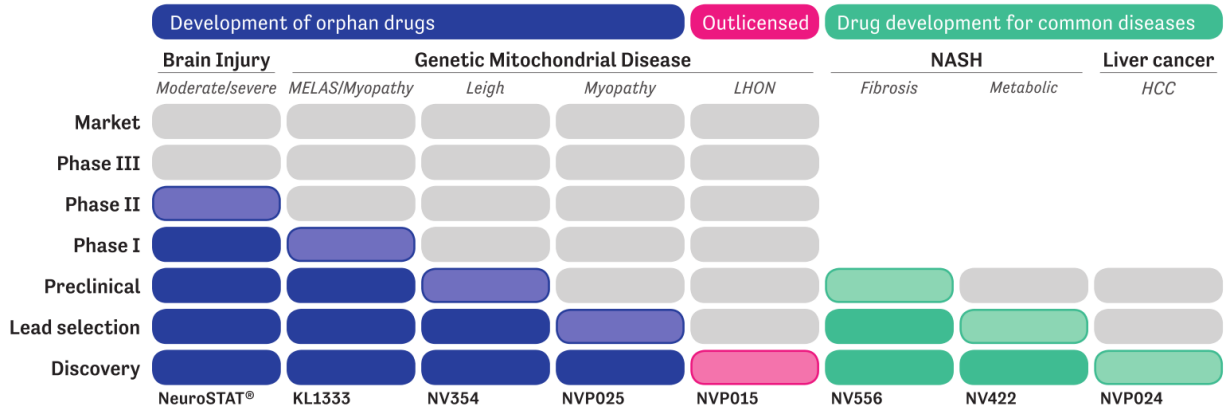
NV354 is the selected preclinical lead compound in the NVP015 program, which is focusing on the development of succinate prodrugs targeting complex I deficiency. Mitochondrial complex I deficiency is the most prevalent defect in the respiratory chain in paediatric mitochondrial diseases (around 50%) and clinically presents as a group of syndromes, which can be caused by changes in

either the nuclear or mitochondrial genome. The next steps with NV354, expected in 2019, are further in vivo dose-response data and the initiation of toxicology studies.

As part of the NPV015 discovery programme, NeuroVive evaluated many other succinate prodrugs and, on June 2018, the company announced that it had out-licensed a subset of these prodrugs to private biotech BridgeBio, based in California, US. BridgeBio plans to develop these compounds for the localised treatment of Leber's hereditary optic neuropathy (LHON) in its new subsidiary Fortify Therapeutics. The total deal value could reach $60m (a 'limited' amount will be provided upfront for research funding). We believe this deal provides external validation of the science behind the NVP015 programme.

We reviewed the remainder of NeuroVive's R&D pipeline in our last outlook report.

Exhibit 1: NeuroVive's R&D pipeline



Source: NeuroVive

Valuation

Our updated, risk-adjusted NPV valuation of NeuroVive is marginally higher at SEK1.55bn or SEK8.3/share vs SEK1.51bn or SEK8.1/share previously. This is due to rolling the model forward and the positive forex effect. We maintain our financial forecasts and R&D assumptions as described in our initiation report and last outlook note. As previously, in our valuation we include clinical-stage NeuroSTAT (TBI) and KL1333 (genetic mitochondrial disorders), as well as advanced preclinical products. We continue to exclude NVP025 (mitochondrial myopathy) and NVP022 (NASH) as both remain at an early stage.

Exhibit 2: NeuroVive sum-of-the parts valuation

Product	Launch	Peak sales* ($m)	NPV ($m)	NPV/share ($)	Probability	rNPV ($m)	rNPV/share ($)
NeuroSTAT	2025	454	297.0	1.6	15%	35.9	0.2
KL1333	2024	574	608.3	3.3	10%	57.1	0.3
NVP015	2027	875	466.5	2.5	5%	20.8	0.1
NV556	2027	1,743	143.5	0.8	8%	31.2	0.2
NVP024	2029	730	32.0	0.2	3%	7.7	0.0
Net cash, last reported			12.1	0.1	100%	12.1	0.1
Valuation			**1,559.4**	**8.4**		**164.8**	**0.9**
			SEKm	**SEK**		**SEKm**	**SEK**
NeuroSTAT			2,792.0	15.0	15%	337.8	1.8
KL1333			5,718.4	30.8	10%	536.9	2.9
NVP015			4,385.1	23.6	5%	195.4	1.1
NV556			1,348.9	7.3	8%	293.7	1.6
NVP024			300.8	1.6	3%	72.2	0.4
Net cash, last reported			113.3	0.6	100%	113.3	0.6
Valuation			**14,658.4**	**78.8**		**1,549.2**	**8.3**

Source: Edison Investment Research. Note: *Peak sales reached six years after launch. WACC = 12.5% for product valuations.

Exhibit 3: Financial summary

SEK000s	2017	2018	2019e	2020e
Year end 31 December	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS				
Revenue	585	2,466	1,500	1,500
Cost of Sales	0	0	0	0
Gross Profit	585	2,466	1,500	1,500
Research and development	(27,926)	(37,922)	(59,533)	(80,840)
EBITDA	(67,897)	(66,675)	(91,847)	(114,867)
Operating Profit (before amort. and except.)	(69,492)	(68,589)	(91,995)	(114,999)
Intangible Amortisation	0	0	0	0
Exceptionals	(1,595)	(4,771)	0	0
Other	56	66	0	0
Operating Profit	(71,031)	(73,294)	(91,995)	(114,999)
Net Interest	(571)	(200)	0	0
Profit Before Tax (norm)	(70,063)	(68,789)	(91,995)	(114,999)
Profit Before Tax (reported)	(71,602)	(73,494)	(91,995)	(114,999)
Tax	0	0	0	0
Profit After Tax (norm)	(70,007)	(68,723)	(91,995)	(114,999)
Profit After Tax (reported)	(66,727)	(68,373)	(86,874)	(109,878)
Average Number of Shares Outstanding (m)	50.2	78.5	152.8	186.0
EPS - normalised (SEK)	(1.49)	(0.94)	(0.64)	(0.65)
EPS - normalised fully diluted (SEK)	(1.49)	(0.94)	(0.64)	(0.65)
EPS - reported (SEK)	(1.33)	(0.87)	(0.57)	(0.59)
Dividend per share (SEK)	0.0	0.0	0.0	0.0
Gross Margin (%)	100.0	100.0	100.0	100.0
EBITDA Margin (%)	N/A	N/A	N/A	N/A
Operating Margin (before GW and except.) (%)	N/A	N/A	N/A	N/A
BALANCE SHEET				
Fixed Assets	87,579	86,681	86,681	86,681
Intangible Assets	74,315	73,440	73,440	73,440
Tangible Assets	162	140	140	140
Investments	13,102	13,101	13,101	13,101
Current Assets	30,560	27,383	43,539	1,432
Stocks	0	0	0	0
Debtors	0	0	0	0
Cash	28,992	25,951	42,107	0
Other	1,568	1,432	1,432	1,432
Current Liabilities	(14,259)	(18,296)	(18,296)	(18,296)
Creditors	(14,259)	(18,296)	(18,296)	(18,296)
Short term borrowings	0	0	0	0
Long Term Liabilities	0	0	0	(72,830)
Long term borrowings	0	0	0	(72,830)
Other long term liabilities	0	0	0	0
Net Assets	103,880	95,768	111,924	(3,013)
CASH FLOW				
Operating Cash Flow	(58,039)	(63,630)	(91,847)	(114,867)
Net Interest	(84)	(199)	0	0
Tax	0	0	0	0
Capex	(40)	(82)	(87)	(70)
Acquisitions/disposals*	(11,035)	0	0	0
Financing	9,031	64,656	108,090	0
Other	(4,092)	(3,786)	0	0
Dividends	0	0	0	0
Net Cash Flow	(64,259)	(3,041)	16,156	(114,937)
Opening net debt/(cash)	(93,251)	(28,992)	(25,951)	(42,107)
HP finance leases initiated	0	0	0	0
Other	0	(0)	0	(0)
Closing net debt/(cash)	(28,992)	(25,951)	(42,107)	72,830

Source: NeuroVive accounts, Edison Investment Research

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