

NeuroVive Pharmaceutical

R&D update

Steady progress with core assets

NeuroVive's core R&D assets in genetic mitochondrial diseases have made steady progress over the past several months. Notable newsflow includes KL1333 proceeding to the second part of its study and NeuroSTAT receiving the FDA's fast track designation. Potential near-term milestones include initial results from KL1333 Phase Ia/b, a non-dilutive financing solution to enable the start of the NeuroSTAT Phase II clinical trial and an out-licensing of NV556. Our updated valuation is slightly higher at SEK1.63bn or SEK8.8/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	(94.1)	(0.65)	0.0	N/A	N/A
12/20e	1.5	(117.9)	(0.66)	0.0	N/A	N/A

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

KL1333 data in healthy volunteers by end-2019

In July 2019, NeuroVive announced it had initiated the [second part](#) of the Phase Ia/b study ongoing in the UK with KL1333 in genetic mitochondrial diseases such as MELAS, PEO, KSS and Pearson's syndrome. Healthy volunteers in this study will now receive repeated doses of KL1333. This followed the successful completion of the first part of the study, where healthy volunteers received single doses of KL1333 and the effect of food intake on the drug's absorption was measured. Healthy volunteer safety data should be released later this year.

NV354 could enter clinical development in 2020

With its Q219 report, NeuroVive described progress with its other two projects in the core R&D portfolio. NV354, a succinate prodrug targeting complex I deficiency, should enter clinical development in 2020. NeuroVive expects to select a drug candidate from its earliest mitochondrial disease programme, NVP025, targeting mitochondrial myopathies.

NeuroSTAT receives FDA's fast track designation

Another significant recent announcement was that NeuroSTAT has received fast track designation from the FDA. This designation has benefits such as more frequent meetings and communication with the FDA, continuous feedback on the New Drug Application and the possibility of a shorter review period than the typical 10 months. This designation was received after the FDA approved the Investigational New Drug application for NeuroSTAT in May 2019.

Valuation: SEK1.63bn or SEK8.8/share

Our updated, risk-adjusted NPV valuation of NeuroVive has increased slightly to SEK1.58bn or SEK8.5/share due to rolling our model forward and a positive foreign exchange rate effect, which was partially offset by a lower net cash position. We leave our financial forecasts and R&D assumptions virtually unchanged. On 9 October 2019, NeuroVive will host a capital markets day in Stockholm.

Pharma & biotech

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Price **SEK1.54**
Market cap **SEK286m**

Net cash (SEKm) at end Q219 99.1

Shares in issue 186.0m

Free float 95%

Code NVP

Primary exchange Nasdaq Stockholm

Secondary exchange OTCQX

Share price performance



% 1m 3m 12m

Abs (28.0) 27.6 (57.6)

Rel (local) (31.3) 24.4 (59.0)

52-week high/low SEK3.82 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. KL1333 (genetic mitochondrial diseases) and NeuroSTAT (neurotrauma, Phase IIb ready) are the most advanced assets.

Next events

Further interim results from Phase Ia/b with KL1333 H219

Capital markets day 9 October 2019

Q319 results 20 11 2019

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Core asset portfolio updates

KL1333 Phase Ia/b final results in 2020

KL1333, a small molecule NAD+ modulator, is intended for oral use in a variety of mitochondrial diseases. NeuroVive started a Phase Ia/b study in March 2019. Following the completion of the second part of the study, the third and final part will evaluate repeated doses of KL1333 in mitochondrial disease patients with final results due next year (the first two parts of the study involved healthy volunteers). This will be the first time KL1333 will be tested in such patients. Yungjin Pharm based in South Korea is NeuroVive's partner (licensor) and tested KL1333 in healthy volunteers in a prior Phase I trial (single ascending dose). Positive safety results reported from this study in May 2018 somewhat derisk NeuroVive's Phase Ia/b, in our view. Additional interesting early efficacy insights could be obtained from NeuroVive's trial because mitochondrial disease patients will also be enrolled.

NV354 could enter clinical development in 2020

NV354 is the selected preclinical lead compound in the NVP015 programme, which is focusing on developing 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%). With its Q219 report, NeuroVive indicated that preclinical development is going according to plan and the initial experimental results are positive. The company is conducting toxicology studies and scaling up manufacturing to prepare for the drug to enter clinical development in 2020.

As part of the NPV015 discovery programme, NeuroVive evaluated many other succinate prodrugs and, in June 2018, the company announced 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 in its new subsidiary, Fortify Therapeutics. The total deal value could reach \$60m.

Drug candidate from NVP025 programme to be selected

The NVP025 programme targets mitochondrial myopathies, a subgroup of neuromuscular diseases with hallmark symptoms such as muscle weakness, exercise intolerance, fatigue and heart problems, often accompanied by neurological symptoms such as dementia, movement diseases, stroke-like episodes, deafness and blindness. NVP025 is an early programme with the goal of developing a compound that prevents the weakening of muscle fibres associated with these diseases. The NVP025 mechanism of action is different to that of succinate prodrugs or KL1333 and comes from NeuroVive's sangamide class of compounds. The company expects to select a lead drug candidate within the NVP025 programme by end-2019.

Exhibit 1: Core R&D portfolio focusing on genetic mitochondrial diseases

Project (Partner)	Disease/symptom	Discovery	Preclinical	Phase I	Phase II	Phase III	Market
KL1333* (Yungjin)	MELAS/myopati	██████████	██████████	██████████			
NV354	Leigh	██████████	██████████				
NVP025	Myopathy	██████████	██████████				
Discovery projects		██████████					

*Orphan drug designation in the US and Europe.

Source: NeuroVive

NeuroSTAT receives the FDA’s fast track designation

NeuroSTAT is an innovative, patent-protected formulation of ciclosporin without the use of Cremophor or ethanol. There is still no neuroprotective treatment available for traumatic brain injury (TBI). The most advanced dataset with NeuroSTAT was generated in the Phase IIa Copenhagen Head Injury Ciclosporin (CHIC) study (n=16). The drug 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 (piglet) study, which showed a 35% reduction of brain injury volume in TBI. The CHIC study was open-label and non-controlled, therefore the next step is a proof-of-concept Phase II clinical trial. Because the IND is now place, US centres can be included in the upcoming study. NeuroSTAT is part of the portfolio, which NeuroVive aims to partner for further development. Therefore, the design of the trial has not been disclosed yet. We reviewed the remainder of NeuroVive’s R&D pipeline in our last [outlook report](#).

Exhibit 2: R&D assets for out-licensing

Project (Partner)	Disease/symptom	Discovery	Preclinical	Phase I	Phase II	Phase III	Market
NeuroSTAT* (Sihuan, Sanofi)	Traumatic brain injury (TBI)	██████████	██████████	██████████	██████████	██████████	██████████
NV556	NASH (fibrosis)	██████████	██████████	██████████	██████████	██████████	██████████
NV422	NASH (metabolic)	██████████	██████████	██████████	██████████	██████████	██████████
NVP024	Liver cancer (HCC)	██████████	██████████	██████████	██████████	██████████	██████████

*Orphan drug designation in the US and Europe.

Source: NeuroVive

Financials and valuation

The company reported an H119 operating loss of SEK34.6m versus SEK38.2m a year ago. H119 R&D costs were SEK19.5m (vs SEK23.0m in H118), but we expect this to increase now the KL1333 Phase Ia/b trial is underway. H119 personnel costs of SEK7.8m were in line with H118. NeuroVive’s cash position was SEK99.1m at the end of H119, which should fund the company’s operations well into 2020.

Our updated, risk-adjusted NPV valuation of NeuroVive is slightly higher at SEK1.63bn or SEK8.8/share vs SEK1.55bn or SEK8.3/share previously. This is due to rolling the model forward and a positive foreign exchange rate effect, partially offset by lower cash position. We maintain our financial forecasts and R&D assumptions as described in our last outlook note. As previously, in our valuation we include clinical-stage and advanced preclinical products.

Exhibit 3: NeuroVive sum-of-the parts valuation

Product	Launch	Peak sales* (\$m)	NPV (\$m)	NPV/share (\$)	Probability	rNPV (\$m)	rNPV/share (\$)
KL1333	2024	574	626.7	3.4	10%	58.8	0.3
NV354**	2027	875	480.6	2.6	5%	21.4	0.1
NeuroSTAT	2025	454	306.0	1.6	15%	37.0	0.2
NV556	2027	1,743	147.8	0.8	8%	32.2	0.2
NVP024	2029	730	33.0	0.2	3%	7.9	0.0
Net cash, last reported			10.2	0.1	100%	10.5	0.1
Valuation			1,604.2	8.6		167.5	0.9

			SEKm	SEK/share	Probability	SEKm	SEK/share
KL1333			6,103.7	32.8	10%	573.1	3.1
NV354			4,680.6	25.2	5%	208.5	1.1
NeuroSTAT			2,980.2	16.0	15%	360.5	1.9
NV556			1,439.8	7.7	8%	313.5	1.7
NVP024			321.1	1.7	3%	77.0	0.4
Net cash, last reported			99.1	0.5	100%	99.1	0.5
Valuation			15,624.5	84.0		1,631.7	8.8

Source: Edison Investment Research. Note: *Peak sales reached six years after launch. WACC = 12.5% for product valuations.
 **Formerly NVP015.

Exhibit 4: Financial summary

	SEK'000s	2017	2018	2019e	2020e
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)	(61,687)	(83,764)
EBITDA		(67,897)	(66,675)	(94,001)	(117,791)
Operating Profit (before amort. and except.)		(69,492)	(68,589)	(94,148)	(117,923)
Intangible Amortisation		0	0	0	0
Exceptionals		(1,595)	(4,771)	0	0
Other		56	66	0	0
Operating Profit		(71,031)	(73,294)	(94,148)	(117,923)
Net Interest		(571)	(200)	0	0
Profit Before Tax (norm)		(70,063)	(68,789)	(94,148)	(117,923)
Profit Before Tax (reported)		(71,602)	(73,494)	(94,148)	(117,923)
Tax		0	0	0	0
Profit After Tax (norm)		(70,007)	(68,723)	(94,148)	(117,923)
Profit After Tax (reported)		(66,727)	(68,373)	(89,027)	(112,802)
Average Number of Shares Outstanding (m)		50.2	78.5	152.8	186.0
EPS - normalised (SEK)		(1.49)	(0.94)	(0.65)	(0.66)
EPS - normalised fully diluted (SEK)		(1.49)	(0.94)	(0.65)	(0.66)
EPS - reported (SEK)		(1.33)	(0.87)	(0.58)	(0.61)
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	41,385	1,432
Stocks		0	0	0	0
Debtors		0	0	0	0
Cash		28,992	25,951	39,953	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	(77,908)
Long term borrowings		0	0	0	(77,908)
Other long term liabilities		0	0	0	0
Net Assets		103,880	95,768	109,770	(8,091)
CASH FLOW					
Operating Cash Flow		(58,039)	(63,630)	(94,001)	(117,791)
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)	14,002	(117,861)
Opening net debt/(cash)		(93,251)	(28,992)	(25,951)	(39,953)
HP finance leases initiated		0	0	0	0
Other		0	(0)	0	0
Closing net debt/(cash)		(28,992)	(25,951)	(39,953)	77,908

Source: NeuroVive accounts, Edison Investment Research

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