

NeuroVive Pharmaceutical

Rights issue

New funds allow progress of key trials

In February 2019, NeuroVive completed a rights issue, which was followed by a private placement. These brought in a total of SEK108.1m (net estimated), which should be sufficient to 2020. In its recent 2018 annual report, NeuroVive provided a detailed update on its R&D activities and outlined the goals for 2019 achievable with the new funding. Potential near-term share price catalysts include KL1333 Phase Ib initial results, non-dilutive financing and the start of the NeuroSTAT Phase II clinical trial, and an out-licensing of NV556. Our updated valuation is SEK1.51bn or SEK8.1/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	(90.9)	(0.63)	0.0	N/A	N/A
12/20e	1.5	(113.5)	(0.64)	0.0	N/A	N/A

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

KL1333 Phase Ia/b trial top-line data in 2019

The newly raised funds will be used to advance NeuroVive's clinical and preclinical programmes, with one of the key trials being the Phase Ia/b study testing KL1333 in development for mitochondrial diseases, such as MELAS, PEO, KSS and Pearson's syndrome. KL1333, a small molecule NAD+ modulator, was tested in healthy volunteers in a [Phase I trial](#) (single ascending dose) by the licensor Yungjin Pharm in South Korea, which found the compound safe, with a favourable PK profile. NeuroVive's own Phase I trial will include multiple ascending doses in healthy volunteers and patients. We therefore believe the likelihood of confirming the safety profile is high, but additional interesting early efficacy insights could be obtained from patient data. The trial has already enrolled the first healthy volunteer. Initial data from healthy volunteers are expected in H219.

NeuroSTAT, NV556 and NV354 also in focus in FY19

NeuroVive also plans to initiate the proof-of-concept Phase II trial with NeuroSTAT in traumatic brain injury, where there is no specific, approved therapeutic treatment. Additional funding will be required to complete the trial, which management indicated could be carried out via non-dilutive funding or a partnership. Out-licensing preclinical assets in the non-core portfolio, especially NV556 (NASH), is another potential catalyst and a source of cash. NV354 (selected compound from the NVP015 programme) is one of the preclinical projects also gaining pace and could enter the clinic in 2020. Our last [outlook report](#) describes the ongoing R&D programmes in detail.

Valuation: SEK1.51bn or SEK8.1/share

Our updated, risk-adjusted NPV valuation of NeuroVive is SEK1.51bn or SEK8.1/share compared to SEK1.51bn or SEK9.2/share previously due to an increased cash position, revision of the operating and rNPV models, and rolling the model forward. The slight decrease in valuation per share is mostly technical adjustment after the increased number of shares.

Pharma & biotech

4 April 2019

Price **SEK1.42**
Market cap **SEK264m**

SEK8.83/US\$

Net cash (SEKm) at end-2018 + newly raised funds 134.0

Shares in issue 186.0m

Free float 95%

Code NVP

Primary exchange NASDAQ Stockholm

Secondary exchange OTCQX

Share price performance



%	1m	3m	12m
Abs	(0.6)	2.1	(33.7)
Rel (local)	(3.9)	(13.0)	(39.9)

52-week high/low SEK5.1 SEK1.2

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

Top line data from the Phase Ia/b with KL1333	H219
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Initiation of NeuroSTAT Phase II	2019
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Financials and valuation

The rights issue raised a total of SEK99m gross or an estimated net SEK81m (guarantee commitment fee was SEK9.1m). A few weeks after the share issue, NeuroVive announced a private placement, which brought in an additional SEK28.2m gross. The total number of shares outstanding increased from 91.7m to 186.0m after the rights issue and the private placement. Previously we have already included the guaranteed amount of SEK93m in our model, while the total newly raised funds amount to SEK108.1m (net of fees estimate), which we include in our model now. This and the last reported end-Q418 cash of SEK26.0m should be sufficient to fund operations into 2020, according to the company, which is also in line with our model. This includes several R&D events as discussed, most notably expected top-line data from the Phase Ia/b trial with KL1333 and the initiation of the Phase II study with NeuroSTAT.

Exhibit 1: Remaining 2019 milestones and near-term value inflection points

KL1333	<ul style="list-style-type: none"> • Top-line data from the Phase Ia/b study expected (first patient in March 2019) • Prepare for Phase II study
NeuroSTAT	<ul style="list-style-type: none"> • Secure non-dilutive financing for Phase II study • IND application • Initiate Phase II study
NVP015/NV354	<ul style="list-style-type: none"> • Further preclinical studies including in vivo dose-response, toxicology, production scale-up
NV556	<ul style="list-style-type: none"> • Out-licensing activities for NASH
NVP024	<ul style="list-style-type: none"> • Candidate selection
NVP025	<ul style="list-style-type: none"> • Candidate selection
NVP022/NV422	<ul style="list-style-type: none"> • Preclinical dose-response studies in NASH disease model

Source: [NeuroVive annual report](#), Edison Investment Research.

In 2018, total R&D-related expenses were SEK37.9m versus SEK27.9m, mainly due to a combination of more intensive R&D, but also the change in accounting approach from capitalising R&D costs to expensing in April 2017. Although NeuroVive's FY18 results were largely in line with our expectations, we reviewed our R&D spend projections after the company published its 2018 annual report, in which the 2019 goals were listed. We have made no changes to the lead projects NeuroSTAT and KL1333, as these trials are progressing with the new funding. The main revisions to our R&D model include moving the expected licensing deal for NV556 from 2018 to 2019 and the initiation of the Phase I trial with compounds from the NVP015 programme from 2018 to 2020 (we note that a subset of NVP015 compounds was out-licensed to BridgeBio Pharma in June 2018, as discussed in our [outlook report](#)). These were the main reasons for the downward revision of R&D costs in FY19.

Exhibit 2: Key changes to our financial forecasts

SEKm	FY18			FY19e			FY20e
	Estimate	Actual	Change (%)	Old	New	Change (%)	New
Revenue	1.500	2.466	+64%	1.500	1.500	+0%	1.500
R&D expenses	(40.560)	(37.922)	-7%	(103.243)	(58.457)	-43%	(79.378)
Personnel expenses	(14.738)	(14.454)	-2%	(15.475)	(15.177)	-2%	(15.936)
Operating profit/(loss) (reported)	(71.394)	(73.360)	+3%	(132.968)	(90.918)	-32%	(113.537)
Profit/(loss) before tax (reported)	(71.594)	(73.494)	+3%	(132.968)	(90.918)	-32%	(113.537)
Profit/(loss) after tax (reported)	(67.594)	(68.373)	+1%	(128.968)	(85.797)	-33%	(108.416)
EPS (reported), SEK	(0.94)	(0.94)	+0%	(1.00)	(0.62)	-38%	(0.58)

Source: NeuroVive accounts, Edison Investment Research

Our updated, risk-adjusted NPV valuation of NeuroVive is SEK1.51bn or SEK8.1/share compared to SEK1.51bn or SEK9.2/share previously due to the increased cash position, revision of the operating and rNPV models, and rolling the model forward. We maintain all other 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), and the advanced

preclinical products. We continue to exclude NVP025 (mitochondrial myopathy) and NVP022 (NASH) for the time being, as both are at an early stage.

Exhibit 3: NeuroVive sum-of-the parts valuation							
Product	Launch	Peak sales* (\$m)	NPV (\$m)	NPV/share (\$)	Probability	rNPV (\$m)	rNPV/share (\$)
NeuroSTAT	2025	454	289.7	1.6	15%	35.0	0.2
KL1333	2024	574	593.4	3.2	10%	55.7	0.3
NVP015	2027	875	455.0	2.4	5%	20.3	0.1
NV556	2027	1,743	140.0	0.8	8%	30.5	0.2
NVP024	2029	730	31.2	0.2	3%	7.5	0.0
Net cash end-Q418 + proceeds from rights issue and private placement			14.5	0.1	100%	14.5	0.1
Valuation			1,523.9	8.2		163.5	0.9
			SEKm	SEK		SEKm	SEK
NeuroSTAT			2,674.3	14.4	15%	323.5	1.7
KL1333			5,477.1	29.5	10%	514.2	2.8
NVP015			4,200.1	22.6	5%	187.1	1.0
NV556			1,292.0	6.9	8%	281.3	1.5
NVP024			288.1	1.5	3%	69.1	0.4
Net cash end-Q418 + proceeds from rights issue and private placement			134.0	0.7	100%	134.0	0.7
Valuation			14,065.6	75.6		1,509.3	8.1

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

Exhibit 4: Financial summary

	SEK'000s	2016	2017	2018	2019e	2020e
December		IFRS	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS						
Revenue		14	585	2,466	1,500	1,500
Cost of Sales		0	0	0	0	0
Gross Profit		14	585	2,466	1,500	1,500
Research and development		(12,000)	(27,926)	(37,922)	(58,457)	(79,378)
EBITDA		(69,868)	(67,897)	(66,675)	(90,771)	(113,405)
Operating Profit (before amort. and except.)		(70,989)	(69,492)	(68,589)	(90,918)	(113,537)
Intangible Amortisation		0	0	0	0	0
Exceptionals		(1,121)	(1,595)	(4,771)	0	0
Other		0	56	66	0	0
Operating Profit		(72,110)	(71,031)	(73,294)	(90,918)	(113,537)
Net Interest		265	(571)	(200)	0	0
Profit Before Tax (norm)		(70,724)	(70,063)	(68,789)	(90,918)	(113,537)
Profit Before Tax (reported)		(71,845)	(71,602)	(73,494)	(90,918)	(113,537)
Tax		0	0	0	0	0
Profit After Tax (norm)		(70,724)	(70,007)	(68,723)	(90,918)	(113,537)
Profit After Tax (reported)		(70,240)	(66,727)	(68,373)	(85,797)	(108,416)
Average Number of Shares Outstanding (m)		42.0	50.2	78.5	152.8	186.0
EPS - normalised (SEK)		(1.72)	(1.49)	(0.94)	(0.63)	(0.64)
EPS - normalised fully diluted (SEK)		(1.72)	(1.49)	(0.94)	(0.63)	(0.64)
EPS - reported (SEK)		(1.67)	(1.33)	(0.87)	(0.56)	(0.58)
Dividend per share (SEK)		0.0	0.0	0.0	0.0	0.0
Gross Margin (%)		100.0	100.0	100.0	100.0	100.0
EBITDA Margin (%)		N/A	N/A	N/A	N/A	N/A
Operating Margin (before GW and except.) (%)		N/A	N/A	N/A	N/A	N/A
BALANCE SHEET						
Fixed Assets		84,645	87,579	86,681	86,681	86,681
Intangible Assets		71,151	74,315	73,440	73,440	73,440
Tangible Assets		274	162	140	140	140
Investments		13,220	13,102	13,101	13,101	13,101
Current Assets		94,901	30,560	27,383	44,615	1,432
Stocks		0	0	0	0	0
Debtors		0	0	0	0	0
Cash		93,251	28,992	25,951	43,183	0
Other		1,650	1,568	1,432	1,432	1,432
Current Liabilities		(12,413)	(14,259)	(18,296)	(18,296)	(18,296)
Creditors		(12,413)	(14,259)	(18,296)	(18,296)	(18,296)
Short term borrowings		0	0	0	0	0
Long Term Liabilities		0	0	0	0	(70,292)
Long term borrowings		0	0	0	0	(70,292)
Other long term liabilities		0	0	0	0	0
Net Assets		167,133	103,880	95,768	113,000	(475)
CASH FLOW						
Operating Cash Flow		(57,614)	(58,039)	(63,630)	(90,771)	(113,405)
Net Interest		237	(84)	(199)	0	0
Tax		0	0	0	0	0
Capex		(139)	(40)	(82)	(87)	(70)
Acquisitions/disposals*		0	(11,035)	0	0	0
Financing		77,332	9,031	64,656	108,090	0
Other		(23,227)	(4,092)	(3,786)	0	0
Dividends		0	0	0	0	0
Net Cash Flow		(3,411)	(64,259)	(3,041)	17,232	(113,475)
Opening net debt/(cash)		(96,662)	(93,251)	(28,992)	(25,951)	(43,183)
HP finance leases initiated		0	0	0	0	0
Other		0	0	(0)	0	0
Closing net debt/(cash)		(93,251)	(28,992)	(25,951)	(43,183)	70,292

Source: NeuroVive accounts, Edison Investment Research

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