

NeuroVive Pharmaceutical

Rights issue

SEK124m rights issue underway 80% guaranteed

On 10 December 2018, NeuroVive announced a rights issue (subject to EGM approval) aiming to raise up to SEK123.8m gross at a price of SEK1.35 per share, of which 80% (SEK99m) is guaranteed. Our model suggests this would cover operating costs for 2019 and into 2020, if the total amount is raised. NeuroVive outlined a number of [operational goals](#) achievable during this period, while potential share price catalysts include KL1333 Phase Ib initial results, the start of the NeuroSTAT Phase II clinical trial and the planned out-licensing of NV556. Our updated valuation is SEK1.51bn or SEK9.2/share, which includes the guaranteed amount of the rights issue.

Year end	Revenue (SEKm)	PBT* (SEKm)	EPS* (SEK)	DPS (SEK)	P/E (x)	Yield (%)
12/16	0.0	(70.7)	(1.7)	0.0	N/A	N/A
12/17	0.6	(70.1)	(1.5)	0.0	N/A	N/A
12/18e	1.5	(69.7)	(1.0)	0.0	N/A	N/A
12/19e	1.5	(133.0)	(1.1)	0.0	N/A	N/A

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

Financed to KL1333 Phase Ia/b trial readout

The proceeds from the planned rights issue will be used to advance the clinical and preclinical programmes, with one of the key trials being the Phase Ia/b study testing KL1333 for mitochondrial diseases. 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 recently received the green light from regulatory authorities to proceed with its own Phase I trial (single and multiple ascending doses), which will include healthy volunteers and patients. We therefore believe the likelihood of confirming the safety profile has increased, but additional interesting insights could be obtained from patient data. Results are expected in H219.

NeuroSTAT Phase II trial to start in 2019

With the new funds, NeuroVive will also initiate the Phase II trial with NeuroSTAT for a proof-of-concept study in traumatic brain injury (TBI) where there is no specific, approved therapeutic treatment. Additional funding will be required to complete the trial, which management indicated could be done via non-dilutive funding or a partnership. Out-licensing common disease preclinical assets in the non-core portfolio, especially NV556 (NASH), is another potential catalyst and a source of cash. Our recently published [outlook report](#) describes the ongoing R&D programmes in detail.

Valuation: SEK1.51bn or SEK9.2/share

Our updated, risk-adjusted NPV valuation of NeuroVive is SEK1.51bn or SEK9.2/share compared to SEK1.64bn or SEK17.9/share previously. The positive effect of increased cash from the guaranteed part of the proposed rights issue was offset by revising parts of the R&D programme, where we moved the trial initiations from 2018 to 2019. The decrease in valuation per share is mostly technical adjustment after including the guaranteed part of the rights issue.

Pharma & biotech

17 December 2018

Price **SEK1.36**
Market cap **SEK125m**

SEK8.83/US\$

Net cash (SEKm) at 30 September 2018 38.4

Shares in issue (does not include potential new 91.7m shares in the ongoing rights issue) 91.7m

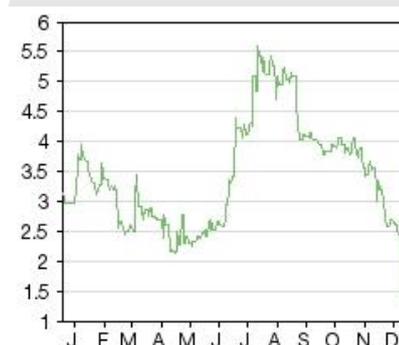
Free float 95%

Code NVP

Primary exchange NASDAQ Stockholm

Secondary exchange OTCQX

Share price performance



% 1m 3m 12m

Abs (54.6) (65.1) (54.0)

Rel (local) (53.7) (61.1) (51.2)

52-week high/low SEK5.6 SEK1.4

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

Start of Phase Ib with KL1333 (MAD EU) H119

Initiation of NeuroSTAT Phase IIb 2019

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Financials

The rights issue could raise up to SEK123.8m gross at a price of SEK1.35 per share and is structured in a similar way to the last issue in [April 2018](#), in that a large portion (80%) of the amount is guaranteed (equal to SEK99m gross) by existing and external investors. NeuroVive plans to issue a total of 91,697,076 shares (the same amount as the current number of outstanding shares). Therefore, the maximum dilution for non-participating shareholders is 50%. The subscription period ends on 6 February 2019 and the outcome will be announced on 11 February 2019.

With its Q318 results, NeuroVive reported Q318 R&D expenses of SEK11.2m (vs SEK9.8m in Q317) and personnel expenses of SEK3.2m (vs SEK3.0m in Q317). R&D costs were somewhat lower than our expectations, but we believe this is mainly related to timing for the initiations of clinical trials for KL1333 and NeuroSTAT, which are now planned after the rights issue. Our estimates for 2019 are therefore largely unchanged. As of end-September Q318, cash was SEK38.4m.

Valuation

Our updated, risk-adjusted NPV valuation of NeuroVive is SEK1.51bn or SEK9.2 per share compared to SEK1.64bn or SEK17.9 per share previously. We include an estimated net guaranteed amount of SEK93m in our model which, when added to estimated end-2018 cash, is SEK125m. We have also updated our R&D model assumptions, mainly focusing on timelines to reflect listed [management goals for 2019](#), together with the rights issue. To maintain realistic timelines, we have added one year of development to our estimated project timelines which, on an absolute basis, had an offsetting effect after including 80% of the rights issue in our valuation. The significant decrease in valuation per share is mainly a technical adjustment, reflecting the increased number of shares outstanding (we currently include the guaranteed new shares only, ie 73,357,661). For our valuation, we currently use 165m shares.

Exhibit 1: 2019 milestones

	H119	H219
KL1333	<ul style="list-style-type: none"> Initiate Phase Ia/b study 	<ul style="list-style-type: none"> Top-line data expected 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 	<ul style="list-style-type: none"> Secure non-dilutive financing for Phase II study IND application Initiate Phase II study
NVP015	<ul style="list-style-type: none"> Further preclinical studies including in vivo dose-response, toxicology 	<ul style="list-style-type: none"> Further preclinical studies including in vivo dose-response, toxicology
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	<ul style="list-style-type: none"> Preclinical dose-response studies in NASH disease model 	
Rights issue	<ul style="list-style-type: none"> 17 January EGM 23 January subscription period starts 6 February subscription period ends 11 February announcement of the outcome of the rights issue 	

Source: [NeuroVive Q318 report](#), [NeuroVive rights issue press release](#), Edison Investment Research. Note: **Bold** indicates key catalysts (efficacy data, marketing authorisation).

We maintain all other R&D assumptions described in our recent [outlook note](#) and [initiation report](#). 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 2: NeuroVive sum-of-the parts valuation

Product	Launch	Peak sales* (\$m)	NPV (\$m)	NPV/share (\$)	Probability	rNPV (\$m)	rNPV/share (\$)
NeuroSTAT	2025	454	278.0	1.7	15%	31.7	0.2
KL1333	2024	574	573.6	3.5	10%	53.1	0.3
NVP015	2025	875	683.0	4.1	5%	27.3	0.2
NV556	2027	1,716	182.0	1.1	8%	38.4	0.2
NVP024	2029	702	29.7	0.2	3%	6.8	0.0
Net cash est-Q418 + 80% of the planned rights issue + exercised warrants			14.1	0.1	100%	14.1	0.1
Valuation			1,760.5	10.7		171.4	1.0

			SEKm	SEK		SEKm	SEK
NeuroSTAT			2,455.1	14.9	15%	280.0	1.7
KL1333			5,064.6	30.7	10%	469.1	2.8
NVP015			6,031.2	36.5	5%	240.7	1.5
NV556			1,607.4	9.7	8%	339.0	2.1
NVP024			262.5	1.6	3%	60.0	0.4
Net cash est end-Q418 + 80% of the planned rights issue + exercised warrants			124.7	0.8	100%	124.7	0.8
Valuation			15,545.5	94.2		1,513.5	9.2

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

Exhibit 3: Financial summary

	SEK'000s	2016	2017	2018e	2019e
December		IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS					
Revenue		14	585	1,500	1,500
Cost of Sales		0	0	0	0
Gross Profit		14	585	1,500	1,500
Research and development		(12,000)	(27,926)	(40,560)	(103,243)
EBITDA		(69,868)	(67,897)	(69,310)	(132,815)
Operating Profit (before amort. and except.)		(70,989)	(69,492)	(69,452)	(132,968)
Intangible Amortisation		0	0	0	0
Exceptionals		(1,121)	(1,595)	(1,942)	0
Other		0	56	0	0
Operating Profit		(72,110)	(71,031)	(71,394)	(132,968)
Net Interest		265	(571)	(200)	0
Profit Before Tax (norm)		(70,724)	(70,063)	(69,652)	(132,968)
Profit Before Tax (reported)		(71,845)	(71,602)	(71,594)	(132,968)
Tax		0	0	0	0
Profit After Tax (norm)		(70,724)	(70,007)	(69,652)	(132,968)
Profit After Tax (reported)		(70,240)	(66,727)	(67,594)	(128,968)
Average Number of Shares Outstanding (m)		42.0	50.2	72.0	128.4
EPS - normalised (SEK)		(1.72)	(1.49)	(1.02)	(1.07)
EPS - normalised fully diluted (SEK)		(1.72)	(1.49)	(1.02)	(1.07)
EPS - reported (SEK)		(1.67)	(1.33)	(0.94)	(1.00)
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		84,645	87,579	87,579	87,579
Intangible Assets		71,151	74,315	74,315	74,315
Tangible Assets		274	162	162	162
Investments		13,220	13,102	13,102	13,102
Current Assets		94,901	30,560	32,757	1,568
Stocks		0	0	0	0
Debtors		0	0	0	0
Cash		93,251	28,992	31,189	0
Other		1,650	1,568	1,568	1,568
Current Liabilities		(12,413)	(14,259)	(14,259)	(14,259)
Creditors		(12,413)	(14,259)	(14,259)	(14,259)
Short term borrowings		0	0	0	0
Long Term Liabilities		0	0	0	(8,635)
Long term borrowings		0	0	0	(8,635)
Other long term liabilities		0	0	0	0
Net Assets		167,133	103,880	106,077	66,253
CASH FLOW					
Operating Cash Flow		(57,614)	(58,039)	(71,252)	(132,815)
Net Interest		237	(84)	(200)	0
Tax		0	0	0	0
Capex		(139)	(40)	(141)	(107)
Acquisitions/disposals*		0	(11,035)	0	0
Financing		77,332	9,031	73,790	93,098
Other		(23,227)	(4,092)	0	0
Dividends		0	0	0	0
Net Cash Flow		(3,411)	(64,259)	2,197	(39,824)
Opening net debt/(cash)		(96,662)	(93,251)	(28,992)	(31,189)
HP finance leases initiated		0	0	0	0
Other		0	0	0	0
Closing net debt/(cash)		(93,251)	(28,992)	(31,189)	8,635

Source: NeuroVive accounts, Edison Investment Research

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