

NeuroVive Pharmaceutical

KL1333 Ph I positive; rights issue oversubscribed

On 27 April 2018, NeuroVive announced that the planned rights issue was oversubscribed (104%), delivering SEK78.5m in gross proceeds and funding the operations into 2019. The fundraising allows NeuroVive to focus on the initiation of the NeuroSTAT (traumatic brain injury) Phase IIb trial (H218/H119) and the Phase Ib KL1333 (genetic mitochondrial diseases) trial in Europe (H218). The latter project was bolstered by the recent news from the South Korean partner, Yungjin Pharm, which reported a positive outcome in its own locally run Phase I trial with KL1333. Our updated valuation is SEK1.62bn or SEK17.7/share (SEK18.0/share previously).

Year end	Revenue (SEKm)	PBT* (SEKm)	EPS* (öre)	DPS (SEK)	P/E (x)	Yield (%)
12/16	0.0	(70.7)	(172.3)	0.0	N/A	N/A
12/17	0.6	(70.1)	(149.3)	0.0	N/A	N/A
12/18e	0.6	(83.6)	(132.6)	0.0	N/A	N/A
12/19e	0.6	(132.2)	(170.7)	0.0	N/A	N/A

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

Phase I trial with KL1333 in South Korea positive

Recently, Yungjin reported positive results from the [KL1333 Phase I trial](#) in healthy volunteers performed by partner Yungjin Pharm in South Korea (n=60). The researchers found that KL1333 has a favourable PK profile and no serious adverse events were observed. This was a direct positive catalyst for NeuroVive's share price, as the company is about to start a Phase Ib study with KL1333 in Europe (UK sites; NeuroVive owns the rights to territories outside Japan and South Korea). The study is planned to start in H218, with results expected in H119. As with Yungjin's study, it will involve a dose escalation in healthy volunteers, but will also include a multiple ascending dosing (MAD) in healthy volunteers as well as patients with genetic mitochondrial disease generating the first-ever such human data. NeuroVive has received orphan drug designation by the FDA for KL1333 in mitochondrial diseases, in addition to the existing EMA designation. These could provide seven and 10 years of market exclusivity in the US and Europe, respectively, if KL1333 receives marketing authorisation before competitors.

Now financed into 2019, ramping up R&D

We maintain all our current forecasts but now include the full amount from the rights issue (SEK78.5m less costs), compared with the previous guaranteed amount (SEK55.0m). Adding this to the end-Q118 net cash results in approximately SEK94m, which according to our model should fund the company's activities into 2019. Further capital may be required to complete the NeuroSTAT Phase IIb trial, but the results from the Phase I MAD study with KL1333 should be in H119 and the company is working on several potential funding sources (detailed below).

Valuation: Updated to SEK1.62bn or SEK17.7/share

Our updated valuation of NeuroVive is SEK1.62bn or SEK17.7/share, compared to SEK1.44bn or SEK18.0/share previously, mainly due to proceeds from the rights issue and the appreciation of the US\$ versus the SEK. The initiation of the next trials with KL1333 and NeuroSTAT, and potential out-licensing of a preclinical asset NV556 (NASH) are near-term R&D events.

Q118 company update

Pharma & biotech

4 June 2018

Price **SEK2.62**

Market cap **SEK240m**

SEK8.94/US\$

Net cash (SEKm) at end-Q118 + the proceeds from the rights issue 94.3

Shares in issue 91.6m

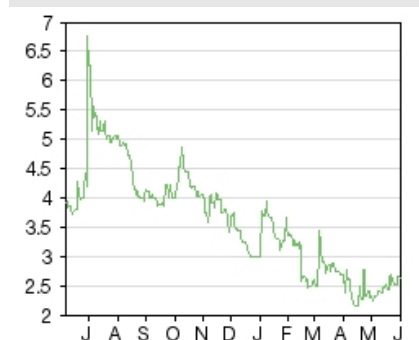
Free float 98.3%

Code NVP

Primary exchange Nasdaq Stockholm

Secondary exchange OTCQX

Share price performance



% 1m 3m 12m

Abs 14.4 13.5 (26.6)

Rel (local) 14.1 10.8 (25.0)

52-week high/low SEK6.0 SEK2.1

Business description

NeuroVive Pharmaceutical is a Swedish biopharmaceutical company with deep expertise in mitochondrial medicine. It 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 (mitochondrial diseases) are the most advanced assets.

Next events

Start of NeuroVive's Phase Ib with KL1333 H218

NeuroVive initiation of NeuroSTAT Phase IIb H218/H119

Out-licensing deal for NV556 H218

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NeuroVive Pharmaceutical is a research client of Edison Investment Research Limited

Financials and valuation

Q1 financial results

NeuroVive reported income of SEK174k and total operating expenses of SEK13.2m, which is largely in line with our model and lower than a year ago (SEK21.3m). The y-o-y decrease was mainly due to a one-off, non-cash cost item of SEK11.0m booked in Q117 relating to administrative expenses associated with the [disposal of a subsidiary](#). We make no changes to our forecast of total opex of SEK84.2m for 2018 (versus reported SEK71.7m in 2017), with cash burn accelerating later in 2018 as NeuroVive initiates the clinical trials.

We now include the full amount from the rights issue (SEK78.5m less costs). Adding this to the end-Q118 cash (no debt) results in approximately SEK94.3m, which, according to our model, should fund the company's activities into 2019. Further capital may be required to complete the NeuroSTAT Phase IIb trial, but the results from the Phase I MAD study with KL1333 should be in H119. In addition, the company indicated that it is also working towards securing co-funding for the Phase IIb NeuroSTAT trial, as well as non-dilutive funding from a potential licensing deal for NV556 (NASH) in H218 and potential further research grants. Furthermore, a total exercise of warrants exercisable in November 2018 could bring in another SEK37.3m gross in cash (strike price SEK3.80).

Valuation update

Our updated valuation of NeuroVive is SEK1.62bn or SEK17.7/share compared to SEK1.44bn or SEK18.0/share previously. The increase in absolute value and decrease in valuation per share reflect the higher number of shares outstanding after the rights issue. The main changes were the addition of the full amount of proceeds from the issue and a significant appreciation of the US\$ versus the SEK from the start of this year (from SEK/US\$8.2 to 8.9). We maintain the R&D assumptions described in our [initiation report](#). As previously, in our valuation we include clinical-stage NeuroSTAT (traumatic brain injury) 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 1: NeuroVive sum-of-the parts valuation

Product	Launch	Peak sales* (\$m)	NPV (\$m)	NPV/share (\$)	Probability	rNPV (\$m)	rNPV/share (\$)
NeuroSTAT	2024	454	320.4	3.5	15%	38.3	0.4
KL1333	2023	574	619.3	6.8	10%	57.4	0.6
NVP015	2024	875	777.5	8.5	5%	31.3	0.3
NV556	2026	1,716	185.7	2.0	8%	37.2	0.4
NVP024	2029	702	31.8	0.3	3%	6.5	0.1
Net cash at end-Q118 + the proceeds from rights issue			10.5	0.1	100%	10.5	0.1
Valuation			1,945.2	21.2		181.1	2.0
			SEKm	SEK		SEKm	SEK
NeuroSTAT			2,864.1	31.3	15%	342.0	3.7
KL1333			5,536.9	60.5	10%	512.8	5.6
NVP015			6,950.7	75.9	5%	279.9	3.1
NV556			1,660.4	18.1	8%	332.3	3.6
NVP024			283.9	3.1	3%	57.9	0.6
Net cash at end-Q118 + the proceeds from rights issue			94.3	1.0	100%	94.3	1.0
Valuation			17,390.2	189.9		1,619.2	17.7

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

Exhibit 2: Financial summary

SEK000s	2016	2017	2018e	2019e
	IFRS	IFRS	IFRS	IFRS
December				
PROFIT & LOSS				
Revenue	14	585	585	585
Cost of Sales	0	0	0	0
Gross Profit	14	585	585	585
Research and development	(12,000)	(27,926)	(57,170)	(104,380)
EBITDA	(69,868)	(67,897)	(83,481)	(132,031)
Operating Profit (before amort. and except.)	(70,989)	(69,492)	(83,623)	(132,185)
Intangible Amortisation	0	0	0	0
Exceptionals	(1,121)	(1,595)	0	0
Other	0	56	0	0
Operating Profit	(72,110)	(71,031)	(83,623)	(132,185)
Net Interest	265	(571)	0	0
Profit Before Tax (norm)	(70,724)	(70,063)	(83,623)	(132,185)
Profit Before Tax (reported)	(71,845)	(71,602)	(83,623)	(132,185)
Tax	0	0	0	0
Profit After Tax (norm)	(70,724)	(70,007)	(83,623)	(132,185)
Profit After Tax (reported)	(70,240)	(66,727)	(79,623)	(128,185)
Average Number of Shares Outstanding (m)	42.0	50.2	66.1	79.8
EPS - normalised (ore)	(172.27)	(149.31)	(132.64)	(170.66)
EPS - normalised & fully diluted (ore)	(172.27)	(149.31)	(132.64)	(170.66)
EPS - reported (SEK)	(1.67)	(1.33)	(1.21)	(1.61)
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	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	20,728	1,568
Stocks	0	0	0	0
Debtors	0	0	0	0
Cash	93,251	28,992	19,160	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	(112,978)
Long term borrowings	0	0	0	(112,978)
Other long term liabilities	0	0	0	0
Net Assets	167,133	103,880	94,048	(38,090)
CASH FLOW				
Operating Cash Flow	(57,614)	(58,039)	(83,481)	(132,031)
Net Interest	237	(84)	0	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	0
Other	(23,227)	(4,092)	0	0
Dividends	0	0	0	0
Net Cash Flow	(3,411)	(64,259)	(9,832)	(132,138)
Opening net debt/(cash)	(96,662)	(93,251)	(28,992)	(19,160)
HP finance leases initiated	0	0	0	0
Other	0	0	0	0
Closing net debt/(cash)	(93,251)	(28,992)	(19,160)	112,978

Source: NeuroVive's accounts, Edison Investment Research. Note: *Related to the disposal of a subsidiary in 2017, the net effect of which was neutral on cash flows.

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