EDISON

NeuroVive Pharmaceutical

Q419 results

Rights issue and focus on core assets

Pharma & biotech

In February 2020, NeuroVive announced a rights issue (subject to EGM approval) aiming to raise up to SEK74m gross at a price of SEK0.80 per share, of which 90% (SEK67m) is guaranteed. According to its updated strategy, the main focus will be on KL1333 and NV354 for primary mitochondrial diseases (PMDs), NeuroVive's area of expertise. Our model suggests this would cover operating costs for 2020 and into 2021. The most significant share price catalyst in the near term is KL1333 Phase Ia/b results, due in H220. Our updated valuation is SEK1.72bn or SEK6.4 per share, which includes the guaranteed amount of the rights issue.

Year end	Revenue (SEKm)	PBT* (SEKm)	EPS* (SEK)	DPS (SEK)	P/E (x)	Yield (%)
12/18	2.5	(68.8)	(0.94)	0.0	N/A	N/A
12/19	3.6	(74.7)	(0.50)	0.0	N/A	N/A
12/20e	3.6	(80.6)	(0.38)	0.0	N/A	N/A
12/21e	3.6	(82.3)	(0.32)	0.0	N/A	N/A

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

KL1333 and NV354 key value drivers going forward

Over the course of 2019 NeuroVive shifted towards a more focused strategy to develop orphan drugs for PMDs. The ongoing rights issue will primarily fund the development of the two core assets, KL1333 and NV354. KL1333 is a small molecule NAD+ modulator used to restore intracellular energy balance. NV354 is a succinate prodrug targeting complex I deficiency, such as Leigh syndrome and LHON. NeuroVive confirmed that it will no longer invest in the development of NeuroSTAT (Phase IIb ready) or NV556 (preclinical), but will seek other funding options for these assets.

KL1333 Ph Ia/b results in H220; NV354 progressing

Together with the FY19 results, NeuroVive confirmed that the first two parts of the Phase Ia/b study with KL1333 were successfully completed. The third and final part will include patients with PMD and recruitment is expected to begin shortly. Results from this part are expected in H220 and are potentially a significant catalyst for the share price. NV354 is the second lead drug candidate in NeuroVive's core portfolio targeting mitochondrial diseases. The mechanism of action is different to KL1333, but has the same goal of increasing the production of cellular energy. IND-enabling studies are ongoing and the Phase I study could start in 2021.

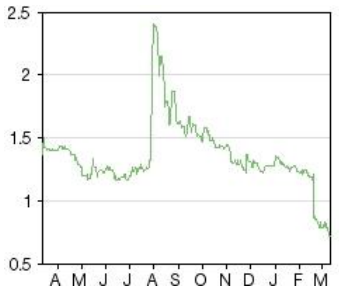
Valuation: SEK1.72bn or SEK6.4 per share

Our updated, risk-adjusted NPV valuation of NeuroVive is SEK1.72bn or SEK6.4 per share compared to SEK1.63bn or SEK8.8 per share previously. The decrease in the valuation per share was mainly a result of the technical dilution due to the rights issue. We have also revised our R&D projects to bring them into line with NeuroVive's updated strategy of focusing more on the core assets (see details below). This revision had a small net positive effect, as shown in the higher absolute valuation (which also includes the guaranteed amount of SEK67m from the issue).

11 March 2020

Price	**SEK0.72**
Market cap	**SEK134m**
Net cash (SEKm) at end Q419 plus guaranteed (90%) rights issue amount	125.3
Shares in issue, pre rights issue	186.0m
Free float	95%
Code	NVP
Primary exchange	Nasdaq Stockholm
Secondary exchange	OTCQX

Share price performance



%	1m	3m	12m
Abs	(40.7)	(44.0)	(49.2)
Rel (local)	(28.8)	(37.3)	(50.1)
52-week high/low	SEK2.40	SEK0.72	

Business description

NeuroVive Pharmaceutical is a Swedish biopharmaceutical company with deep expertise in mitochondrial medicine. Its main focus area is primary mitochondrial diseases (PMDs) with lead assets KL1333, a NAD+ modulator (Phase I), and NV354, a succinate prodrug (preclinical). NeuroSTAT is a non-core asset in Phase II for neurotrauma.

Next events

Final results from Phase Ia/b with KL1333	H220
Extraordinary general meeting	17 March 2020
Subscription period in the ongoing rights issue	6–22 April 2020

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Edison profile page

Right issue to secure funding for core assets

The rights issue could raise up to SEK74m gross at a price of SEK0.80 per share and a large portion of the amount is guaranteed (90% or SEK67m gross) by investors. NeuroVive plans to issue a total of c 93.0m shares (vs 186.0m currently outstanding). Therefore, the maximum dilution for non-participating shareholders is 33%. The rights issue is subject to approval at the EGM on 17 March 2020, the ex-rights day is 30 March 2020 and the subscription period is 6–22 April 2020. The outcome should be known by 28 April 2020.

Over the course of 2019 NeuroVive shifted towards a more focused strategy of developing orphan drugs for PMDs. The ongoing rights issue will primarily fund the development of two core assets KL1333 and NV354. NeuroVive has confirmed that it will no longer invest in the development of NeuroSTAT or NV556, but will seek other funding options. Proceeds from the planned rights issue will be used to:

- finish the ongoing Phase Ia/b study with KL1333 and present results from the final part of the study (patient treatment data) in H220;
- initiate preparations for the Phase II study, planned to start in H121; and
- finish the preclinical development of NV354 in H220 with the goal of initiating clinical development in 2021.

KL1333: Phase Ia/b results in H220 – key catalyst

KL1333 is being developed for primary mitochondrial disease, for example due to an m.3243 A>G mutation (eg MELAS, MIDD, PEO). NeuroVive started a Phase Ia/b study in March 2019. Together with the FY19 results, it has confirmed that the first two parts (single ascending dose and multiple ascending dose) of the study were successfully completed. The third and final part will include patients with PMD and recruitment is expected to be begin shortly. Results from this part are expected in H220.

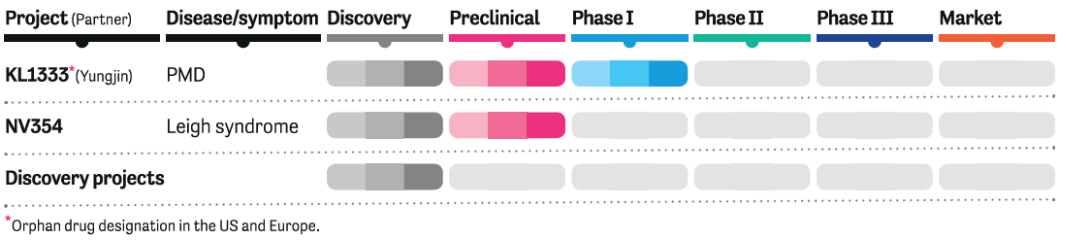
This will be the first time KL1333 is given to patients. Typically, the primary goal of Phase I development is the assessment of safety, tolerability and PK profile. However, since the last part of the trial will also enrol patients with PMD, some initial data indicating a pharmacological effect on exploratory biomarkers and functional measures could be obtained as early as H220. This is a potentially major catalyst for NeuroVive's shares. The ongoing rights issue should be more than sufficient to complete the Phase Ia/b study. In the case of positive results, NeuroVive would be able to start the Phase II in 2021. KL1333 has received orphan drug designation in both the US and Europe.

some initial data

NV354: Progressing to clinical development

NV354 is the second lead drug candidate in NeuroVive's core portfolio targeting mitochondrial diseases. The mechanism of action is different to KL1333, but has the same goal of increasing the production of cellular energy. IND-enabling studies are ongoing and the Phase I study could start in 2021. Historically, the NV354 compound was selected from NeuroVive's preclinical NVP015 project, which evaluated many other succinate prodrugs. In June 2018, the company out-licensed a subset of these prodrugs to private biotech BridgeBio, based in California, US. BridgeBio is developing these compounds for the localised treatment of Leber's hereditary optic neuropathy (LHON) in its new company Fortify Therapeutics. As the total deal value could reach $60m, we view the deal as a substantial external validation of NeuroVive's NVP015 chemistry.

Exhibit 1: NeuroVive's core assets



Source: NeuroVive

Potential upside from non-core assets

NeuroSTAT, an innovative formulation of ciclosporin, is the most advanced asset in the portfolio for out-licensing and partnering, and is positioned for the treatment of traumatic brain injury, where there is no neuroprotective treatment available yet. NeuroSTAT has accumulated some initial efficacy data and has received IND approval from the FDA. NeuroVive indicated that, while promising, NeuroSTAT will require too much resource for NeuroVive to take to the market and hence it is focusing on finding partners and/or non-dilutive funding that can finance the Phase II trial.

NV556, a sangamide class cyclophilin inhibitor, has a direct antifibrotic mechanism of action in the liver. The asset has undergone extensive preclinical development, has favourable drug-like properties and a confirmed antifibrotic effect in several animal models. NeuroVive is no longer investing in this project, but aims to out-license it.

Financials and valuation

NeuroVive reported SEK3.6m in income in 2019, of which SEK3.5m was part of a grant from Vinnova, which awarded a total of SEK5m to advance the NV354 compound to clinical stage. Personnel costs were similar y-o-y (SEK14.9m in FY19 vs SEK14.5m in FY18), while other external expenses, which include the bulk of other operating expenses, were somewhat higher y-o-y (SEK63.1m in FY19 vs SEK55.8m in FY18) due to the ongoing clinical Phase Ia/b trial.

A decrease in other external expenses is the main change we have made to our financial estimates: to SEK68.6m from SEK103.5m in 2020 and to SEK69.6m from SEK128.8m in 2021. This was a result of revised assumptions for the NeuroSTAT and NV556 projects in our valuation (see below). As of end-Q419, cash was SEK58.3m which, together with expected proceeds from the rights issue, should (SEK67m guaranteed) be sufficient to fund operations well into 2021, according to our model.

In line with the company's updated strategy and increased focus on its core assets, we have made several changes to our valuation:

- We have increased the **success probability** for KL1333 to 15% from 10%, as the healthy volunteer part of the study has been completed, as described above.
- We have **revised the NeuroSTAT** and **NV556 projects** in our valuation. We view both assets as valuable for NeuroVive, but to reflect the decision not to invest in them anymore and to seek non-dilutive funding, we have delayed the cash flows associated with both projects by two years. This is a conservative technical adjustment, but clearly the company could announce the arrangements for these projects at any time, at which point we would update our estimates accordingly.
- We have removed the small NVP024 project from our valuation, which we had included previously as an asset intended for out-licensing. NVP024 is an early preclinical project that

evaluated the potential of NeuroVive's cyclophilin inhibitor in cancer, specifically hepatocellular carcinoma (HCC), which we reviewed in our previous reports. It is not part of the core strategy at the moment, although presumably this could be reviewed in the future depending on available resources.

Our updated, risk-adjusted NPV valuation of NeuroVive is SEK1.72bn or SEK6.4 per share compared to SEK1.63bn or SEK8.8 per share previously. The decrease in the valuation per share was mainly a result of the dilution due to the rights issue, while the R&D project revision had a small net positive effect, as evident in the higher absolute valuation (which also includes the guaranteed amount of SEK67m from the issue).

Exhibit 2: NeuroVive sum-of-the parts valuation

Product	Launch	Peak sales ($m)	NPV ($m)	NPV/share ($)	Probability	rNPV ($m)	rNPV/share ($)
Core assets							
KL1333	2024	574	663.9	2.5	15%	97.8	0.4
NV354	2027	875	509.4	1.9	5%	23.5	0.1
Non-core assets							
NeuroSTAT		454	209.2	0.8	15%	28.8	0.1
NV556		1,828	86.6	0.3	8%	13.6	0.1
Net cash, last reported plus guaranteed (90%) rights issue amount			12.9	0.0	100%	12.9	0.0
Valuation			**1,482.0**	**5.5**		**176.6**	**0.7**
			SEKm	**SEK/share**	**Probability**	**SEKm**	**SEK/share**
Core assets							
KL1333			6,466.8	24.0	15%	952.2	3.5
NV354			4,961.2	18.4	5%	229.1	0.8
Non-core assets							
NeuroSTAT			2,037.8	7.6	15%	280.6	1.0
NV556			843.6	3.1	8%	132.8	0.5
Net cash, last reported plus guaranteed (90%) rights issue amount			125.3	0.5	100%	125.3	0.5
Valuation			**14,434.6**	**53.5**		**1,720.1**	**6.4**

Source: Edison Investment Research. Note: WACC = 12.5% for product valuations. Only the guaranteed part of the rights issue included in the valuation, ie 270m of shares outstanding assumed for valuation purposes and SEK67m gross in proceeds.

Exhibit 3: Financial summary

SEK'000s	2017	2018	2019	2020e	2021e
December	IFRS	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS					
Revenue	585	2,466	3,634	3,634	3,634
Cost of Sales	0	0	0	0	0
Gross Profit	585	2,466	3,634	3,634	3,634
Other external expenses	(46,415)	(55,812)	(63,133)	(68,616)	(69,563)
EBITDA	(67,897)	(66,675)	(72,317)	(78,178)	(79,870)
Operating Profit (before amort. and except.)	(69,492)	(68,589)	(74,696)	(80,598)	(82,325)
Intangible Amortisation	0	0	0	0	0
Exceptionals	(1,595)	(4,771)	(2,379)	0	0
Other	56	66	0	0	0
Operating Profit	(71,031)	(73,294)	(77,075)	(80,598)	(82,325)
Net Interest	(571)	(200)	(46)	0	0
Profit Before Tax (norm)	(70,063)	(68,789)	(74,742)	(80,598)	(82,325)
Profit Before Tax (reported)	(71,602)	(73,494)	(77,121)	(80,598)	(82,325)
Tax	0	0	0	0	0
Profit After Tax (norm)	(70,007)	(68,723)	(74,742)	(80,598)	(82,325)
Profit After Tax (reported)	(66,727)	(68,373)	(72,000)	(75,477)	(77,204)
Average Number of Shares Outstanding (m)	50.2	78.5	159.5	227.8	269.6
EPS - normalised (SEK)	(1.49)	(0.94)	(0.50)	(0.38)	(0.32)
EPS - normalised fully diluted (SEK)	(1.49)	(0.94)	(0.50)	(0.38)	(0.32)
EPS - reported (SEK)	(1.33)	(0.87)	(0.45)	(0.33)	(0.29)
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	87,579	86,681	88,573	89,734	90,637
Intangible Assets	74,315	73,440	74,686	75,807	76,670
Tangible Assets	162	140	99	139	179
Investments	13,102	13,101	13,788	13,788	13,788
Current Assets	30,560	27,383	59,460	44,644	1,141
Stocks	0	0	0	0	0
Debtors	0	0	0	0	0
Cash	28,992	25,951	58,319	43,503	0
Other	1,568	1,432	1,141	1,141	1,141
Current Liabilities	(14,259)	(18,296)	(20,337)	(20,337)	(20,337)
Creditors	(14,259)	(18,296)	(20,337)	(20,337)	(20,337)
Short term borrowings	0	0	0	0	0
Long Term Liabilities	0	0	(361)	(361)	(40,087)
Long term borrowings	0	0	0	0	(39,726)
Other long term liabilities	0	0	(361)	(361)	(361)
Net Assets	103,880	95,768	127,335	113,680	31,355
CASH FLOW					
Operating Cash Flow	(58,039)	(63,630)	(72,367)	(78,178)	(79,870)
Net Interest	(84)	(199)	(46)	0	0
Tax	0	0	0	0	0
Capex	(40)	(82)	(69)	(40)	(40)
Acquisitions/disposals*	(11,035)	0	0	0	0
Financing	9,031	64,656	107,780	66,943	0
Other	(4,092)	(3,786)	(2,930)	(3,540)	(3,319)
Dividends	0	0	0	0	0
Net Cash Flow	(64,259)	(3,041)	32,368	(14,816)	(83,229)
Opening net debt/(cash)	(93,251)	(28,992)	(25,951)	(58,319)	(43,503)
HP finance leases initiated	0	0	0	0	0
Other	0	(0)	(0)	0	0
Closing net debt/(cash)	(28,992)	(25,951)	(58,319)	(43,503)	39,726

Source: NeuroVive accounts, Edison Investment Research. Note: Only the guaranteed part of the rights issue included, ie proceeds of SEK67m and a total number of 270m of shares outstanding after the issue.

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