EDISON

NeuroVive Pharmaceutical

Capital markets day

Capital markets day take aways

Pharma & biotech

On 9 October 2019, NeuroVive held its capital markets day. Management presented its strategic focus on the company's primary mitochondrial disease programmes, high unmet medical need in this area and advantages of the orphan drug development compared to drugs for common diseases. As expected, no major new details were disclosed. We note an interesting presentation on regulatory perspectives on orphan drug development by NeuroVive's clinical and regulatory affairs director, Matilda Hugerth. It is not that often investors have straightforward access to expert knowledge about such a specialised topic presented in a clear format. Our valuation is unchanged 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 and NV354 lead assets in core portfolio

KL1333, a small molecule NAD+ modulator used to restore intracellular energy balance, is in the multiple ascending dose (MAD) part of the Phase Ia/b trial. The single ascending dose (SAD) part of the trial delivered positive PK and safety data. KL1333 is being developed for primary mitochondrial disease, for example due to an m.3243 A>G mutation (eg MELAS, MIDD, PEO). The MAD part will also recruit mitochondrial disease patients (expected in H120). This will be the first time KL1333 is tested in patients and could potentially deliver interesting initial efficacy signs. If results are positive, the Phase II trial could start as soon as 2020. NV354, a succinate prodrug targeting complex I deficiency (such as Leigh syndrome and LHON), is the second lead drug candidate in the core portfolio targeting mitochondrial disease. The mechanism of action (MoA) is different to KL1333, but has the same goal of increasing the production of cellular energy (Exhibit 3). IND-enabling studies are ongoing and the Phase I study could start in 2020.

NeuroSTAT ready for Phase II development

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 that can finance the Phase II trial.

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

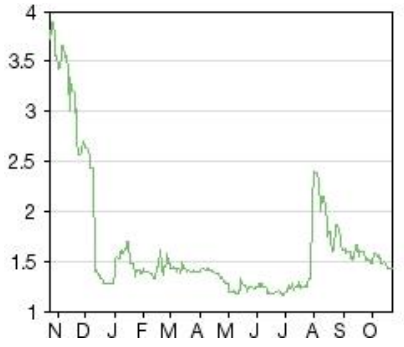
We keep our valuation unchanged at SEK1.63bn or SEK8.8/sh. Potential near-term milestones include initial results from KL1333 Phase Ia/b, a non-dilutive financing solution for NeuroSTAT Phase II trial and NV354 entering clinical development. More detail on the projects are given in our recent update report.

23 October 2019

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

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	(11.5)	13.8	(60.1)
Rel (local)	(13.2)	8.9	(65.0)
52-week high/low	SEK3.52		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, NV354 (mitochondrial diseases) and NeuroSTAT (neurotrauma) are the most advanced assets.

Next events

Further interim results from Phase Ia/b with KL1333	H219
Q319 results	20 November 2019

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Edison profile page

Capital markets day take aways (exhibits)

Exhibit 1: NeuroVive's R&D pipeline

Projects for development to the market (with or without partner)

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.

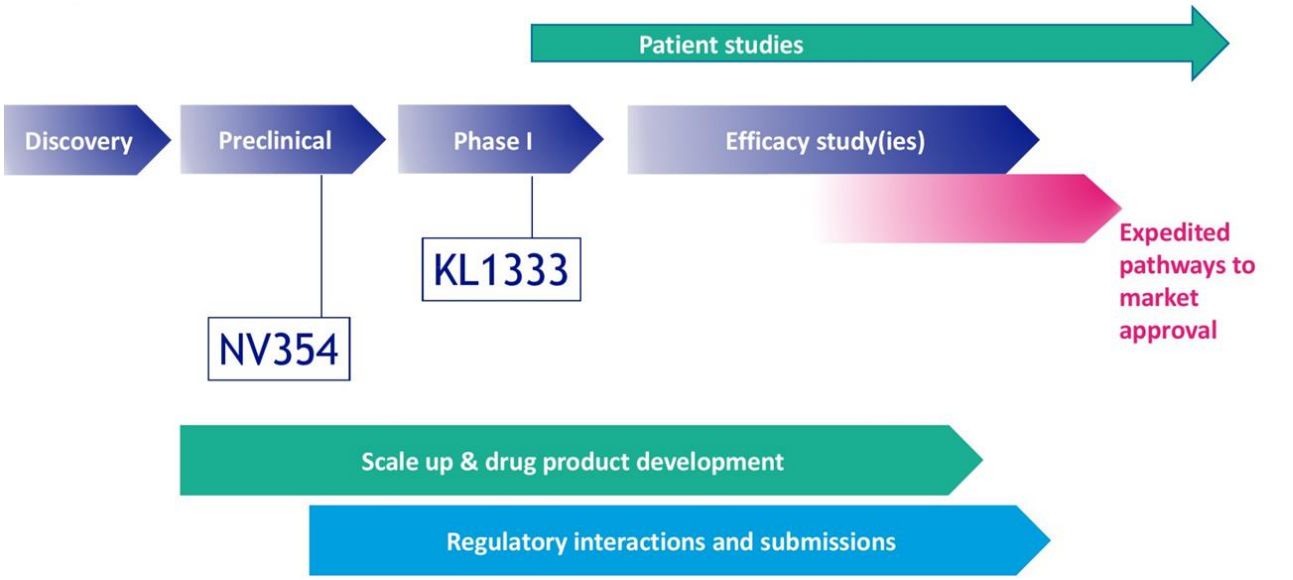
Projects for out-licensing

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.

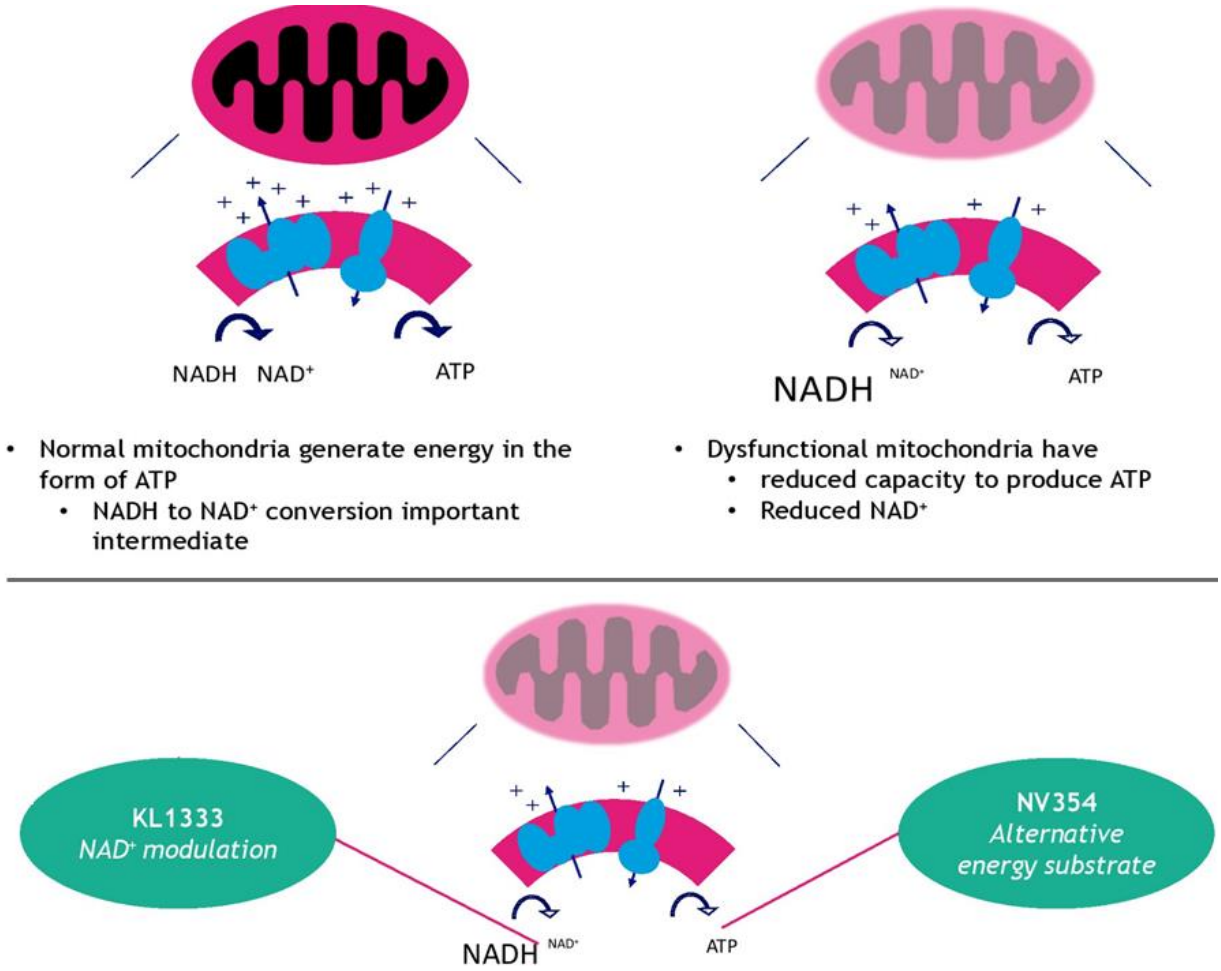
Source: NeuroVive

Exhibit 2: KL1333 and NV354 projects



Source: NeuroVive

Exhibit 3: NeuroVive's lead assets have different MoAs, but share the goal of increasing energy production



Source: NeuroVive

Exhibit 4: Orphan drug designation benefits

Direct benefits and incentives

- Regulatory assistance – protocol assistance and scientific advice meetings
- Financial regulatory incentives
  - Fee reductions, eg the EMA application fee of €278k waived for SMEs
  - Tax benefit, eg 50% of clinical costs in the US
- National incentives, eg grants
- Market exclusivity
  - EU: 10 years, plus two years if paediatric studies conducted
  - US: seven years

Additional effects of orphan designation

- Lower clinical development costs (fewer patients need to be recruited)
- Access to expedited programmes
  - Fast-track designation, breakthrough designation (US), PRIME (EU)
  - Conditional approval (EU), accelerated approval (US), accelerated review (EU), priority review (US)
  - Rare paediatric priority review voucher (US)
- Historically likelihood of success is higher for orphan drugs (32% vs 11% for non-orphans)
- Pricing and reimbursement: separate pool compared to non-orphans, premium price is more common

Source: NeuroVive

Exhibit 5: 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 6: 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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