EDISON

Abliva

Company results

New strategic investor on board and CMD

Pharma & biotech

The rights issue announced on 19 February 2020 is now complete with 90% of the total amount of offered shares subscribed raising a total SEK67m. A positive surprise was the announcement that Nordic life sciences investor Hadean Ventures also decided to invest via a direct private placement of SEK20m. This brings the total amount of new funds to SEK87m gross, which will primarily fund the development of the two core assets for primary mitochondrial diseases (PMD): KL1333, a small molecule NAD+ modulator, and NV354, a succinate prodrug. The most significant share price catalyst in the near term is the KL1333 Phase Ia/b results from the final part of the study, which should start enrolling PMD patients in H220. Our valuation is SEK1.76bn or SEK5.93 per share.

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)	(0.43)	0.0	N/A	N/A
12/20e	3.6	(81.0)	(0.34)	0.0	N/A	N/A
12/21e	3.6	(82.3)	(0.28)	0.0	N/A	N/A

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

Strategic rebranding and CMD update

With the financing in place and a new significant shareholder on board, the company has made another strategic step to rebrand and has changed its name to Abliva (from NeuroVive Pharmaceutical). These developments will be stepping stones to an R&D strategy more focused on PMD and the lead assets. NeuroSTAT, a Phase IIb-ready drug candidate for traumatic brain injury (TBI), will be spun out to a new wholly owned subsidiary in the US to increase the flexibility of access to funding. The updated strategy was presented in detail during the virtual capital markets day on 23 June 2020.

R&D progress: Mitigating COVID-19 pandemic impact

The first two parts of the Phase Ia/b study with KL1333 were completed. The third and final part (Phase Ib) will include patients with PMD and recruitment is expected to begin shortly. Although it is too early to forecast COVID-19 impact with certainty and there could be some delays to the final part of the KL1333 Phase Ia/b trial, Abliva still expects to initiate the next Phase II trial within the guided timeline (H121), so the overall effect on the program should be minimal. NV354 is a succinate prodrug targeting complex I deficiency, such as Leigh syndrome. The currently ongoing preclinical development has not been affected by the pandemic and the candidate should move into clinical development in 2021, as expected.

Valuation: SEK1.76bn or SEK5.93 per share

After rolling our model forward, our risk-adjusted NPV valuation of Abliva is SEK1.76bn or SEK5.93 per share compared to SEK1.72bn or SEK6.40 per share previously. The technical decrease in valuation per share is due to the addition of the new shares. The most significant share price catalyst in the near term is the KL1333 Phase Ia/b results from the final part of the study.

26 June 2020

Price	**SE0.95**
Market cap	**SEK281m**
Net cash (SEKm) at end Q120 plus rights issue and private placement proceeds	116.6
Shares (post-rights issue and private placement)	296.3m
Free float	95%
Code	NVP
Primary exchange	Nasdaq Stockholm
Secondary exchange	OTCQX

Share price performance

%	1m	3m	12m
Abs	(12.4)	35.9	(21.5)
Rel (local)	(16.0)	13.1	(25.6)
52-week high/low	SEK2.40		SEK0.59

Business description

Abliva is a Swedish biopharmaceutical company with deep expertise in mitochondrial medicine. Its main focus area is primary mitochondrial diseases 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, depends on COVID-19 developments
Completion of preclinical safety studies with NV354	H220
Q220 results	21 August 2020

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Edison profile page

Rights issue complete; positive private placement surprise

The rights issue announced on 19 February 2020 is now complete. In total, 90% of the offered shares were subscribed: 63.5% by the issue guarantors and 26.5% by the participants in the rights issue, bringing in SEK67m gross. The total outstanding number of shares prior to the subsequent Hadean investment increased to 270m versus 186m before the issue. Abliva confirmed the goals the proceeds will be used to achieve are:

- finish the ongoing Phase Ia/b study with KL1333 and present results from the final part of the study (patient treatment data) in H220, depending on COVID-19 developments;
- 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.

On 22 April 2020, Abliva announced that Nordic life sciences investor Hadean Ventures also decided to invest via a direct private placement of SEK20m gross. This was completed on 15 June 2020 by the issue of 26.7m new shares priced at the high end of the possible range of SEK0.70–0.75 per share. Hadean Ventures is a new strategic investor with offices in Oslo and Stockholm and has delegated one new board member. Specialist life sciences investors typically conduct rigorous due diligence before investing in a new company. So, we believe this is a significant external validation of Abliva's technology. In addition, given the active involvement with the new board member, we believe Hadean is likely to support Abliva's fund raising in the future. Overall Hadean Ventures seems to be a strong new strategic investor.

R&D update

KL1333: Some uncertainty about Phase Ia/b results timing, but the next Phase II trial still planned to start in H121

KL1333 is being developed for primary mitochondrial disease, for example due to an m.3243 A>G mutation (eg MELAS, MIDD, PEO). Abliva started a Phase Ia/b study in March 2019. The first two parts (single ascending dose and multiple ascending dose) of the study were successfully completed. The third and final part (Phase Ib) will include patients with PMD and recruitment is expected to be begin shortly. Results from this part were expected in H220, but according to Abliva's COVID-19 update there might be some delays to enrolling the patients into this part of the study, so there is some uncertainty about the timing of results. However, Abliva continues to prepare for the next Phase II trial and still expects to initiate it within the guided timeline of 2021. This means the progress of the overall KL1333 programme is intact.

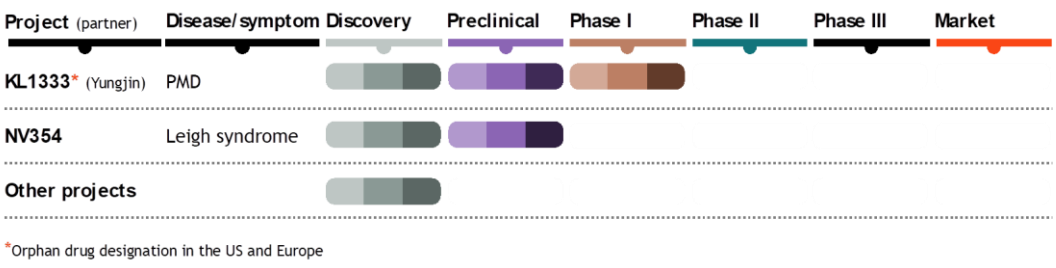
The Phase Ib part will be the first time KL1333 is given to patients. Typically, the primary goal of Phase I development is the assessment of safety, tolerability and the PK profile. However, because this last part of the trial will also enrol patients with PMD, some initial data indicating a pharmacological effect on exploratory biomarkers and functional measures should be obtained. This is a potentially major catalyst for Abliva's shares. KL1333 has received orphan drug designation in both the US and Europe.

NV354: Progress towards clinical development; no major effects from COVID-19

NV354 is the second lead drug candidate in Abliva's core portfolio targeting mitochondrial diseases. The mechanism of action is different to KL1333 but it 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. In its COVID-19 update, Abliva indicated that the preclinical development is continuing and the clinical development should still start in 2021, so no major effects from COVID-19 pandemic have affected its progress.

Historically, the NV354 compound was selected from Abliva'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 in its new company Fortify Therapeutics. As the total deal value could reach $60m, we view the deal as a substantial external validation of Abliva's NVP015 chemistry.

Exhibit 1: Abliva's core assets



Source: Abliva

Non-core assets

Abliva confirmed it will no longer invest in the development of NeuroSTAT (Phase IIb ready) or NV556 (preclinical), but will seek other funding options or partnerships for these 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 TBI, where there is no neuroprotective treatment available yet. Currently, Abliva is in a process of setting up a new US-based company and will transfer the rights to NeuroSTAT to it. Abliva is now focused solely on mitochondrial diseases and TBI is a distinctly different area. The company believes the new corporate structure (subject to funding) will give flexibility to raise the funding necessary for the next development steps. NeuroSTAT is aimed at addressing a large unmet need as non-invasive brain trauma treatment options are very limited. The drug has accumulated some initial efficacy data and received IND approval from the FDA, so it is ready for the Phase IIb study.

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. Abliva is no longer investing in this project but aims to out-license it.

Financials and valuation

According to Abliva's Q120 report, personnel costs were similar year on year (SEK3.6m in Q120 vs SEK3.5m in Q119), while other external expenses, which include the bulk of other operating

expenses such as preclinical and clinical R&D costs, were somewhat higher year on year (SEK12.0m in Q120 vs SEK9.6m in Q119) due to the progress of the clinical Phase Ia/b trial. We make no changes to our estimates as the effect of the COVID-19 pandemic is still not known.

At the end-Q120, cash was SEK29.6m. This is still before the proceeds from the rights issue and the expected proceeds from the private placement (total amount of new funds SEK87m gross). This should be sufficient to fund operations well into 2021, according to our model.

After rolling forward our model and adding the private placement, our updated, risk-adjusted NPV valuation of Abliva is SEK1.76bn or SEK5.93 per share compared to SEK1.72bn or SEK6.40 per share per share previously. The technical decrease in valuation per share is due to the addition of the new shares.

Exhibit 2: Abliva sum-of-the parts valuation

Product	Launch	Peak sales ($m)	NPV ($m)	NPV/share ($)	Probability	rNPV ($m)	rNPV/share ($)
Core assets							
KL1333	2024	574	683.5	2.30	15%	100.6	0.34
NV354	2027	875	524.4	1.76	5%	24.2	0.08
Non-core assets							
NeuroSTAT		454	215.4	0.72	15%	29.7	0.10
NV556		1,828	89.2	0.30	8%	14.0	0.05
Net cash, Q120 plus gross proceeds from rights offering and private placement			12.0	0.04	100%	12.0	0.04
Valuation			**1,524.4**	**5.12**		**180.5**	**0.61**
			SEKm	**SEK/share**	**Probability**	**SEKm**	**SEK/share**
Core assets							
KL1333			6,657.4	22.5	15%	980.3	3.31
NV354			5,107.4	17.2	5%	235.9	0.80
Non-core assets							
NeuroSTAT			2,097.9	7.1	15%	288.9	0.97
NV556			868.4	2.9	8%	136.7	0.46
Net cash, Q120 plus gross proceeds from rights offering and private placement			116.6	0.4	100%	116.6	0.39
Valuation			**14,847.6**	**50.1**		**1,758.4**	**5.93**

Source: Edison Investment Research. Note: WACC = 12.5% for product valuations. Total number of shares 296.3m (Hadean shares will be registered in July 2020).

Exhibit 3: Financial summary

SEK'000s	2018	2019	2020e	2021e
December	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS				
Revenue	2,466	3,634	3,634	3,634
Cost of Sales	0	0	0	0
Gross Profit	2,466	3,634	3,634	3,634
Other external expenses	(55,812)	(63,133)	(68,616)	(69,563)
EBITDA	(66,675)	(72,317)	(78,578)	(79,870)
Operating Profit (before amort. and except.)	(68,589)	(74,696)	(80,998)	(82,325)
Intangible Amortisation	0	0	0	0
Exceptionals	(4,771)	(2,379)	(2,379)	(2,379)
Other	66	0	0	0
Operating Profit	(73,294)	(77,075)	(83,377)	(84,704)
Net Interest	(200)	(46)	0	0
Profit Before Tax (norm)	(68,789)	(74,742)	(80,998)	(82,325)
Profit Before Tax (reported)	(73,494)	(77,121)	(83,377)	(84,704)
Tax	0	0	0	0
Minority Interests	(5,121)	(6)	(6)	(6)
Profit After Tax (norm)	(68,723)	(74,742)	(80,998)	(82,325)
Profit After Tax (reported)	(68,373)	(77,115)	(83,371)	(84,698)
Average Number of Shares Outstanding (m)	78.5	171.6	241.1	296.3
EPS - normalised (SEK)	(0.94)	(0.43)	(0.34)	(0.28)
EPS - normalised fully diluted (SEK)	(0.94)	(0.43)	(0.34)	(0.28)
EPS - reported (SEK)	(0.87)	(0.45)	(0.35)	(0.29)
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	86,681	88,573	89,734	90,637
Intangible Assets	73,440	74,686	75,807	76,670
Tangible Assets	140	99	139	179
Investments	13,101	13,788	13,788	13,788
Current Assets	28,627	59,919	62,381	3,600
Stocks	0	0	0	0
Debtors	0	0	0	0
Cash	25,951	58,319	60,781	2,000
Other	2,676	1,600	1,600	1,600
Current Liabilities	(18,296)	(20,337)	(20,337)	(20,337)
Creditors	(18,296)	(20,337)	(20,337)	(20,337)
Short term borrowings	0	0	0	0
Long Term Liabilities	0	(361)	(361)	(27,187)
Long term borrowings	0	0	0	(26,826)
Other long term liabilities	0	(361)	(361)	(361)
Net Assets to shareholders and minority interests	97,012	127,794	131,417	46,713
Minority interests	11	5	5	5
CASH FLOW				
Operating Cash Flow	(63,630)	(72,367)	(80,957)	(82,249)
Net Interest	(199)	(46)	0	0
Tax	0	0	0	0
Capex	(82)	(69)	(40)	(40)
Acquisitions/disposals*	0	0	0	0
Financing	64,656	107,780	87,000	0
Other	(3,786)	(2,930)	(3,540)	(3,319)
Dividends	0	0	0	0
Net Cash Flow	(3,041)	32,368	2,462	(85,608)
Opening net debt/(cash)	(28,992)	(25,951)	(58,319)	(60,781)
HP finance leases initiated	0	0	0	0
Other	(0)	(0)	(0)	0
Closing net debt/(cash)	(25,951)	(58,319)	(60,781)	24,826

Source: Abliva accounts, Edison Investment Research.

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