Abliva

Sector: Biotech

More Reasons to Believe

Redeye believes current valuation implies a too cautious view of Abliva's project portfolio. Early evidence and positive regulatory feedback validate the development of lead candidate KL1333 in primary mitochondrial disease, an untapped orphan drug opportunity. A key element to further successful clinical development and hence rerating, in our opinion, is if Abliva can secure additional financing.

Regulatory Feedback a Boost for Lead Candidate

Already last year, Abliva agreed with the FDA that one pivotal trial for KL333 in primary mitochondrial disease (PMD) is enough for possible registration. We view this as surprisingly accommodating as Abliva had not presented any patient data at that point. It underlines that regulators are concerned about the lack of approved treatments for this rare genetic disease and consider preclinical and safety observations for KL1333 as supportive. If all goes to plan, we believe Abliva could file an NDA in about three years.

Early Efficacy Signals Timely in Quest for Capital

Clinical evidence is still preliminary, but the first efficacy signals from a recent Phase Ib study in PMD patients are intriguing. To reach the next clinical inflection points for KL1333, Abliva needs to raise significant capital (equivalent to the current market cap), likely from outside investors to a large extent. Specialist investor Hadean Ventures became the largest owner in 2020. In March, Abliva raised SEK 80m in a directed issue and now has leeway to prepare for the next step. The recently updated Phase I data could help attract investor interest.

On a Threshold

Following completed Phase I development, we see a significant rerating potential when Abliva can take the next step for KL1333 into a pivotal trial. We believe this view is supported by relative valuation of late-stage Orphan Drug companies. The interest in the primary mitochondrial disease field is building, and Abliva is a contender for a position at the forefront. We reiterate our base case of SEK 1.4 per share due to uncertainty about upcoming financing terms but our confidence in the lead project KL1333 is strengthened.

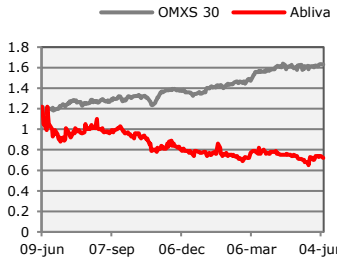
Key Financials

SEKm	2019	2020	Q1	Q2E	Q3E	Q4E	2021E	2022E	2023E
Net Sales	**0.1**	**0.2**	**0**	**0**	**0**	**0**	**0**	**0**	**0**
Y/Y	*n.m*	*62%*	*n.m*	*n.m*	*n.m*	*n.m*	*n.m*	*n.m*	*n.m*
EBITDA	**-75**	**-58**	**-21**	**-22**	**-20**	**-13**	**-76**	**-191**	**-109**
margin (%)	*n.m*	*n.m*	*n.m*	*n.m*	*n.m*	*n.m*	*n.m*	*n.m*	*n.m*
EBIT	**-77**	**-60**	**-21**	**-22**	**-21**	**-14**	**-78**	**-194**	**-111**
margin (%)	*n.m*	*n.m*	*n.m*	*n.m*	*n.m*	*n.m*	*n.m*	*n.m*	*n.m*
EV/Sales	**nm**	**nm**					**nm**	**nm**	**nm**
EV/EBITDA	**neg**	**neg**					**neg**	**neg**	**neg**
EV/EBIT	**neg**	**neg**					**neg**	**neg**	**neg**

FAIR VALUE RANGE

BEAR	BASE	BULL
0.8	1.4	4.0

ABLI.st VERSUS OMXS30



REDEYE RATING

KEY STATS

Ticker	ABLI.st
Market	small cap
Share Price (SEK)	0.7
Market Cap (MSEK)	290
Net Debt 21E (MSEK)	-59
Free Float	85 %

ANALYSTS

Niklas Elmhammer

niklas.elmhammer@redeye.se

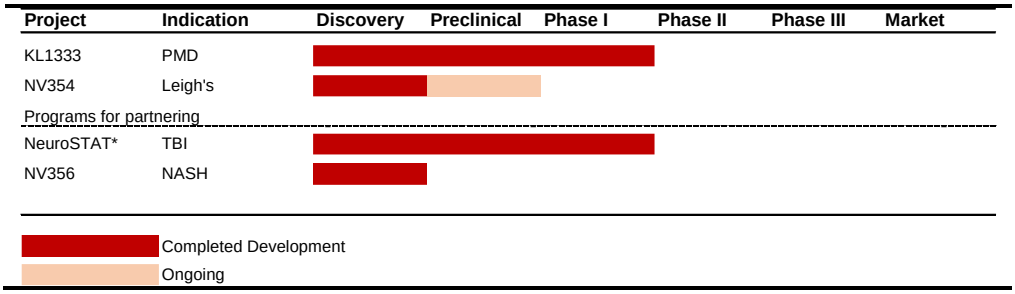
Investment Thesis

Start of Pivotal Trial Looming

Redeye believes Abliva turned a corner in 2020, as regulatory feedback at a pre-IND meeting with the FDA was surprisingly accommodating. Instead of a phase II trial, the regulators recommended a registrational study already as the next step for lead candidate KL1333 in primary mitochondrial disease (PMD). If the continued clinical development is successful, Abliva could potentially file for approval in about three years. Hence, the Company could move to the forefront in primary mitochondrial disease, a potential multi-billion-dollar orphan drug market with no approved drug treatments in the U.S.

While Abliva has a chequered history in drug development from, e.g., CicloMulsion in the emergency setting, we believe the subsequent redirected focus to rare mitochondrial disease is now starting to bear fruit. There is a solid scientific background in mitochondrial medicine in the current management team, and the Company has an extensive network of experts and KOLs, including a U.S. advisory board.

Project Pipeline



*Source: Redeye. PMD: Primary Mitochondrial Disease. TBI: Traumatic Brain Injury. *Phase IIa completed.*

At the beginning of the year, Abliva hired Dr. Ellen Donnelly as the new CEO. She has extensive experience in the biopharmaceutical industries, including leadership positions at the Neuroscience and Pain Division at Pfizer and investment banking in healthcare industries. Between 2017 and 2020, she was CEO at Modus Therapeutics overseeing clinical development in several regions and helping raise some USD 60m from specialist investors and strategic owners. As we expect clinical activities to intensify and require a significant capital injection, we think her background fits the bill for heading Abliva in the subsequent development steps.

Promising Early Data

Treatment with KL1333 appears safe based on administration in 132 human subjects so far (including six patients). Preclinical data shows that KL1333 improves muscle function and histology in disease models. KL1333's mode of action is to support the electron transport chain in dysfunctional mitochondria and stimulate the formation of new mitochondria.

In a small patient cohort, treatment with KL1333 for ten days was associated with improvements in clinical endpoints of patient-reported fatigue and exercise tolerance (30-second sit-to-stand test), all numerically better than placebo. Although it is still early days, the positive outcome already after ten days of treatment bodes well for further clinical development and longer follow-ups.

The primary aim is to alleviate severe fatigue, one of the most common symptoms in PMD patients. For the upcoming pivotal Phase II/III trial, patient-reported fatigue after twelve

months of treatment is the primary endpoint. As external projects in PMD so far have failed on functional physical exercise-based endpoints (e.g., walk tests), we argue that the agreement on a different primary endpoint is a positive for Abliva.

Go-to-Market Opportunity

Abliva wants to address rare genetic diseases, and the regulators acknowledge the unmet medical need and the difficulty in conducting extensive randomized clinical trials for these patients. Even small biotechs can run pivotal trials in the primary mitochondrial disease field. With regulators being accommodating, we believe there is a realistic chance for Abliva to bring KL1333 to the market on its own. While first drug launches are arguably challenging and hard to predict, a small patient population could facilitate roll-out. The possibility of launching products on its own provides Abliva with more options to enhance the value of the project portfolio. Abliva is still very early in the process of planning for a commercial organization, and we use simplified assumptions regarding future margins at this stage.

The existing drug market for primary mitochondrial disease is currently tiny as there is only one drug (Idebenone/Raxone) on the market (conditional approval in Europe) with so far modest uptake (sales of USD 31m in 2019). However, using similar pricing as for Raxone (e.g., SEK 45,000 per month in Sweden) indicates a potential multi-billion-dollar market for KL1333 in relevant mutations in Europe and the U.S. We believe higher pricing is likely for a more efficacious drug.

Financing Missing Piece

Abliva plans to start a pivotal trial towards the end of this year, after the final read-out of the Phase Ib trial and completing a qualitative study evaluating the experience of fatigue in PMD patients. Financing is still a missing piece, however. Abliva has stated a capital need of USD 30-40m. For small biotech, it is a considerable amount, but within reach, we believe. Abliva recently raised SEK 80m in a directed issue as a first step.

A key component to a successful capital raise and a higher valuation is if Abliva's efforts to attract international investors are successful. It could also ignite the interest from Swedish institutions who remain on the sidelines ever since CicloMulsion failed in late-stage development some five years ago. The market caps of US-listed peers indicate a considerable upside rerating potential.

Relative Valuation Indicates Considerable Potential

Abliva has an EV of less than SEK 170m. For a company about to enter late-stage development, the low valuation clearly stands out. We believe the main reason is the relatively large capital need and prospects of a significantly increased share base.

Below we list some late-stage listed Orphan Drug developers. It includes U.S. listed companies Cyclerion Therapeutics, Reneo Pharmaceuticals, and Stealth Biotherapeutics, all active in the primary mitochondrial disease space.

Peer Group Valuation

Peer group valuation (SEKm)	Market Cap	Share price	Net Cash	EV	No. Projects	Dev. Stage
Cyclerion	1132	4.03	420	712	3	Phase II
Egetis	994	6.02	250	744	2	Phase III
Reneo Pharma	1975	9.89	1450	525	1	Phase III
Saniona	1145	18.36	574	571	3	NDA
Stealth BioTher.	780	1.7	196	584	7	Phase III
Vicore Pharma	1354	22.4	321	1033	3	Phase II
Average				**695**		
Median				**648**		
Abliva	290	0.72	124	166	2	Phase II

Source: Redeye

The market caps of US-listed peers indicate a considerable upside rerating potential. A valuation (E.V.) in line with the peer group implies a share price of about SEK 1.9.

Catalysts

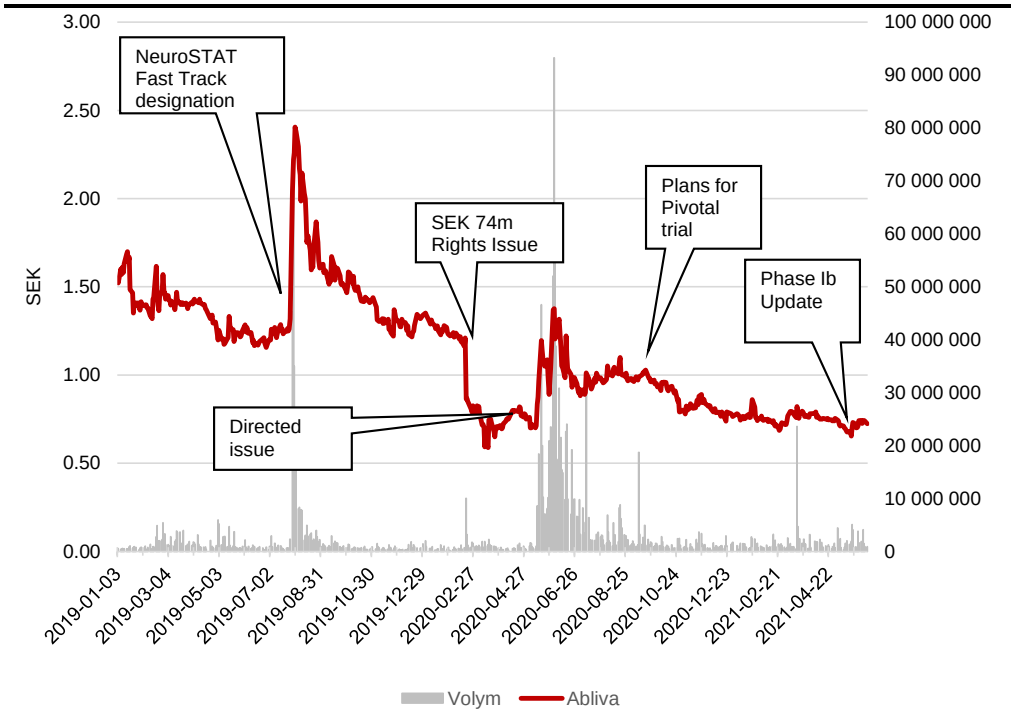
Additional Data from Phase I trial. Abliva has reported promising safety and efficacy top-line results from the Phase I trial. More data regarding, e.g., disease biomarkers and other secondary endpoints could strengthen the picture.

A Successful Capital Raise. Following the recent clinical progress, Abliva should be in a stronger position to raise funds from external investors. The subscription price in the recent directed issue, SEK 0.75, is a benchmark, we believe. While we see a risk that potential new investors push for a deep discount, the case of Saniona in 2020 is hopefully a cautionary tale for the Abliva board.

Start of Pivotal Trial. Pending financing, Abliva plans to initiate a pivotal trial in primary mitochondrial disease for KL1333 before the end of the year.

Successful Preclinical Development. We believe there is a good likelihood of preclinical toxicology studies for NV354 being successful.

Abliva Share Price Development



Source: Bloomberg, Redeye

Counter Thesis

Limited Efficacy Data. While observations in preclinical models indicate activity for the active projects KL1333 and NV354, Abliva has only limited clinical efficacy data from small patient cohorts for KL1333 and NeuroSTAT, respectively. A pivotal trial for KL1333 will require long follow-ups; however, an interim analysis will provide essential clues, possibly one year into the study.

Capital Need. Abliva likely needs to reach beyond the current shareholder base to raise capital for the pivotal trial for KL1333. A large directed issue may entail significant technical dilution for existing shareholders.

KL1333 is a Differentiated Approach

Stimulates the Cell's Respiratory Chain

Mitochondria are essential for the transformation of nutrients into energy in cells. In mitochondrial disease, this function is hampered due to mutations (healthy mitochondria need over 1,500 proteins), often leading to multisystemic disorders (especially in organs highly dependent on aerobic metabolism) and significant morbidity and low life expectancy. KL1333 aims to alleviate mitochondrial dysfunction by improving the electron transport chain (ETC) function and stimulating mitochondrial biogenesis (i.e., increasing mitochondrial content). Specifically, it modulates the cofactor NAD (Nicotinamide adenine dinucleotide), a carrier of electrons in the ETC.

- It oxidizes the enzyme NQQ1, which in turn oxidizes the reduced form of NAD, NADH, into NAD+, hence increasing relative levels of NAD+. Low levels of NAD+ are associated with mitochondrial dysfunction. In healthy mitochondria, the re-oxidization of NADH naturally occurs as NADH reduces another molecule.
- Reduced KL1333 may also be recycled in the ETC to function again as an oxidizer of NADH – a virtuous "ping-pong" effect.
- Restoring NAD+ levels also benefits the activation of signals involved in mitochondrial biogenesis, i.e., the production of new mitochondria

External Evidence Supports Mode of Action

External preclinical and clinical evidence has demonstrated that i) NADH oxidization increases NAD+ levels and lifespan in animal models of mitochondrial disease ii) NAD+ levels are lower in patients with primary mitochondrial disease iii) NAD supplement can improve NAD+ levels. All in all, we believe there is a clear rationale for the KL-1333 approach.

KL1333 is a synthetic derivative of beta-Lapachone, a naturally occurring quinone obtained from the bark of the lapacho tree. We believe Idebenone is a relevant comparison to KL1333 with a somewhat similar mechanism of action, as it functions as an electron carrier in the respiratory chain. Idebenone has conditional approval in the E.U. for treatment of LHON, a rare mitochondrial disorder in the eye. Early clinical evidence suggests Idebenone also has a positive effect on fatigue in so-called MELAS patients, one of the indications Abliva is targeting. However, there is, to our knowledge, no ongoing clinical development of Idebenone in this indication.

Abliva Wants to Address Common Symptom

With KL-1333, Abliva targets patients with a mutation in mitochondrial DNA called "m.3243A>G" associated with MELAS and MIDD syndromes, and patients with KSS-CPEO spectrum disorders with single, large scale mitochondrial DNA deletions. The estimated prevalence is 3.5 and 1.5 per 100,000, respectively. MELAS is one of the most common primary mitochondrial diseases and encompasses many different deliberating symptoms, including hearing loss, metabolic dysfunction (such as diabetes), myopathy, and fatigue. Severe symptoms involve stroke-like episodes and encephalopathy.

In the upcoming pivotal trial for KL-1333, the primary endpoint is reducing patient-reported fatigue versus placebo. According to surveys, chronic fatigue is among the most common symptoms in patients with primary mitochondrial disease and is also among the lead symptoms encouraging participation in clinical trials. Based on expert input, Abliva estimates that the majority (almost 65 percent) of the prevalent population suffers from at

least moderate fatigue. This ratio translates into a target population of about 30,000 patients in the U.S., E.U., and U.K. in total.

The Evidence so Far

Preclinical investigations of KL1333 demonstrate that KL1333 increases NAD+ and mitochondrial biogenesis in fibroblasts (biopsies) from MELAS patients. Also, in mice disease models, treatment with KL1333 significantly improved grip strength and normalized muscle histology.

Partner YungJin Pharm conducted a single ascending dose Phase I trial in South Korea in healthy volunteers. The investigators did not observe any serious adverse events at dose levels up to 800 mg. The pharmacokinetic analysis confirmed dose-dependent blood levels of KL-1333.

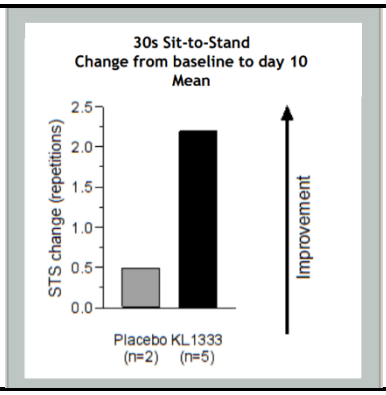
Abliva initiated a hybrid single and multiple ascending dose (MAD) trial in 2019. In the MAD part, administration of ten days of daily dosing of up to 250 mg has been evaluated without serious adverse events. At the end of 2020, Abliva started a Phase Ib part that included eight patients. Abliva recently completed the trial, again without any serious adverse events. The main dose-limiting tolerability factor was some gastrointestinal side effects. This side effect was reportedly mitigated with a change in the dosing schedule (split dosing). A drug-to-drug interaction study has also generated satisfactory results, i.e., only mild inhibition of one metabolizing enzyme.

First Efficacy Signals Already after Ten Days Treatment

Interestingly, Abliva reported early efficacy signals in the patient cohort. In six primary mitochondrial patients dosed with KL1333, there was a mean numerical better outcome in two patient-reported scales of fatigue and a 30-Second Sit to Stand test compared to two patients given placebo. Abliva observed the best effect in patients with the highest levels of KL1333. The study was not primarily designed to evaluate efficacy, and the treatment was only for ten days, so any conclusions are very preliminary. Still, these first observations in patients are encouraging, we believe.

There was a mean four-point improvement over placebo in the Neuro-QoL Short Form Fatigue scale and about two repetition improvement compared to baseline in 30-second sit to stand test. We do not know the baseline characteristics of these patients; however, Abliva judges that they were representative of the patient population, and the changes are clinically relevant if maintained with more extended treatment. We believe the functional, sit-to-stand test provided the most notable results. As a comparison, in a Phase Ib study, Reneo reported a mean 1.6 repetition improvement (or a 23 percent change) over baseline for its candidate REN001 in the same test after 12 weeks of treatment in primary mitochondrial myopathy patients (Reneo included patients with poor muscle strength (worse than 80-year-olds)).

30-second Sit-to-Stand Test Change



Source: Abliva

Abliva is currently evaluating biomarker data that could provide additional clues, including disease biomarkers FGF21 and GDF15.

Including the trial conducted by YungJin, KL-1333 has been investigated in 132 subjects so far.

The Next Step is a Pivotal Trial

Abliva has received positive feedback from the FDA regarding the clinical development plan for KL1333. Notably, FDA recommends one pivotal randomized trial as the next step. As previously described, the primary endpoint is reducing fatigue as patient-reported outcome after 12 months of treatment. In parallel, Abliva will conduct long-term toxicology investigations.

We believe the primary endpoint of patient-reported outcome of fatigue is somewhat unique in clinical trials. Most frequently, it is investigated as part of a composite of patient-reported symptoms. Patient-reported outcomes may be prone to placebo effects. Still, we think it is reasonable to regard them as a "lower bar" compared to functional endpoints, provided the trial has enough statistical power.

The Phase II/III trial will have an adaptive design, and preliminarily, Abliva expects to include 120-180 patients (80 to 120 in the active arm). We consider this as a comparatively small sample size. However, there will be an interim analysis to test for futility and to calculate the final sample size. We would expect 2-3 years of clinical development and follow-up.

We assume Abliva will include some functional secondary endpoint(s) as well. Functional data could be important for market uptake, eventually. We believe preclinical results and the first data in patients also provide a rationale for including a functional endpoint.

No drug treatment for primary mitochondrial disease has so far been approved based on either fatigue reduction or exercise tolerance tests. Late in 2019, Stealth Biotherapeutics announced that drug candidate **Elamipretide** failed to improve exercise intolerance or fatigue (the co-primary endpoints) compared to controls in a Phase III trial in patients with primary mitochondrial disease. However, besides Abliva, there are still some hopefuls in clinical development.

Metabolic Regulator Drugs Main Competitors

US Reneo Pharmaceuticals is developing a selective PPAR δ agonist (**REN001**) for the treatment of, e.g., Primary Mitochondrial Myopathies. Reneo has reported that results from a Phase Ib study in 23 patients suggest that REN001 is safe and well-tolerated (patients received at least 12 weeks of daily treatment). Early data from functional tests (12-minute walk test and VO2 capacity) indicates improved exercise tolerance. Patient-reported outcome data seems promising for fatigue reduction. Reneo plans to initiate a larger randomized Phase 2b (200 patients) trial ("STRIDE") in 2021. According to ClinicalTrials.gov, the primary endpoint in STRIDE is a walk test after 24 weeks of treatment compared to baseline.

Selected Clinical Data From Trials in Primary Mitochondrial Myopathy

Selected Clinical Trials in PMM							
Regimen	**Control**	**Phase**	**MoA**	**12 min Walk Test, vs baseline**	**6m Walk Test, vs baseline**	**Fatigue Reduction (PMMSA)**	**Fatigue/Energy improvement (SF-36)**
REN001	Open label	Ib	PPAR delta	17%	5%	-	39%
Elamipretide	Placebo	II	Cardiolipin	-	NS	-19%	-

Source: Reneo, Pharmaceuticals, Stealth Biotherapeutics

Japanese pharma company Astellas is also developing a PPAR δ-agonist in PMM. Astellas expects to start a Phase II/III trial soon. The drug, **ASP0367**, has been tested in healthy volunteers but, as far as we know, has not been administered to PMM patients yet.

PPAR δ-agonists are known to enhance fatty acid metabolism. There are currently no approved drugs belonging to this class, but there are several candidates in late-stage development in hepatology and gastroenterology indications. In preclinical development of early versions of PPAR δ agonists, an increased risk for cancer was observed. Since then, drug developers have focused on more selective agonists.

Besides a different mechanism of action, REN001 also appears to be addressing somewhat different symptoms than KL1333, i.e., myopathies (muscle disorders) primarily, but not exclusively, related to mitochondrial disease. Several renowned investors, e.g., Novo Nordisk and Abingworth, have backed Reneo. Reneo was recently listed on Nasdaq, has a market cap of USD 360m, and has raised almost USD 250m in total.

Other projects in clinical development include **CY6463** (Cyclerion Therapeutics), a compound that can penetrate the central nervous system and stimulate enzymes that help regulate cardiovascular activity. Cyclerion is currently recruiting MELAS patients to a Phase IIa trial. Based on the mechanism of action, we would expect Cyclerion to primarily address the neurological symptoms of MELAS.

Sonlicromanol (Khondrion BV) is a redox-modulating compound. In a randomized Phase IIa study in patients with m.3243A>G mutation, Sonlicromanol was safe. The primary efficacy endpoint (improved gait) was not reached, which could be due to the study design, but some attention and mood parameters improved versus control. A Phase IIb trial is ongoing, with cognitive functioning as the primary endpoint.

To conclude, we consider REN001 as the leading project currently given early but promising clinical evidence. Compared to KL1333, it is slightly ahead but all in all at a similar stage of development. We predict that REN001 would be addressing patients with generally milder symptoms compared to KL-1333, although there would also likely be an overlap if both drugs were eventually approved.

We Assume USD 500m Peak Sales

We assume that the U.S. and E.U. are the target geographical markets for Abliva. Based on estimates of the prevalence of the relevant mitochondrial DNA mutations, this constitutes a patient population of 33,000. We assume a diagnosis rate of 80 percent, expecting genetic testing to become more available. As previously discussed, we expect Abliva to focus on moderate to severe chronic fatigue (about 65 percent). We pencil in penetration of some 25 percent in this group (assuming some competition) and a compliance rate of 80 percent.

We assume net pricing of USD 159,000 per annum in the U.S., based on pricing models for orphan drugs, and USD 113,000 in Europe. All in all, we calculate peak sales of some USD 500m. We assume a considerable gross-to-net adjustment, and our net pricing assumptions are conservative, partly reflecting uncertainty regarding commercial structure.

NV354 – Rare Pediatric Disease Opportunity

NV354 is Abliva's in-house mitochondrial disease project, developed in collaboration with Lund University and British Isomerase Therapeutics.

Prodrug Formulation of Natural Energy Source

It is a succinate prodrug and is designed as an alternate energy source independent of the so-called complex I of the mitochondrial respiratory chain. Complex I is the first of five protein complexes where oxidative phosphorylation, i.e., ATP formation, takes place in the mitochondria. Complex I dysfunction is characteristic of many primary mitochondrial diseases. It is associated with severe symptoms affecting tissues and organs that consume a lot of energy (e.g., brain, heart). Natural succinate is generated in the mitochondria, but synthesis might be impaired in some mitochondrial diseases. Succinate cannot penetrate the cell membrane; hence a prodrug formulation is needed to deliver the supplementary active substance to the mitochondria.

Preclinical in vitro and in vivo studies with NV354 have demonstrated desired bioavailability properties and distribution to the brain. Also, Abliva has observed signs of efficacy in preclinical models (rat toxin and mouse genetic models of Leigh's syndrome).

Collaborations With Academia and Industry

Some external validation exists in the form of a collaboration with the Children's Hospital of Philadelphia on evaluating succinate prodrugs in mitochondrial disease. In 2018, Abliva out-licensed the rights to develop a locally administered formulation of a succinate prodrug in primary mitochondrial disease LHON to Fortify Therapeutics. However, the attempt was unsuccessful, and Fortify returned the rights in 2021.

A Challenging Indication

Abliva intends to initiate development in Leigh's syndrome. Leigh's syndrome is a devastating inborn primary mitochondrial disease characterized by significant neurological impairment from a very early age due to severe mitochondrial encephalopathy. The onset is typically before two years of age, and life expectancy is only a few years. The prevalence is estimated at 1 in 36,000 births.

NV354 is undergoing regulatory preclinical toxicology studies. Abliva has not yet presented the plan for clinical development. However, Abliva targets filing CTAs by the end of the

year. We would expect a similar development compared to KL-1333, i.e., once safety is established, a pivotal phase II/III trial could follow. Although some time off, a key element is eventually agreeing with regulators on the primary endpoint in a pivotal trial. In previous clinical trials, reduction in disease severity according to validated staging scores has featured as the primary endpoint (e.g., EPI-743 developed by BioElectron).

There is no approved treatment for Leigh's, and by all appearances, it is a very challenging indication for drug development. It is, therefore, at this point tough to estimate the likelihood of approval. We see a clear theoretical rationale for supplying an alternate energy source such as succinate to these patients. Of course, it remains to see just how effective NV354 is in humans. As with any neurodegenerative disease, it is likely crucial to start treatment as early as possible to optimize the chances of affecting neurocognitive development.

Priority Review Voucher an Important Incentive

We view it as a logical step to eventually apply for a Rare Pediatric Disease Designation in the U.S. A prerequisite is the drug candidate being approved for clinical development in the U.S. One strong advantage of a Rare Pediatric Disease Designation is that it opens for an application for a Rare Pediatric Disease Priority Review Voucher (PRV), which the FDA will grant in the event NV354 is approved for a U.S. pediatric population.

Congress recently voted to extend the Rare Pediatric Disease Priority Review Voucher Program until 30 September 2026. As a reminder, a Priority Review Voucher can be redeemed to receive a priority review of a subsequent marketing application for a different product. A priority review means a commitment (however, no guarantee) by the FDA to complete a marketing application review within six months compared to about a year for the standard procedure. The voucher is transferable any number of times before it is redeemed. Since 2009, FDA has granted 24 Rare Pediatric Disease Priority Review Vouchers. The market value is around USD 100m per voucher, according to the recent transfers.

Value of a U.S. Priority Review Voucher

Priority Review Vouchers Transactions			
Seller	**Buyer**	**Year**	**USDm**
Y-mAbs	United Therapeutics	2020	105
Lumos	Merck	2020	100
Argenx	Bayer	2020	98
Bavarian Nordic	Undisclosed	2020	95
Average			**100**

Source: Redeye Research

To conclude, there is a clear financial incentive to pursue development in Leigh's syndrome initially. Label expansion into other indications could follow in a longer-term perspective.

Forecast

As mentioned, the prevalence of Leigh's is about one in 36,000 *births*. However, due to the short life expectancy of this population, it is an ultra-rare disease. We assume a prevalence of about two per million or some 1,200 in the U.S. and the largest European markets.

Due to an estimated low prevalence, the business case rests on orphan drug pricing. Provided NV354 can demonstrate a clear health benefit in this debilitating disease; we believe a very high cost per treatment is possible. We assume a net price of USD 300,000

per year in the U.S. and 213,000 in Europe and Japan. We forecast high diagnosis and treatment rates and a penetration of about one-third of estimated prevalence, translating into peak sales of USD 160m.

Our assumptions are highly uncertain due to the early stage of development and the challenges of treating this severe disease. However, we believe there are opportunities to expand into other indications supporting a relatively robust peak sales estimate.

Sales of Drugs for Rare Metabolical or Neurological Diseases

Indication	Drug, example	Sales (USDm)	Year	Prevalence
Batten Disease	Brineura	110	2020	0.003%
Hunter's Disease	Elaprase	628	2019	0.001%
Tyrosinemia	Orfadin	98	2019 (Europe)	0.001%
Leigh's Disease	NV354	?	?	0.0002%

Source: Redeye Research

Institutional Support for NeuroSTAT is Key

Abliva is looking for research grants and external partners for the future clinical development of NeuroSTAT (CicloMulsion) in traumatic brain injury. In 2020, Abliva confirmed it is in preliminary discussions with the TRACK-TBI network in the U.S. for a potential collaboration for a Phase IIb study.

TRACK TBI runs several programs financed by the Department of Defence, including the "Precision Medicine Project." One aim is to eventually initiate Phase II trials in traumatic brain injury funded by grants from the U.S. Army. We understand that there will be a study to value imaging and blood-based biomarkers for subsequent clinical trials. According to the TRACK TBI homepage, "The [TRACK-TBI Precision Medicine] project […] will conduct a multicenter, double-blind, placebo-controlled exploratory clinical trial comparing the impact of cyclosporine A on blood-based and imaging biomarkers of diffuse axonal injury and neuroinflammation in moderate/severe TBI patients". From the face of it, it bodes well for the possible inclusion of NeuroSTAT (a new formulation of cyclosporine A.)

We still apply a cautious valuation of NeuroSTAT but are encouraged by the apparent increase in interactions with the TRACK TBI. Investigator-initiated clinical development is usually a slow process. Therefore, ideally, a collaboration should involve a commercial partner as well.

The rationale for NeuroSTAT in traumatic brain injury is that Ciclosporin has neuroprotective properties, as demonstrated in several preclinical models. Abliva hypothesizes this is due to inhibition of secondary injury cascades and consequently mitigating damage to the mitochondria.

- In the Phase IIa" CHIC" trial, NeuroSTAT was shown to be safe and well-tolerated when administered by infusion for up to five days to traumatic brain injury patients. The pharmacokinetic analysis confirmed a dose-dependent brain exposure. Further, there was a time-dependent reduction in biomarkers for brain injury. While there was no control group, this trend contrasts with the rise typically observed in TBI cases. A major limitation of the study was the prolonged time between injury and NeuroSTAT administration (several days).
- In a preclinical porcine contusion injury model, animals treated with NeuroSTAT displayed a 35 percent lower brain injury volume.

The counter-thesis is that despite preclinical activity, no clinical benefit on neurological outcome from treatment with ciclosporin has been demonstrated in TBI patients.

Nevertheless, Abliva has received positive feedback from regulators on using biomarkers and imaging as primary endpoints in a proof-of-concept trial.

We estimate a target population of 230,000 annually in the U.S., E.U., and Japan combined, consisting of patients with closed head traumas and suspected moderate to severe diffuse axonal brain injury.

Financials

We expect project costs to increase in 2021 due to preparations for a Phase II/III trial for KL1333 and Phase I for NV354. Also, we expect a milestone payment to YungJin Pharm of USD 1m from the completion of Phase I. From 2022 onwards, Abliva could potentially be running two clinical projects, in which case the cost structure will be much different. A previously mentioned, Abliva predicts the KL1333 pivotal trial to cost USD 30-40m. As a comparison, Reneo estimated USD 20m for a randomized Phase IIb trial in 200 patients.

Following a SEK 80m directed issue at the end of March, Abliva now has leeway to complete necessary preparation work. Still, the next steps in clinical development will require additional capital.

Financial forecasts

Income Statement	2015	2016	2017	2018	2019	2020	2021E	2022E	2023E
Revenues	**3**	**0**	**0**	**0**	**0**	**0**	**-**	**-**	**-**
Cost of Revenues	-	-	-	-	-	-	-	-	-
Gross Profit	**3**	**0**	**0**	**2**	**4**	**2**	**-**	**-**	**-**
Other external costs	49	34	46	56	63	46	56	174	91
Personnel costs	16	15	12	14	15	13	20	17	18
Depreciation	-	-	-	-	-	-	-	-	-
Other Op. Expense / (Income)	29	22	11	1	0	0	0	-	-
Exchange Rate Differences	-	-	-	-	-	-	-	-	-
EBITDA	**(90)**	**(71)**	**(69)**	**(69)**	**(75)**	**(58)**	**(76)**	**(191)**	**(109)**
Depreciation	-	-	-	-	-	-	-	-	-
Amortization	1	1	2	5	2	3	2	3	2
Amortization of Right-to-Use Assets	-	-	-	-	-	-	-	-	-
EBIT	**(91)**	**(72)**	**(71)**	**(73)**	**(77)**	**(60)**	**(78)**	**(194)**	**(111)**

Source: Abliva, Redeye

Abliva has a go-to-market strategy for KL1333 and NV354. It is arguably a challenging task for a company that is still virtual to a large extent. To complete clinical development, we calculate costs of almost SEK 600m for KL1333 and NV354 in total. Further, it needs to build a commercial organization successfully and cost-efficiently.

Once on the market, we expect high operating margins of 50 percent +, including royalty payments to YungJin Pharm and the Research group at Lund University. We believe this view is supported by expected gross margins of well over 90 percent from orphan drug pricing and presumably low production costs for small molecule compounds and comparison of cost structures in mature Orphan Drug Biotechs.

Costs as Percentage of Net Sales, Orphan Drug Companies

Orphan Drug Companies Cost Components			
Company	**Gross Margin**	**SG&A**	**R&D**
SOBI	77%	25%	10%
Alexion	91%	23%	17%
BioMarin	79%	40%	42%
Vertex	88%	12%	29%
Jazz Pharma	94%	34%	14%
Average	**86%**	**27%**	**22%**
Median	**88%**	**25%**	**17%**

Source: Thomson Reuters

Valuation

Our valuation of Abliva is based on the risk-adjusted NPV sum-of-the-parts (SOTP) model.

Likelihood of Approval

We have based our assumptions on the Likelihood of Approval (LOA) on an average of statistics from relevant indications (neurology and metabolical/endocrinology) as estimated by Informa and Wong, Ch et al., "Estimation of clinical trial success rates and related parameters," *Biostatistics* 2019). We consider Leigh's a challenging indication and assume a rather conservative LOA for NV354 until we learn more about clinical development plans.

Assumed Project Risk and Development Phase

Development risk at each stage							
	Indication	**Preclinical**	**Phase 1**	**Phase 2**	**Phase 3**	**NDA**	**Sum**
Year				2022			
KL1333	PMD	100%	90%	23%		87%	**18%**
Year			2022				
NV354	Leigh's	75%	70%	31%	52%	90%	**8%**
Year				2022			
NeuroSTAT	TBI	100%	100%	26%	53%	87%	**12%**

Source: Redeye Research, Wong (2019), BioMedtracker

Sum-of-the-Parts Valuation

Base case assumptions:

- As stated above, peak sales forecast of USD 500m and USD 100m for KL1333 and NV354, respectively
- We assume development and sales milestones to YungJin Pharm of USD 110m
- Due to uncertainty regarding the outlook for partnering or financing further clinical development, we include NeuroSTAT at book value in our valuation.
- A WACC of 14 percent.

Abliva Valuation

Sum-of-the-parts Valuation									
Project	**Indication**	**Likelihood of approval**	**Royalty rate**	**Peak sales (USDm)**	**Launch**	**rNPV* (Active)**	**rNPV* (Partnering)**	**Group rNPV***	**rNPV per share**
KL1333	Primary Mitochondrial Disease	18%	-	530	2025/26	693		693	1.7
NV354	Leigh's	8%	-	160	2027	61		61	0.2
NeuroSTAT	Traumatic Brain Injury	12%	20%	1 100	2027	52	505	505	0.1
Technology value						**806**	**505**	**1 259**	**2.0**
General and admin costs, incl taxes						-377		-377	-0.9
Isomerase						13		13	0.0
Net cash (21 'Q1e)						124		124	0.3
Shareholder Value						**566**		**1 019**	**1.4**
Number of shares						403.0		403	
Shareholder Value per share						**1.40**		**2.5**	

* SEKm

Source: Redeye Research

Our base case remains unchanged at about SEK 1.4 per share. On balance, we have become more optimistic about KL1333 but more cautious regarding the opportunities in Leigh's syndrome (NV354), a challenging and small indication.

We have conservatively valued NeuroSTAT at book value in our base case valuation as we believe further development and financing are dependent on finding a partner. For illustration, we have assumed a blockbuster opportunity (25 percent penetration) and an LOA of 12 percent. Based on (a small sample of) previous license deals, we have assumed a deal worth USD 125m and an upfront of USD 7m. On these assumptions, we calculate a value of about SEK 500m following a deal for NeuroSTAT.

Scenario Analysis

Our valuation of Abliva is highly dependent on pricing, LOA assumptions, and market penetration assumptions. To illustrate their potential impact, we also calculate optimistic and pessimistic scenarios for the Company.

Our **bear case** scenario, which gives a fair value of SEK 0.75, reflects more cautious assumptions:

- Discontinued development of NV354 and NeuroSTAT
- We expect Abliva to raise SEK 300m at a 50 percent discount
- We lower the WACC to 13 percent.

Our optimistic **bull case** scenario, which gives a fair value of SEK 2.7bn or SEK 4 per share, assumes:

- Abliva initiates Phase II/III and Phase I trials for KL1333 and NV354, respectively
- Abliva successfully raises SEK 300m at SEK 1 per share
- We assume blockbuster peak sales for KL1333
- We consider a licensing deal for NeuroSTAT
- We lower the WACC to 12 percent.

All in all, we have tightened the valuation range in view of clinical progress for KL1333 and factoring in technical dilution from the recent as well future expected capital raises.

Investment Case

Valuation

Bear Case 0.8 SEK

- Development of NV354 and NeuroSTAT is discontinued
- We assume a capital raise at a significant discount

Base Case 1.4 SEK

- We see a high likelihood for the start of a pivotal Phase II/III trial in H2 2021
- We assume an 8-18 percent likelihood of approval for the projects in mitochondrial disease
- We assume a discount rate of 14 percent

Bull Case 4.0 SEK

- Abliva starts a pivotal trial for KL1333 in primary mitochondrial disease
- Abliva finds a partner for NeuroSTAT in a deal worth USD 175m
- Abliva raises SEK 300m at a premium to current valuation

Summary Redeye Rating

The rating consists of three valuation keys, each constituting an overall assessment of several factors that are rated on a scale of 0 to 1 points. The maximum score for a valuation key is 5 points.

Rating changes in the report

People: 3

NeuroVive has a very competent core team. The founder still remains a significant owner. All employees are science graduates, with five holding PhDs in medical sciences. Most of the company's researchers are qualified physicians engaged in identifying segments with unmet medical needs and in conducting early basic research and clinical research towards approval of drug candidates.

Business: 2

NeuroVive focuses on primary mitochondrial disorders and compounds with orphan drug potential. Since 2017 NeuroVive has strengthened its project portfolio in primary mitochondrial diseases, notably through the in-licensing of the clinical asset KL-1333. A phase I study has recently been completed. In addition, the internally developed drug candidate NV354 is making good progress towards the clinical stage.

Financials: 1

NeuroVive does not generate any meaningful net sales and we do not expect them to do so in the near future.

Income Statement	2015	2016	2017	2018	2019	2020	2021E	2022E	2023E
Revenues	**3**	**0**	**0**	**0**	**0**	**0**	**-**	**-**	**-**
Cost of Revenues	-	-	-	-	-	-	-	-	-
Gross Profit	**3**	**0**	**0**	**2**	**4**	**2**	**-**	**-**	**-**
Other external costs	49	34	46	56	63	46	56	174	91
Personnel costs	16	15	12	14	15	13	20	17	18
Depreciation	-	-	-	-	-	-	-	-	-
Other Op. Expense / (Income)	29	22	11	1	0	0	0	-	-
Exchange Rate Differences	-	-	-	-	-	-	-	-	-
EBITDA	**(90)**	**(71)**	**(69)**	**(69)**	**(75)**	**(58)**	**(76)**	**(191)**	**(109)**
Depreciation	-	-	-	-	-	-	-	-	-
Amortization	1	1	2	5	2	3	2	3	2
Amortization of Right-to-Use Assets	-	-	-	-	-	-	-	-	-
EBIT	**(91)**	**(72)**	**(71)**	**(73)**	**(77)**	**(60)**	**(78)**	**(194)**	**(111)**
EBIT Margin (%)	(3655.7%)	#########	#########	#########	(57518.7%)	(27682.0%)	#########	#########	#########
Associated Income / (loss)	-	0	0	0	0	-	-	-	-
Interest Income	1	0	0	0	-	-	-	-	-
Interest Expenses	0	0	1	1	0	0	-	-	-
Interest Expenses, Lease Liabilities	-	-	-	-	-	-	-	-	-
Exchange Rate Differences	-	-	-	-	-	(0)	-	-	-
Non-recurring Income / (Expenses)	-	-	-	-	-	-	-	-	-
EBT	**(91)**	**(72)**	**(72)**	**(73)**	**(77)**	**(60)**	**(78)**	**(194)**	**(111)**
Income Tax Expenses	-	-	-	-	-	-	-	-	-
Effective Tax Rate (%)	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Non-Controlling Interest	-	-	-	-	-	-	-	-	-
Net Income	**(91)**	**(72)**	**(72)**	**(73)**	**(77)**	**(60)**	**(78)**	**(194)**	**(111)**
Non-Recurring Items / (Loss), Post Tax	-	-	-	-	-	-	-	-	-
Recurring Net Income	**(91)**	**(72)**	**(72)**	**(73)**	**(77)**	**(60)**	**(78)**	**(194)**	**(111)**
Net Income Margin (%)	(3629.1%)	#########	#########	#########	(57462.7%)	(27696.3%)	#########	#########	#########

Source: Abliva & Redeye Research

Earnings Per Share	2015	2016	2017	2018	2019	2020	2021E	2022E	2023E
Basic EPS	(3.10)	(1.79)	(1.41)	(0.94)	(0.45)	(0.24)	(0.22)	(0.48)	(0.28)
Diluted EPS	(3.10)	(1.79)	(1.41)	(0.94)	(0.45)	(0.24)	(0.22)	(0.48)	(0.28)
Adjusted Basic EPS	(3.10)	(1.79)	(1.41)	(0.94)	(0.45)	(0.24)	(0.22)	(0.48)	(0.28)
Adjusted Diluted EPS	(3.10)	(1.79)	(1.41)	(0.94)	(0.45)	(0.24)	(0.22)	(0.48)	(0.28)
Dividend Per Share	-	-	-	-	-	-	-	-	-
Dividend Payout Ratio	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%

Source: Abliva & Redeye Research

Shares Outstanding	2015	2016	2017	2018	2019	2020	2021E	2022E	2023E
Basic Weighted Average S/O	29.3	40.1	50.9	78.5	171.6	250.3	349.7	403.0	403.0
Diluted Weighted Average S/O	29.3	40.1	50.9	78.5	171.6	250.3	349.7	403.0	403.0
Basic Shares Outstanding, EOP	30.7	49.5	52.3	91.7	186.0	296.3	403.0	403.0	403.0
Diluted Shares Outstanding, EOP	30.7	49.5	52.3	91.7	186.0	296.3	403.0	403.0	403.0

Source: Abliva & Redeye Research

Balance Sheet	2015	2016	2017	2018	2019	2020	2021E	2022E	2023E
Current Assets									
Cash & Equivalents	97	93	29	26	58	62	52	0	0
Inventories	-	-	-	-	-	-	-	-	-
Accounts Receivable	2	2	2	1	1	1	-	-	-
Other Current Assets	-	-	-	-	-	-	-	-	-
Total Current Assets	**100**	**96**	**33**	**29**	**60**	**63**	**52**	**0**	**0**
Non-Current Assets									
Property, Plant & Equipment, Net	0	0	0	0	0	0	0	0	0
Goodwill	13	18	21	20	22	21	21	21	21
Intangible Assets	62	51	52	52	52	52	50	48	45
Right-of-Use Assets	-	-	-	-	1	0	0	0	0
Shares in Associates	-	13	13	13	13	13	13	13	13
Other Long-Term Assets	0	2	2	2	1	1	1	1	1
Total Non-Current Assets	**75**	**85**	**88**	**87**	**89**	**88**	**86**	**83**	**81**
Total Assets	**175**	**181**	**120**	**115**	**148**	**151**	**137**	**83**	**81**
Current Liabilities									
Short-Term Debt	-	-	-	-	-	-	-	140	249
Short-Term Lease Liabilities	-	-	-	-	-	-	-	-	-
Accounts Payable	5	6	8	10	14	4	-	-	-
Advances From Customers	-	-	-	-	-	-	-	-	-
Prepaid Income	-	-	-	-	-	-	-	-	-
Accrued Expenses	14	6	6	7	5	5	-	-	-
Other Current Liabilities	1	0	1	1	1	1	-	-	-
Total Current Liabilities	**20**	**12**	**14**	**18**	**20**	**10**	**-**	**140**	**249**
Non-Current Liabilities									
Long-Term Debt	-	-	-	-	-	-	-	-	-
Long-Term Lease Liabilities	-	-	-	-	-	-	-	-	-
Other Long-Term Liabilities	-	-	-	-	0	0	-	-	-
Other Long-Term Liabilities, % of Rev.	0.0%	0.0%	0.0%	0.0%	269.4%	42.4%	#########	#########	#########
Total Non-current Liabilities	**-**	**-**	**-**	**-**	**0**	**0**	**-**	**-**	**-**
Non-Controlling Interests	-	-	-	-	-	-	-	-	-
Shareholder's Equity	155	168	106	97	128	140	138	(56)	(167)
Book Value Per Share	5.0	3.4	2.0	1.1	0.7	0.5	0.3	(0.1)	(0.4)
Total Liabilities & Equity	**175**	**181**	**120**	**115**	**148**	**151**	**138**	**84**	**81**
Net Debt	(97)	(93)	(29)	(26)	(58)	(62)	(52)	140	249
Net Gearing (%)	-62.5%	-55.4%	-27.4%	-26.8%	-45.6%	-43.9%	-37.5%	-250.4%	-148.7%

Source: Abliva & Redeye Research

Cash Flow Statement	2015	2016	2017	2018	2019	2020	2021E	2022E	2023E
Operating Activities									
Net Income	-	-	-	-	-			(194)	(111)
Non-Controlling Interest	-	-	-	-	-			-	-
Associated Income / (loss)	-	-	-	-	-			-	-
Dividends Received from Associates	-	-	-	-	-			-	-
Depreciation	-	-	-	-				-	-
Amortization	-	-	-	-	-			3	2
Amortization of Right-to-Use Assets	-	-	-	-	-			-	-
Net Working Capital Change, Decrease / (Increa	-	-	-	-	-			-	-
Other Long-Term Liabilities, Increase / (Decreas	-	-	-	-	-		(0)	-	-
Operating Cash Flow	**(67)**	**(57)**	**(58)**	**(64)**	**(72)**	**(68)**	**(86)**	**(191)**	**(109)**
Cash EPS	(2.3)	(1.4)	(1.1)	(0.8)	(0.4)	(0.3)	(0.2)	(0.5)	(0.3)
Investing Activities									
Capital Expenditures	-	(0)	(0)	(0)	(0)	-	-	-	-
Capital Expenditures, % of Rev.	0.0%	992.9%	148.1%	16400.0%	51.5%	0.0%	#########	#########	#########
Investment in Intangible Assets	-	(18)	(4)	(4)	(3)	(1)	(0)	-	-
Investment in Intangible Assets, % of Rev.	0.0%	128942.9%	15570.4%	758200.0%	1959.7%	648.8%	#########	#########	#########
Other Long Term Assets	-	(7)	-	-	-	-	-	-	-
Other Long Term Assets, % of Rev.	0.0%	(48885.7%)	0.0%	0.0%	0.0%	0.0%	#########	#########	#########
Acquisitions	-	-	-	-	-			-	-
Divestments	-	-	-	-	-			-	-
Goodwill	-	-	-	-	-			-	-
Investing Cash Flow	**(23)**	**(25)**	**(15)**	**(4)**	**(3)**	**(1)**	**(0)**	**-**	**-**
Financing Activites									
Short-Term Debt, Issuance / (Repayment)	-	-	-	-				140	109
Long-Term Debt, Issuance / (Repayment)	-	-	-	-				-	-
Share Issuance / (Repurchase)	-	-	-	-				-	-
Dividends Paid to Shareholders	-	-	-	-				-	-
Dividends Paid to Non-Controlling Interest	-	-	-	-	-			-	-
Repayment of Lease Liabilities	-	-	-	-	-			-	-
Other Financing Activites	-	-	-	-	-			-	-
Financing Cash Flow	**138**	**77**	**9**	**65**	**108**	**72**	**76**	**140**	**109**
Net Cash Flow	**48**	**(5)**	**(64)**	**(3)**	**33**	**3**	**(10)**	**(52)**	**-**
Cash Balance	**97**	**93**	**29**	**26**	**58**	**62**	**52**	**0**	**0**

Source: Abliva& Redeye Research

Redeye Rating and Background Definitions

Company Quality

Company Quality is based on a set of quality checks across three categories; PEOPLE, BUSINESS, FINANCE. These are the building blocks that enable a company to deliver sustained operational outperformance and attractive long-term earnings growth.

Each category is grouped into multiple sub-categories assessed by five checks. These are based on widely accepted and tested investment criteria and used by demonstrably successful investors and investment firms. Each sub-category may also include a complementary check that provides additional information to assist with investment decision-making.

If a check is successful, it is assigned a score of one point; the total successful checks are added to give a score for each sub-category. The overall score for a category is the average of all sub-category scores, based on a scale that ranges from 0 to 5 rounded up to the nearest whole number. The overall score for each category is then used to generate the size of the bar in the Company Quality graphic.

People

At the end of the day, people drive profits. Not numbers. Understanding the motivations of people behind a business is a significant part of understanding the long-term drive of the company. It all comes down to doing business with people you trust, or at least avoiding dealing with people of questionable character.

The People rating is based on quantitative scores in seven categories:

- Passion, Execution, Capital Allocation, Communication, Compensation, Ownership, and Board.

Business

If you don't understand the competitive environment and don't have a clear sense of how the business will engage customers, create value and consistently deliver that value at a profit, you won't succeed as an investor. Knowing the business model inside out will provide you some level of certainty and reduce the risk when you buy a stock.

The Business rating is based on quantitative scores grouped into five sub-categories:

- Business Scalability, Market Structure, Value Proposition, Economic Moat, and Operational Risks.

Financials

Investing is part art, part science. Financial ratios make up most of the science. Ratios are used to evaluate the financial soundness of a business. Also, these ratios are key factors that will impact a company's financial performance and valuation. However, you only need a few to determine whether a company is financially strong or weak.

The Financial rating is based on quantitative scores that are grouped into five separate categories:

- Earnings Power, Profit Margin, Growth Rate, Financial Health, and Earnings Quality.

Redeye Equity Research team

Management

Björn Fahlén
bjorn.fahlen@redeye.se

Tomas Otterbeck
tomas.otterbeck@redeye.se

Technology Team

Jonas Amnesten
jonas.amnesten@redeye.se

Henrik Alveskog
henrik.alveskog@redeye.se

Fredrik Nilsson
fredrik.nilsson@redeye.se

Tomas Otterbeck
tomas.otterbeck@redeye.se

Viktor Westman
viktor.westman@redeye.se

Forbes Goldman
forbes.goldman@redeye.se

Mark Siöstedt
mark.siostedt@redeye.se

Danesh Zare
danesh.zare@redeye.se

Mattias Ehrenborg
mattias.ehrenborg@redeye.se

Editorial

Mark Siöstedt
mark.siostedt@redeye.se

Joel Karlsson
joel.karlsson@redeye.se

Life Science Team

Gergana Almquist
gergana.almquist@redeye.se

Oscar Bergman
oscar.bergman@redeye.se

Anders Hedlund
anders.hedlund@redeye.se

Niklas Elmhammer
niklas.elmhammer@redeye.se

Mats Hyttinge
mats.hyttinge@redeye.se

Filip Einarsson
filip.einarsson@redeye.se

Fredrik Thor
fredrik.thor@redeye.se

Disclaimer

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Redeye Rating (2021-06-09)

Rating	People	Business	Financials
5p	19	15	3
3p - 4p	99	76	37
0p - 2p	6	33	84
Company N	124	124	124

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CONFLICT OF INTERESTS

Niklas Elmhammer owns shares in the company : No
Redeye performs/have performed services for the Company and receives/have received compensation from the Company in connection with this.