Delivering mitochondrial health
Our new name, Abliva, signifies a decisive strategic move

The change of name from NeuroVive to Abliva is of core significance, since it further signifies our strategic move from a company that drives a number of projects in their early phase to a company with a clear focus on developing pharmaceuticals for serious diseases and taking them all the way to the market.

Focus on primary mitochondrial diseases
Our financial assets and our research and development resources are now concentrated on developing effective medical therapies for primary mitochondrial diseases. Specifically, this means that there are two projects in focus: KL1333 and NV354. Our ambition is to develop both of these drug candidates all the way to market, either completely by ourselves or together with a partner who can contribute to making the projects a success.

Severe symptoms and great suffering
Primary mitochondrial diseases are relatively rare, but have a severe effect on patients and their family members. The symptoms generally debut in early childhood, with severe symptoms such as stunted growth, fatigue, heart failure, diabetes, reduced mobility and others. The diseases often lead to a far too premature death. There are no effective drugs currently available for the treatment of primary mitochondrial diseases. We at Abliva would like to change this. Our explicit ambition is to develop a drug that can significantly improve the lives of the patients affected and thus also the lives of their family members.

Orphan drug designation increases the chance for success
Drugs developed for rare disorders have good possibilities to obtain what is called orphan drug designation. The authorities’ goal with orphan drug designation is to make it commercially attractive to develop therapies for particularly rare disorders and entails that the development periods can be shorter and the development costs lower than for traditional drugs. Our KL1333 project has obtained orphan drug designation in both Europe and the US and we deem the outlook favorable that NV354 can also obtain orphan drug designation in a later phase of the development process.

Abliva’s other projects require some form of partnership.
For our projects in traumatic brain injury and NASH, the route to market is longer and will require significant documentation. This means that they require more financial resources than KL1333 and NV354 to proceed all the way to market. Accordingly, Abliva will not continue to drive these projects independently. However, we are keen to identify various forms of partnership and out-licensing that will enable continued financing of the projects and their further development.

Positive reception for our strategy
Our new strategy with an intensified focus on drug candidates for primary mitochondrial diseases has been received positively by analysts and specialist investors. Several of them have emphasized the opportunity of orphan drug designation as particularly important. A key indication that our strategy is genuinely attractive from an investor perspective is that the Norwegian company Hadean Ventures is investing MSEK 20 in Abliva through a private placement. I am very pleased about this investment and that Hadean will now be represented on Abliva’s Board of Directors by Roger Franklin. Hadean is not only bringing a welcome injection of capital, but also a generous amount of expertise, experience and a long-term approach.

The new strategy was also presented at Abliva’s Virtual Capital Markets Day on 23 June. The day offered an excellent opportunity to go through the most important aspects of our company and answer questions from shareholders and analysts.

I look forward to the next few years with a large amount of confidence. With this I want to wish everyone a really nice summer!

Erik Kinnman.
CEO
Abliva’s newest board member sees potential in primary mitochondrial diseases

In late April, Abliva attracted the attention of the Nordic life science sector when it announced that heavyweight investor Hadean Ventures invests MSEK 20 in the company through a directed rights issue. In connection with this it was suggested that Dr Roger Franklin, partner in Hadean Ventures, would be elected as a board member in Abliva at the Annual General Meeting in May. On the occasion of Dr Franklin’s election, he will take up the position starting in early July, BioStock took the opportunity to talk to him about Abliva’s potential and his forthcoming role as board member.

For Lund-based Abliva, the past year has been one of important developments during which the company has advanced its work. One important change came in October last year when the company announced a sharpened focus in its development strategy. Instead of developing projects spanning four indications, Abliva made the decision to hone in on one of these, namely primary mitochondrial diseases. This is an area where the company has considerable internal expertise and experience, and focusing its resources here can optimise the value for both the company and its shareholders.

**Two projects advancing towards market**

In patients afflicted by primary mitochondrial diseases, the mitochondria – responsible for creating the energy needed to perform basic bodily functions – do not work properly, meaning that basic things such as moving and breathing become difficult. Primary mitochondrial diseases are categorised as rare and affect circa 1 out of 5 000 individuals.

For those afflicted, a primary mitochondrial disease means significant suffering and reduced life expectancy. Currently, there is only one treatment for a primary mitochondrial disease on the market – idebenone for the eye disease LHON – and the medical need is significant.

Abliva aims to contribute to meeting this need through its two candidates KL1333 and NV354. KL1333, the company’s most advanced candidate, is being developed against MELAS and similar conditions and already has orphan drug designation in both the US and Europe. The company plans to begin a phase II study with KL1333 in 2021. NV354 aims to treat Leigh syndrome and has shown positive results in preclinical studies. Here the aim is to initiate clinical studies during next year.

**Significant investment from leading investor**

In late April, Abliva were able to mark yet another important development when it was revealed that Hadean Ventures, a leading life science fund manager that invests in life science companies across Europe, steps in as owners in the company through a directed issue of MSEK 20. Hadean Ventures, founded in 2014, is one of the major players in Nordic life science, and the fact that they have singled out Abliva for investment is an important seal of approval for the Swedish company.

Early on, Hadean Ventures announced its intention of being an active owner in Abliva. As a part of this strategy, Dr Roger Franklin, partner in Hadean Ventures, was elected as new board member at this
year’s Annual General Meeting for Abliva. Dr Franklin, who will assume his new role on 9th July, has a PhD in oncology from University of Cambridge as well as extensive experience in the venture capital, finance and consulting industries.

BioStock had the opportunity to talk to Dr Franklin about his new role as a board member and what attracted Hadean Ventures to Abliva.

**Dr Franklin, congratulations on your new position as board member of Abliva. First of all, can you tell us a bit about your background?**

– Of course! I started my career working on my doctorate in Cambridge in the field of the heritable breast cancer gene, BRCA1. Having got fed up of pipetting at 3am I moved to a consulting firm first in Cambridge and then in London working across a number of sectors in private equity due diligence and corporate strategy. From there I moved into investment banking in the pharmaceuticals and biotech sector, covering big cap pharma companies to IPO’ing smaller cap names.

– My goal had always been venture capital and having moved to a large London based fund after banking and gained significant operational and financing experience, I met the founders of Hadean and joined here as a partner in November 2018, re-locating to Stockholm to head up Hadean’s Swedish office.

**How do you think your background and experience can contribute to the work of Abliva’s board?**

– As with all our portfolio companies at Hadean, I am looking forward to working proactively with Abliva to assist in as many ways as I can. Obviously the planning and preparation for the phase II clinical trial of KL1333 starting next year is really key for the company so I will be looking to use our network and my own experiences from multiple previous investments to make sure no stone goes unturned in making this as likely to succeed as possible.

– Clearly, as an investor, I am also in a position to leverage our network when it comes to making sure quality specialist investors are aware of Abliva, particularly given the recent M&A and venture involvement in the mitochondrial disease space. Overall I hope my blend of experiences across areas including trial design, regulatory and financing will prove useful to Abliva over the next period of the company’s life.

**If we focus on Hadean Ventures’ decision to invest in Abliva, what first attracted Hadean Ventures to Abliva?**

– In our view, rare disease is a highly attractive area and mitochondrial disease particularly is a key area in which there is very severe unmet medical need, little competition and less risk than some may perceive. So, this was a key attraction of Abliva.

– We also think the management team is strong and thus Abliva has the people to execute on the opportunity.

Prior to investing in the company, Hadean Ventures conducted a thorough review of Abliva and its projects. Can you tell us what this review found?

– Of course, due diligence is an absolutely key aspect for a venture fund before making any investment. We conducted what in our opinion is thorough due diligence into Abliva and its assets, particularly KL1333.

– Without going into specifics, we believe there is a large market opportunity for KL1333, that the preclinical data is supportive of the potential of the mode of action and the molecule and that some of the clinical work done on non-drug supplements provides an element of de-risking that perhaps some do not realise. As such, whilst of course there is risk in any drug development programme, this risk may be lower than is sometimes thought in this disease area.

**How does Hadean’s investment profile look like? Can you tell us anything about the scope of the funds in question and what kind of investors they have?**

– Hadean is a life science venture capital fund backed by a strong group of international institutional and private investors from Norway, Sweden, the UK and the USA. Leading investors in the fund include Argentum, Saminvest and Investinor whilst the fund size is approximately €85m.

– As I said, we invest solely in the life science sector with a geographical scope that covers western
Europe with a particular focus on regions that have been historically underserved by venture capital, including most particularly the Nordic region. Within the drug/biotech space, we are interested in backing companies with robust science, strong teams and assets where there is both a high unmet need and an element of de-risking from, for example, prior clinical work with similar modes of action. Our sweet spot in terms of stage is where an asset is ready for the clinic or already in early clinical development. While most of our portfolio is composed of private companies, where we see attractive opportunities we are able to invest in public companies as is the case with Abliva.

– As you would expect for a specialist venture investor, our senior team is highly experienced with backgrounds in medicine, medical research, finance/consulting and senior executive operational roles. As an aside, I am happy to share that we have already had our first exit from the Hadean fund with Themis Bioscience recently sold to MSD.

**What role did Abliva’s choice to focus on primary mitochondrial diseases play in Hadean Venture’s decision to invest?**

– This was critical to our interest. For the reasons I have already mentioned, we think this is a very attractive area and we think Abliva is right to focus on it. Having too many programmes that distract attention is an error often made and we are pleased that Abliva is not going down this route and is instead laser focused on the lead programmes.

– More importantly, we are confident mitochondrial disease will prove to be a smart place to be positioned.

**What would you say are the commercial potential for Abliva’s two projects in primary mitochondrial diseases?**

– I do not think I should give precise numbers. But certainly we think the sales opportunity in Abliva’s chosen end markets is in the blockbuster range given the number of patients and likely price point for a drug in this disease area. Given the M&A and venture activity in this area in the US of late, we do not think we are alone in this opinion.

**Finally, if we look further into the future, where do you see Abliva and the company’s projects in two years?**

– The most important thing is designing the right study to prove out efficacy in the upcoming phase II study of KL1333 and have this report positive data. Then we believe the company will have an extremely valuable asset.

– We also think it will be exciting to get NV354 into the clinic so that this exciting compound is also adding meaningfully to the value of the company. In this industry there is no substitute for producing compelling data demonstrating value to patients. Then there will, in our opinion, be value for shareholders.

– In short, I think the next two years will be an interesting and I hope very rewarding time for Abliva and its shareholders.

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Great interest in Abliva’s Virtual Capital Markets Day

On June 23, Abliva arranged the company’s second Capital Markets Day. Due to the ongoing covid-19 pandemic, the capital markets day was conducted virtually from Stockholm, Lund, and London.

The Capital Markets Day began with Erik Kinnman, Abliva’s CEO, presenting the company’s strategy focusing on primary mitochondrial diseases, which can be devastating for the affected patients. All primary mitochondrial diseases, apart from the eye disease LHON, still lack effective treatment options. In other words, the need for new medicines is enormous.

The day continued with a presentation by Magnus Hansson, Abliva’s CMO. Magnus explained, among other things, the mechanisms of action for Abliva’s two focus projects, KL1333 and NV354, and gave an overview of the competitive situation in mitochondrial medicine.

Matilda Hugerth, Abliva’s director of clinical and regulatory affairs, spoke about rare diseases and how common they actually are. Estimates show that 60 million people in the United States and Europe have some form of rare disease and many of them lack effective treatments. Matilda also described the advantages that Abliva gets by working in the orphan drug space.

The day ended with an interview with Roger Franklin from Hadean Ventures, a leading Nordic life science fund manager, who recently invested MSEK 20 in Abliva through a directed issue, and a question and answer session with Erik Kinnman and Magnus Hansson.

See all the presentations from the Capital Markets Day here: http://abliva.com/investor/abliva-capital-markets-day/

Save the date!

During the annual Global Mitochondrial Disease Awareness Week, Abliva will for the third time organize the Mitochondria Day – a day to raise awareness of primary mitochondrial diseases and what is happening in drug development and funding opportunities. Add Wednesday, September 16, 2020 to your calendar!