NeuroVive PHARMACEUTICAL

Newsletter

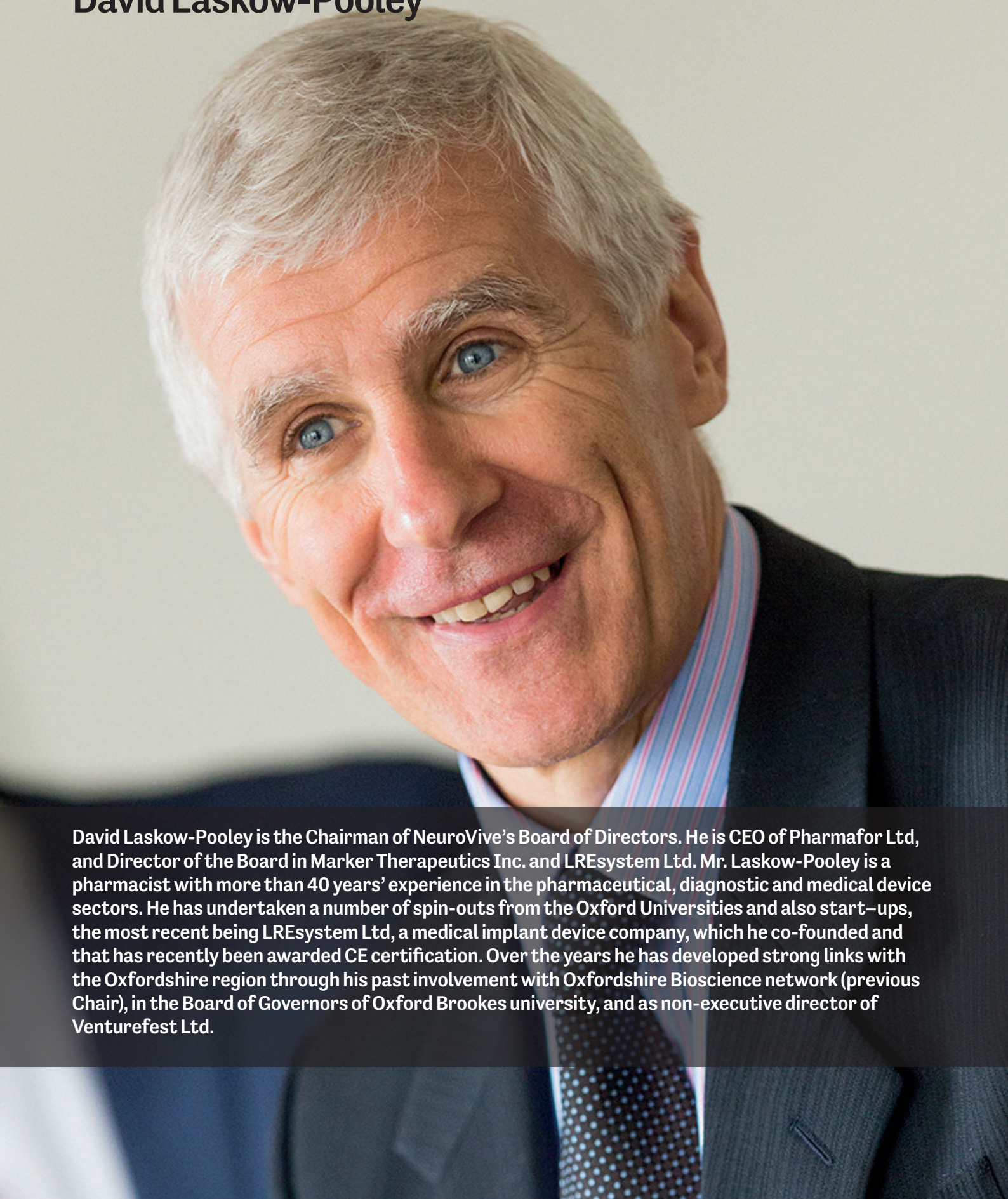
April 2020

Interview with NeuroVive's Chairman

Erik Kinnman on the rights issue

Dr. Robert Pitceathly on KL1333

Interview with NeuroVive's Chairman of the Board, David Laskow-Pooley



David Laskow-Pooley is the Chairman of NeuroVive's Board of Directors. He is CEO of Pharmafor Ltd, and Director of the Board in Marker Therapeutics Inc. and LREsystem Ltd. Mr. Laskow-Pooley is a pharmacist with more than 40 years' experience in the pharmaceutical, diagnostic and medical device sectors. He has undertaken a number of spin-outs from the Oxford Universities and also start–ups, the most recent being LREsystem Ltd, a medical implant device company, which he co-founded and that has recently been awarded CE certification. Over the years he has developed strong links with the Oxfordshire region through his past involvement with Oxfordshire Bioscience network (previous Chair), in the Board of Governors of Oxford Brookes university, and as non-executive director of Venturefest Ltd.

When and why did you join the Board of Directors?
"I was elected as a Board member in 2016 and became Chairman of the Board of Directors in 2017. I was already when I joined the Board, and have been ever since, very impressed with the interesting and strong potential in the portfolio and the organization. Importantly, I obviously saw the collective experience, both scientific, medical and industrial, that my fellow Board members represent. Indeed, the strong links and collaboration with the local university were also a factor."

NeuroVive has changed its focus over the past years. What has prompted the new strategic focus for the Board of Directors?
"The Board of Directors has been heavily involved in the process of carving out the new strategic focus for NeuroVive, focusing the company towards its new core activities, namely the primary mitochondrial disease programs. We believe that a clear focus always is essential in the pharmaceutical business, and even more so for a company of NeuroVive's size. In short, I would say that we see a clear rationale for the path chosen, both when it comes to the expertise in the company and the opportunity to create value for patients and our shareholders. NeuroVive has 20 years´ of scientific experience in mitochondrial diseases, and the primary mitochondrial disease segment offers a strong opportunity as they are orphan indications."

Can you tell us about what preoccupies NeuroVive's Board of Directors in the quite troublesome spring of 2020?
"The last few weeks have been very tough for all of us with the sudden and sharp spread of Covid-19, and its effects may be felt for some time. We need to safeguard the health of our clinical trial participants, cooperative partners, suppliers and employees in this difficult situation. Good corporate governance is crucial in these extraordinary circumstances and NeuroVive is implementing the measures recommended by international and national authorities. You can trust that we are dedicated to timely yet prudent decisions, transparent communication and resilient measures to ensure the long-term success of the company."

Can you develop your view on the company's strategic intent and its core projects?
"I can assure you that the Board fully shares the management's conviction that the chosen strategic focus is the best way for NeuroVive to optimize shareholder value. As you know, orphan drugs generally allow for a faster, less risky, and less costly route to the market, as well as a higher price and improved protection against competitors for the drug. And the primary mitochondrial disease segment offers a strong opportunity with orphan indications. Our most advanced project with the candidate drug KL1333, has been granted orphan drug designation in both the US and Europe."

"In line with the strategy to focus our resources on the primary mitochondrial disease projects, KL1333 and NV354, we have recently announced that we are initiating a process with the aim to transfer the NeuroSTAT program into a new company based in the US. The purpose is to increase the possibilities to leverage value in the Phase II ready NeuroSTAT clinical program in the US, where FDA has approved the IND and given the program a Fast Track designation."

How do you look upon the upcoming rights issue?
"The share issue is very important for the company's ability to deliver going forward. The rights issue, covered by subscription and guarantee commitments corresponding to 90 percent of the share issue, will upon full subscription, bring in approximately MSEK 74 before issue costs. It will ensure that the company has financial resources for its prioritized primary mitochondrial disease programs, primarily the continued clinical development of KL1333 and NV354, again, with significant opportunities to build value."

Do you think that the company's CEO and management team has the expertise and strength to deliver on the opportunities, especially bearing in mind the current problematic situation with delays in clinical trials caused by the Covid-19 pandemia?
"I can ensure you that our team is well prepared and constantly staying on their toes, making thoughtful decisions on an ongoing basis to ensure that NeuroVive is in the best possible position to cope with the uncertainties."

"Being in the business of life science, we acknowledge that it is hard to give an estimate on when the worst effects are over, and when we can go back to normal. We know that biology is tricky and has no timeframe. But under the leadership of Erik Kinnman, our diligent and experienced management team is working in close contact with the Board to actively monitor the implications that Covid-19 may have on our operations. The emphasis is to safeguard that the company can manage the effects of the Covid-19-pandemic with as little impact as possible on the development of the core primary mitochondrial disease programs, KL1333 and NV354. The company has continuous contact with all parties involved and is monitoring the situation closely."

"A good example is how the KL1333 program is being handled. There is currently, and for some time to come, a risk of delays in recruitment for all clinical studies. As this would delay the next part of the Phase Ia/b study with KL1333, NeuroVive is now working to adapt the study program for KL1333, by modifying the structure of the upcoming phase II study, which is still expected to start during the first half of 2021. Thereby, the risk of delays in the overall study program for KL1333 can be minimized without compromising patient safety or the data quality of the study."

So you are quite hopeful on the future prospects for NeuroVive and its shareholders?
"We want our shareholders to take pride in owning an investment which enables them to play a significant role in the development of important therapies that can provide worthwhile quality of life for patients that are so desperately in need of them."

"The Board of Directors and the management team are firmly committed to see to that NeuroVive develops and brings therapies to the patients who are in such great need for them. It is only by making that possible that we can adequately reward our investors and make their investments grow in value in a sustainable way in the long term."

CEO, Erik Kinnman on the rights issue in April 2020

NeuroVive announced in February/March 2020 that the company will conduct a new issue of shares with preferential rights for the company's existing shareholders to secure the financial resources for the company to implement its prioritized projects in primary mitochondrial diseases (PMD), mainly regarding the continued clinical development of KL1333. At the same time, the Covid-19 pandemic is ongoing and, as with the entire industry, it is likely to impact NeuroVive's operations in one way or another. CEO Erik Kinnman explains further.

Why are you choosing to conduct a rights issue now?
"It is in line with our focus on primary mitochondrial diseases and, in particular, KL1333. We want to ensure that we have funding to implement ongoing trials, deliver results and at the same time, prepare the key efficacy study."

What is your current progress in the KL1333 project right now, and how do you believe that the clinical program will be impacted by the ongoing Covid-19 pandemic?
"We have conducted an initial clinical Phase I trial and are now in the second Phase I trial. We have given doses of KL1333 to healthy volunteers and the next step is to commence a patient part. This is the first time that we will administer KL1333, one of the very few drugs developed for this patient category, to patients. At the same time, we are preparing for contact with regulatory agencies – which are important for ensuring that we have a protocol that is acceptable in addition to earlier documentation – for the efficacy study that is scheduled to commence during the first half of 2021. In parallel with this, we will produce the drug materials to be used in the efficacy study. The materials will be produced in accordance with the regulated method and must be approved before use in the clinical trial. When we have all of the data from the Phase I trial in place, we will analyze and evaluate it to elicit as much information as possible regarding potential endpoints and patient inclusion criteria for the efficacy study. This means that much is happening at the same time."

"Currently, NeuroVive's work on the planned final stage of the Phase I a/b study with KL1333 against PMD, has been put on hold. The trial centers in Newcastle and London, where the study is to be conducted, have informed us that, due to the situation with the Covid-19 pandemic, are

VD Erik Kinnman

delays in recruitment to all clinical studies for some time to come. This has lead to the time for inclusion of the first patient in the concluding part of the Phase Ia/b study with KL1333 to be postponed until the Covid-19 situation has been stabilized."

What patient groups are primarily being targeted for KL1333?
"The broad term is primary mitochondrial diseases. With KL1333, we are primarily focused on patients who have a combination of pronounced exhaustion, muscle weakness and metabolic impairment, which manifest themselves, for example, in diabetes that is very difficult to treat."

What market potential does KL1333 have?
"In Europe and the United States, there are approximately 10,000 patients in our target group and there is currently no effective therapy alternatives for them. KL1333 has orphan drug designation, an initiative established by pharmaceutical regulators throughout the world to encourage the development of drugs for the treatment of rare diseases. Orphan drug designation also often entails a significantly higher pharmaceutical pricing. The price of orphan drugs in the United States is approximately USD 140,000 per patient and year. Considering that no approved drug exists for the primary mitochondrial diseases that we are focusing on and the price for an effective drug can be expected to be significant, KL1333 has major market potential."

Read more about the rights issue

Read more about NeuroVive's KL1333 and NV354 projects

Read more about the impact of the Covid-19 pandemic on the company's activities

The Rights issue in short

Preliminary time plan	
Record date for participation	1 April
Trading with subscription rights	6 – 22 April
Subscription period	6 – 24 April
Publication of the outcome	Around 28 april

Terms in short

Subscription price	0.80 SEK
1 existing share ➜	1 subscription right
2 subscription rights ➜	1 new share

University College London (UCL) Queen Square Institute of Neurology and The National Hospital for Neurology and Neurosurgery

Dr. Robert Pitceathly finds the approach of KL1333 particularly exciting

Dr. Robert Pitceathly, MRC Clinician Scientist and Honorary Consultant Neurologist at University College London (UCL) Queen Square Institute of Neurology and The National Hospital for Neurology and Neurosurgery, UK, is the Chief Investigator of the patient part of NeuroVive's ongoing KL1333 clinical Phase Ia/b study, and the Principal Investigator of the London study site.

What made you accept taking on NeuroVive's KL1333 study?
"Despite a growing number of strategies aimed at treating primary mitochondrial diseases, there are currently no licensed disease-modifying therapies available for these patients. One compelling therapeutic approach is to increase the number of mitochondria in the cell to compensate for the energy deficiency. KL1333 aims to achieve this by stimulating mitochondrial production. This approach is particularly exciting because it has the potential to treat many mitochondrial diseases with different underlying genetic causes."

Why do you think NeuroVive reached out to you in particular, to conduct the study?
"In the UK, the NHS supports a nationally-commissioned clinical and diagnostic service for people with primary mitochondrial diseases, which is delivered across three centres located in London, Oxford and Newcastle. This support has helped our multidiscplinary teams to develop experience and expertise in mitochondrial diseases, in addition to the development of large, "trial-ready" patient cohorts. We are also fortunate at UCL in having access to The Leonard Wolfson Experimental Neurology Centre, a state-of-the-art clinical research facility with expertise in "first-in-human" and "early phase" clinical safety studies."

What are the recruitment criteria for this study? Will both women and men be screened/recruited?
"The study is open to both women and men with genetically confirmed mitochondrial disease, between the ages of 18 and 75 years."

For how long will the patients be given KL1333 and how many patients will be included?
"Eight patients will be randomised to receiving either KL1333 (6 patients) or placebo (2 patients) for a total duration of 10 days."

Are the patients with primary mitochondrial disease difficult to recruit?
"Our UK mitochondrial disease national cohort comprises over 1,800 people with genetically confirmed mitochondrial disease, many of whom have expressed a strong interest in participating in trials. While the ongoing Covid-19 pandemic is having a major impact on research globally, I do not anticipate any problems with recruitment once it is safe to start new clinical studies, particularly given the current lack of effective treatments currently available for people living with these diseases."

Why do you think clinical trials in patients with primary mitochondrial diseases are important?
"The UK adult prevalence of mitochondrial diseases is 1 in 4,300, ranking primary mitochondrial diseases among the most common inherited neuromuscular disorders in adults. Despite this, there are currently no licensed disease-modifying therapies available to patients. This therapeutic gap represents a major unmet medical need. Furthermore, fully understanding the different causes of primary mitochondrial diseases is likely to contribute towards unravelling the pathophysiological basis of a large number of other inherited and acquired disorders, because of the diverse roles mitochondria play in cellular metabolism."

On NeuroSTAT, NV556, and business development

NeuroSTAT towards a new company

A process has commenced for NeuroVive's NeuroSTAT program for traumatic brain injury (TBI) aimed at transferring the rights to develop and commercialize NeuroSTAT to a new company in the United States. This is a further step toward focusing the company on its core operations – the programs for primary mitochondrial disease (PMD). NeuroVive will license the development of and the commercial rights for NeuroSTAT to the new company once it is established, apart from the rights in the Asian market, which will remain within NeuroVive Asia Ltd. The purpose of these measures is to increase the possibilities to create value in the NeuroSTAT clinical program, which is ready for Phase II in the United States, where the FDA has approved the IND application and given the program a Fast Track designation. NeuroVive's objective is to appoint and work closely with appropriate U.S. advisors to identify a long-term financing strategy and to optimize the structure of the new company.

No further investments in NV556

NeuroVive's more focused approach, by which financial and human resources are concentrated on therapy for primary mitochondrial diseases, also affects the conditions for the development and commercial development of NV556 for NASH. The NV556 project demonstrated strong preclinical results that supported out-licensing. After the discussions that were conducted over an extended period with several stakeholders, it was clear that further investments were needed in the development of the NV556 project to enable a transaction to be concluded with these parties at the current time. As a consequence of its current focused strategy, the company chose not to invest further in the NV556 project, but has adopted an opportunistic approach to continued licensing activities.

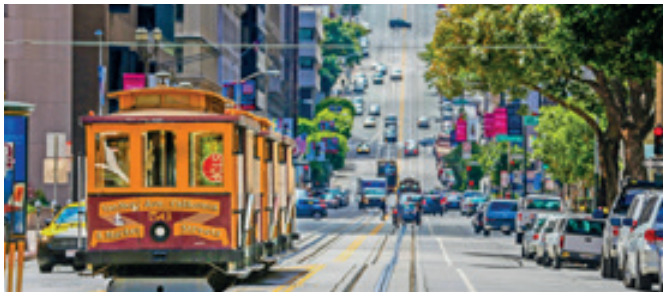
Business development conducted by the CEO

The new situation for NeuroSTAT and NV556 has resulted in a change in NeuroVive's management, with there being no need in the immediate future for a separate position as head of business development. For this reason, the company's Vice President Business Development, Mark Farmery, has left NeuroVive. Instead, the company's business development is being conducted by CEO Erik Kinnman. It remains a key aspect of operations, but in future, the work will be conducted on the basis of an opportunistic approach.

"The changes enable focus and concentration on the PMD strategy. A spin-off of NeuroSTAT could ensure value-creation for TBI patients and for our shareholders. The decision not to invest further in activities related to the NV556 project was also necessary. The changes means that, going forward, we will be able to invest in those activities that have the best conditions for creating most value," says Erik Kinnman. "I want to take this opportunity to thank Mark Farmery for the committed work that he carried out with high energy to thoroughly investigate the options that were available. We wish Mark the very best in his future endeavors," says Erik Kinnman.

Spreading the word

NeuroVive is continuously engaged in the vibrant mitochondrial science community as well as the world of investors and potential partners. Over the past few months alone, NeuroVive has attended and presented at conferences in the US and in Sweden. Because of the current situation with the Covid-19 pandemic, the company's planned participation in scientific, investor and partnering meetings will be replaced as far as possible by digital meetings.



38th Annual J.P. Morgan Healthcare Conference: San Francisco, USA, on 13 -16 January, 2020

Erik Kinnman, CEO, attended this meeting, that gathers over 9,000 participants and 450 private and public companies within the health-care industry and investment community.

Aktiespararna's Aktiedagen: Lund, Sweden, on 28 January, 2020

Erik Kinnman, CEO, presented NeuroVive and the company's latest successes in its projects within primary mitochondrial diseases.

Stockholm Corporate Finance 12th Life Science seminar: Stockholm, on 11 March, 2020

Erik Kinnman, CEO, presented the company's activities and talked about the upcoming rights issue.

Watch NeuroVive's latest company presentations, including

- Aktiedagen Lund,
- Stockholm Corporate Finance 12th Life Science seminar, and
- Erik Penser Bank Bolagsdag, (on 12 March, 2020, without audience)

at http://www.neurovive.com/sv/investor/company-presentations/

In addition, see NeuroVive's latest interviews, including:

- BioStock CEO interview (on 20 February, 2020), and
- 'Sitdown' after Erik Penser Bolagsdag (on 12 March, 2020)

on our YouTube channel:
https://www.youtube.com/channel/UChqP7Ky5caXtp72CELhD6Mg/featured

Effects of the Covid-19 pandemic

Society in general, and the healthcare sector in particular, will be exposed to extraordinary pressures due to the Covid-19 pandemic. At the same time as we want to ensure that our projects continue to develop, we need to consider the changed needs and risks arising from the pandemic. This applies to those affected by the disease, the healthcare sector and our employees and partners. It is probable that the recruitment to clinical trials in general will be delayed, because of factors including the increased risk of the spread of infection, but also because care providers could reassign available resources.

At NeuroVive, we are preparing to manage the situation in the best possible way by ensuring that we have a high level of preparedness to create alternative possibilities for starting the Phase II trial in our key KL1333 project if patient recruitment in the Phase Ia/b trial is severely delayed, with the ambition that it will be able to commence as planned during the first half of 2021. Preparations to take NV354 to clinical trials next year are not currently affected. However, scientific meetings and partner meetings are being held only as web meetings and teleconferences until further notice.

Further reading at www.neurovive.com

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