

Meeting notes – Lyfstone / Cleveland Clinic

Pursuant to meetings with Lyfstone and Cleveland Clinic 24th and 25th September we took note of the following key points:

- Cleveland Clinic, operating worldwide, with hospitals in the US, Canada, Abu Dhabi, China and soon London has 17 million corporate lives enrolled in its program. It has a unified “standard of care” operating principle across all territories and institutions. Cleveland clinic is single-mindedly focused to adopt and develop the best evidence based “standard of care” for its practice. It is therefore of great importance that Dr. Jonathan Schaffer and all his global staff in orthopedics has decided to give Lyfstone full backing to bring this forward in the right manner.
- Dr. Schaffer’s viewpoint is that any successful attempt at introducing a new product, therapy or diagnostic test to the US market needs to be “evidence driven”. Full academic and clinical support needs to be established and published before it is launched. There are examples where Life Science companies have attempted to introduce products ahead of such backing by the scientific and clinical community. This is an approach Cleveland Clinic will not advise to support. In 2018 the requirement for evidence based “standard of care” is now the de-facto approach.
- Cleveland Clinic will be Lyfstone’s partner in organizing and conducting clinical trials for the FDA 510k approval and connected articles to be published. Cleveland has already agreed with a handful other US Hospitals to cooperate in the clinical trials. This gives Lyfstone the benefit of an increased volume of patients, thus speeding up the trial program. A very important secondary benefit is getting these institutions vested in the Lyfstone Calprotectin diagnostic test early on.
- During Dr. Schaffer’s visit with existing and possible new investors in Oslo, Cleveland Clinic reiterated the importance of finding a solution for infection diagnosis. He emphasized that infection risk has the highest priority in the development of improved patient care in arthroplasty. The rapidly growing primary and revision surgery volumes and the growing number of patients exposed to the risk of Prosthetic Joint Infections (PJI) underlines the importance of this.
- Building on Dr. Schaffer’s strong testimony to the importance of a new infection diagnosis standard and his backing of Lyfstone we see strong support in Lyfstone’s opportunities ahead.

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- As we have witnessed significant un-prompted and Lyfstone-independent interest in Calprotectin in Europe at the European Bone and Joint Infection Society's (EBJIS) annual meeting in Helsinki the 6th September 2018, we are confident the professional involvement is on the rise also in Europe.
- Dr Marjan Wouthuyzen-Bakker at University Medical Center Groningen, Nederland is one of the authorities that has already started independent research on Calprotectin for Prosthetic Joint Infection detection.
- Her lecture at EBJIS had the following title:

Calprotectin cost less and is as accurate as Alpha-Defensin in excluding a chronic prosthetic joint infection

Dr Marjan Wouthuyzen-Bakker
University Medical Center Groningen, Nederland

http://ebjis2018.org/fileadmin/user_upload/EBJIS2018_FinalProgramme.pdf

- Supported by a growing interest from the academic community Lyfstone is now progressing with its commercial launch. Lyfstone will have a strong distribution capability with signed and about to be signed distribution agreements with specialist distributors chosen to gain access to key clinics in all significant non-US territories.