



Lumito AB Quarterly Report (1 Jan to 31 March) 2021

Significant events during the first quarter of 2021

- Lumito's advisors in the field of pathology have had the opportunity to review the company's UCNP immunostaining of invasive breast cancer with an antibody against HER2 (the target molecule) at a high image resolution. "The signals are uniquely sharp and clear, which gives the impression of staining almost on the level of individual target molecules; in this sense, it is superior to any method currently in regular use in pathology laboratories," says one of Lumito's advisors, Björn L. Isfoss.
- An account was given of the events that unfolded prior to the publicity that impacted the company and stirred up concern among the company's shareholders.
- The shareholders were informed that the company's development and adjustment efforts relating to images in Sectra's Pacs On Demand system continue.
- A process for listing the company's shares and warrants on Nasdaq First North Growth Market was initiated and subsequently terminated. The company formally withdrew its application for a delisting from NGM Nordic SME. This took place against the background of the issues brought up in the media concerning the company's disclosure. "The effort we have spent on the planned change of listing has not been in vain, but considering the discussion in the media about interpretation of information and the events preceding it, the process is postponed," said Urban Widén, acting CEO of Lumito, in a comment.
- Mattias Lundin took position as CEO in March and shared his first impressions in an Investor Letter. He works on a long-term approach to build a strong and attractive company. The overarching aim is to shape the Company's strategy for the commercial phase. Mattias Lundin clarified that the company currently is in the process of verification and pre-validation. The company will continue the manual production of stained breast tissue imaging, and as a consequence, the company's pre-validation process will continue into Q2 2021. This is due to the capacity shortage that occurred during Q4 2020 in the laboratories that were intended to produce larger volumes of stained tissue samples for the company. The capacity of the laboratories is reserved for the analysis of COVID-19 tests.

CEO Comments

Lumito specializes in digital pathology and develops an advanced medical device. With our proprietary and patented technology, we want to equip healthcare providers with a powerful tool to meet the personalized healthcare's requirements of fast and safe tissue diagnostics.

The technology enables higher-contrast imaging where irrelevant background information is filtered out, making it easier for pathologists to identify cancer indications. The technology, which is based on Up Converting Nano Particles (UCNP), has the potential to improve tissue diagnostics significantly by enhancing the quality of analysis and shortening the analysis time.

I took position as CEO of Lumito on March 8, and I am still analyzing matters to get a clear picture of the company, the technology, the product development and, not least, our conditions and business opportunities in order to create the most attractive company and most

competitive product possible. The ambition is for our product to be robust, competitive and value-generating for pathologists, patients, the healthcare system and our shareholders when we introduce it in the market.

We are an attractive company with a number of business opportunities and potential business models. Our product offers recurring sources of revenue, which is a major advantage in a future commercialization. We have an advanced and complex medical device, which consists of hardware – the scanner – software with advanced imaging technology, and finally our UCNP reagents.

In pathology, there is a high demand for coherent and more rapid analytical results.

Healthcare is pushing for reduced costs and shorter time to treatment after biopsy. Our product has no direct competitors and meets the needs of the market.

The total tissue diagnostics market is very large, worth billions of USD, and is projected to grow by between 5 and 10 percent annually (market data and growth vary across different sources). Digital pathology sees even stronger growth and is gaining ground worldwide as well as in Europe in particular. “While digital pathology offers more freedom from geographic restraints, there are still diagnostic issues, which Lumito has the solution to,” says Björn Isfoss, who, among other things, is the Chief Pathologist at Unilabs Norway and Lumito’s advisor.

The need for rapid and accurate results places significant technical requirements on our product to meet the market needs and the challenges facing pathology. We will be able to offer tissue imaging with high precision and contrast that enables more rapid and more reliable assessments, which likely will lead to earlier and more effective treatment of the patient, as attested by Isfoss.

In recent weeks, we have discussed various application areas that we are eager to look at more closely to see if we can continue to develop the product further and upgrade with additional applications. When we succeed, we will be able to bring an even more competitive product to market, with higher added value.

Lumito has over the past quarter continued to work on further development and verification of the product, and intends to continue this important effort during 2021. As the company now aims to CE mark the product in accordance with the new IVD regulation, more time will be required, and a so-called Notified Body, an independent auditing company, must be involved. It is, therefore, the company’s assessment that we will not be able to obtain CE marking in 2021 as we previously have disclosed as our ambition.

Our method has several possible application areas, but we have initially decided to focus on digital pathology. As always during the product development of medical devices, we are running into some challenges, and these are being solved by Lumito’s team together with our development partner, The Technology Partnership TTP plc. We continue to strengthen the organization, most recently with the addition of a senior software engineer, and we are planning to carry out additional recruitments. Moreover, we have moved to new premises during the quarter, with room for our own laboratory and potential for more efficient development.

Comments on events during January and February

During the first quarter of the year, the company both initiated and terminated a process for listing the company’s shares and warrants on Nasdaq First North Growth Market. One of the reasons for the termination of the process and Lumito’s formal withdrawal of the application for delisting from NGM Nordic MTF was the issues concerning the company’s disclosure that arose in February. However, the work put in by the employees and my predecessor, Urban Widén, was not in vain, as the process is only postponed.

I followed the press coverage that the company was subject to in February, which prompted rumours and speculations. As I have mentioned before, I think it was unfortunate that the discussion between the involved parties took place in the media. It is clear to me that the importance and significance of a cooperation is judged differently by a smaller developing company than a substantially larger, established company.

The situation that arose has caused concern among our shareholders, which I regret. I would like to ensure our shareholders that the work at Lumito is ongoing and has not been affected by the discussion in the media. During the quarter, we worked on and prepared a new patent application. We have registered the product name Acri™ as a trade mark. The product name covers both the scanner and the reagents. The winning idea, Acri, was suggested by our creative team members during a workshop last year. Acri™ is latin and means “sharp”, and can be used both as an adjective – as in sharp, defined, distinct, intelligent – or as a noun, as in acuity, sharp-sightedness and insight. The name Acri™ reflects Lumito’s tissue images. They are sharp and distinct, and free from disturbing background noise.

Finally, we have a very good, sharp product, just like the trade mark implies. But there is always room for improvement.

Our internal verification continues, and the advanced product development includes adjustments and adaptations to make the product as broad, attractive and competitive as possible. In addition, the company must meet the regulatory requirements of the new In Vitro Diagnostic Regulation (IVDR), the purpose of which is to further ensure that diagnostic products in the EU are appropriate, safe and effective.

We are well on our way and we definitely have good indications of the excellence of the technology and the product. The team is working determinedly and intensively towards the objective, but we are not ready for CE marking and launch yet. In the long-term, Lumito shall be strong and successful and generate value in the healthcare system as well as for the shareholders.

Lund, April 28, 2021

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Lumito specializes in imaging technology within medical research and development. The technology is based on so called UCNP:s (Up Converting Nano Particles) and is aiming to increase image quality in biomedical applications. Lumito’s IPR covers high-quality imaging of tissue, for instance in tumours, with UCNP:s as markers. The technology has several possible application areas, but Lumito has initially decided to focus on digital pathology. www.lumito.com

Lumito's share is traded under the ticker LUMITO on the Nordic Growth Market, NGM SME, where the Company's mentor is G&W Fondkommission, telephone: +468-503 000 50.