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# AI Medical Technology Doubles Down On Melanoma With Trials And Financing

by Barnaby Pickering

Over the past month, the company has released positive clinical trial results and raised more cash, both of which will help on its way to combat melanoma.

2023 might just be the toughest year yet for medtech startups.

Public markets are down, venture capital is more hesitant than ever after making staggering losses in 2022 and now more than ever, payers are demanding solid clinical evidence before even entertaining new ideas. (Also see "[Axogen, Dario Health, Biobeat, Immunexpress All Weigh In On 2022 And What Will Succeed In 2023](#)" - Medtech Insight, 2 Feb, 2023.)

However, for Christoffer Ekström, CEO of Sweden-based AI Medical Technology, the developer of Dermalyser, an artificial intelligence-based software which transforms smartphones into a powerful diagnostic tool for melanoma, the upcoming year instead presents opportunity. Speaking to *Medtech Insight*, he first drew focus to the company's most recent round of clinical results.

The observational study included 240 patients from 37 different primary care centers in Sweden who presented with cutaneous lesions that were suspected to be melanomas.

Images of lesions were taken using Dermalyser and a standard dermatoscope mounted in front of the smartphone camera. The study was non-interventional and thus did not impact the standardized flow of care.

Dermalyser' performance was measured against histopathology and specialists' diagnosis (gold standard). Results of the study showed that Dermalyser was 95% sensitive to melanoma and had a specificity of 86%, outperforming primary care and specialist physicians in both metrics.

Compared to previous results, sensitivity remained the same, however specificity increased almost 10%.

According to Ekström, these results came as a surprise to the company.

“We are super excited for these results,” he said. “We have seen so many AI studies fail during this transition because when you go from a retrospective study to a prospective one, you introduce many, many more uncontrolled variables that you never ever could have taken into account in the retrospective study.”

“We were expecting some kind of decrease in performance,” he explained “But it was quite the opposite. Our performance or even better than expected, and it actually outperformed our best-case scenario.”

### **Sensitivity vs Specificity Trade-Off**

A diagnostic’s sensitivity is the probability that it indicates a positive test result when a patient is truly positive. Its specificity is the probability that it indicates a negative test result when a patient is truly negative.

This can mean that diagnostic developers end up in a situation where they begin to start considering a trade-off of either value. Increasing sensitivity can easily be done, at the cost of specificity.

In the case of cancer, this may be warranted. Melanoma incidence rate has risen 140% since the 1990s in the UK and starting treatment early is key to survival. When asked whether AI Medical Technology was considering making changes around the sensitivity/specificity trade-off, Ekström said the answer was “both a yes and no.”

He explained that, due to regulations, the company cannot change its artificial intelligence model and that it had “frozen” its development over a year ago. Any changes now would require more clinical trials, delaying the company’s entry into the market.

Ekström did caveat this, though, and said that “we have internally produced much, much better AIs” and that in the company’s subsequent clinical trials later this year, an increase in both sensitivity and specificity is expected.

### **Finding A Notified Body**

AI Medical Technology is clear with its intent to launch in Europe as soon as possible – beginning of fourth quarter this year if the company’s predicted timeline of Dermalyser’s CE marking is adhered to.

Ekström described the CE mark as the first culmination of “all the hard work” the company has done since being founded and explained that because Dermalyser will be the first product of its kind, AI Medical Technology had to build all the clinical evidence needed for approval from the ground up.

“There’s no shortcut – we had to do it the hard way, running proper clinical trials following ISO 14155. It’s a huge framework that is established to ensure we follow best practices and procedures, running trials that are safe to patients and of course that get the best data,” he said.

Part of the hard work involved contracting a notified body to assess Dermalyser. Ekström explained that his approach for contacting and negotiating with more than 30 notified bodies was to clearly outline his expectations regarding cost, timeline and quality, and then see what they offered in counter.

“We believe we got the best deal – they were able to give us a great price as well as the dates for the process,” he said. “My recommendation for anybody out there is to be a little bit tough. Don’t be too afraid of notified bodies. There’ll be tough but negotiate, look around and see what’s out there.”

### **“Be a little tough”**

As well as being tough with regulators, Ekström expressed the importance of being firm when negotiating with investors.

On 24 January, AI Medical Technology raised SEK10.8 (approximately \$1m) in a round led by Northern CapSek Ventures and joined by other private investors.

“In September, October, we were running short on cash – as we planned,” said Ekström. “I then reached out to my entire network of investors and a lot declined due to market conditions. We were about to be out of cash – I had salaries to pay and no money to do so.”

In the end, though, Ekström found support. “Over a few weeks I got on board all the investors I needed. During this time I kept cool because I really believed in the abilities of our company.”

When asked whether the tricky situation AI Medical Technology found itself in meant that higher proportions of equity had to be given away, Ekström said it was “actually quite the opposite.”

“Our trial outcomes and what we have is really, really good. I had the confidence to not give any discount or lower our valuation at all. That’s why things took a little longer,” he explained.

“We are sitting on a goldmine here and I refuse to give it up. A lot of people know that and some

investors respect our decision not to lower our valuation just because market conditions are not favorable.”

“In general, I do not care about public markets. If they’re good, I’ll pretend they act in my favor. If they’re bad, I’ll just ignore them,” said Ekström.