

Letter from the CEO

As we start 2022, I thought it a good opportunity to review some of the important events of 2021 and discuss our most recent progress.

The pandemic has during 2021 continued to play a role but even with the effects of Covid, it has still been a year including many milestones for SciBase.

SciBase Strategy, MDR and NMSC

SciBase's strategy is based on gaining traction for our melanoma detection test in key markets and leveraging our core technology Electrical Impedance Spectroscopy (EIS) in additional clinical applications. Each new application uses the same core EIS technology but utilizes a different Artificial Intelligence (AI) -based analysis that must be approved by regulatory authorities before it can be released. This year the EU introduced a new set of regulations called the Medical Device Regulation or MDR. SciBase was one of the first companies in Sweden, and within Dermatology in general, to be certificated under MDR. This was completed in May and meant that we could release our first new application module, Non-melanoma Skin Cancer (NMSC).

Today more than 100 sites have the NMSC module installed. Feedback from customers has been good and the module has been one of the key drivers to increase the number of system sales in Germany. We will continue to build on this module and improve it by incorporating clinical data from new studies as they happen.

Skin Barrier and Nevisense Go

SciBase's other 'new application' is the Skin Barrier application, and 2021 has also seen significant progress within this application. Like NMSC, it is based on the same EIS method and proprietary electrode but using barrier-specific AI algorithms. Because it is a relatively new method and application, the focus within barrier has been the research market and Industry collaborations. The goal over time is to develop multiple clinical applications that can be used by non-specialists and even eventually by patients in the home.

Two key articles published this year helped drive the interest in this area, and we have seen a steady increase in sales in this segment. Skin Barrier can be measured both on the Nevisense platform, and also with our new handheld device, Nevisense Go. Nevisense Go is a technological first – it is a handheld device based on SciBase's own integrated circuit for EIS, and it includes an embedded neural network that performs AI analyses at the point-of-care. It promises to be a powerful platform for diagnostic barrier-related testing and eventually other applications.

While a lot has happened within Skin Barrier in 2021, we are excited about what 2022 will bring. Barrier has significant potential within many areas, especially atopic dermatitis and other atopic disorders. Be sure to watch this space in 2022.

US Strategy and reimbursement progress

The US system for reimbursing physicians and their practices for their work is highly complex and introducing a new technology into this system takes time and resources. SciBase made significant progress during 2021 year on this front.

Our US strategy revolves around partnering with the large practice groups and together rolling out the technology across the group while simultaneously securing payment for the Nevisense test. Our key partner during 2021 has been the Advanced Dermatology and Cosmetic Surgery group (ADCS), which has its base (and 70 practices) in Florida. Based on the usage from more than 20 ADCS clinics in Florida, we submitted an application in May to the Medicare Contractor (MAC) for Florida, First Coast Service Organization (FCSO). On July 1st our CPT code became active and is now in use across the US.

The very good news is that First Coast is paying for the Nevisense test using our new code. This will help us with our applications to other regions or MACs and to private payers. There is however work remaining to raise the payment level our customers receive from First Coast. This cost level is based on customer's actual costs and our customers assist us in this process. This work is going on right now and we hope to see results early this year.

At the same time, we are working with our submissions to other MACs. Our second submission was made in December to NGS who cover the New York and North-Eastern US region (and several other states across the US). We will work our way through the different MACs until we have coverage across the major regions in the US. This process is based on building a customer base first in each region, so it takes time and resources. Finally, over the coming quarters, we will increase our activity addressing private payers (insurance companies) to cover Nevisense. We believe we have a good strategy and 'demand momentum' from clinicians for the product.

We expect 2022 to be a year of many milestones in the US, where we roll out Nevisense to more areas and clinicians in co-ordination with reimbursement applications. We will continue to strengthen the team in the US, expanding on the excellent work done so far.

Strengthened ownership base and Board

During the spring we carried out a successful directed issue where we welcomed new specialist investors such as Van Herk, ÖstVäst as well as Dr Matt Leavitt (founder of ADCS) amongst others. To attract strong, long-term specialist investors has been and will continue to be of strategic importance for SciBase so therefore this was an important milestone for us. We also strengthened the Board through the addition of Dr Matt Leavitt and Dr Jvalini Dwarkasing, and both are already helping drive the US strategy.

Though SciBase achieved several key milestones in 2021, the year was still significantly affected by the Covid-19 pandemic. Our customers' practices were for the most part open, but many had opening hours affected or periods of lockdown, and overall patient numbers are down compared to pre-Covid levels. In addition, sales and marketing activities remained (and still remain) at a reduced level for in-person contacts such as Congresses.

Now we look forward to 2022 and expect it to be a year when we show good sales growth. While German sales for melanoma have been the vast majority of our sales until now, we see rapid growth in the US and the new applications in the near future. So, we are working to transform the company from a single application, single market company – to a multiple market multiple product company. This is an exciting phase for the SciBase team that will present both opportunities and challenges, and we very much look forward to both.

I'd also like to take the opportunity to welcome two new members to the SciBase team. Fabio Munroe will drive the development of the Florida region and in Stockholm Alf Laurell assumes the role of Director Quality Assurance and Regulatory Affairs.

On behalf of the SciBase team I would like to thank you all for your interest in SciBase and wish you all the best for 2022!

Simon

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About SciBase and Nevisense

SciBase is a global medical technology company headquartered in Stockholm, Sweden, that has developed a unique point of care platform for the non-invasive detection of skin cancer and other skin conditions. SciBase is a pioneer within augmented intelligence, combining artificial intelligence with Electrical Impedance Spectroscopy (EIS) to provide objective information that assists dermatologists and others in clinical decision-making. SciBase's products include Nevisense and Nevisense Go and to date the platform addresses the areas of melanoma detection, non-melanoma skin cancer detection and skin barrier assessment. Nevisense is the only FDA-approved device for the detection of melanoma and the only MDR-approved technology for skin cancer detection in Europe. SciBase's technology is based on more than 20 years of academic research at the Karolinska Institute in Stockholm, Sweden. For more information please visit www.scibase.com.