

## **Letter from the CEO**

I trust that you have all had a safe and enjoyable summer. Given the high level of interest we have seen from you, our shareholders, I felt it time I update you on where we are as a Company and our plans for the near future.

We are making considerable progress in transforming SciBase from a single application Company built around melanoma detection to a platform Company with applications in several different clinical areas. We believe this will build significant shareholder value. With our unique platform and AI-based applications we are expanding our product line to address new markets with a large potential. Though there are many challenges in the current Covid-19 environment, I am very proud of the progress the team is making on this journey.

The summer has been extremely busy for SciBase. We have seen a return of the market for Nevisense tests in both Germany and the US after the negative effects we saw due to Covid-19 earlier this year. In addition to this return of base business, we have made real progress with our growth projects – our new clinical applications and our new platform, Nevisense Go. All this has been under the backdrop of a massive effort to secure certification under the new European medical device regulations, ‘MDR’ (Medical Device Regulation).

I will take you through each of these points, starting with Nevisense Go, as this is by far the topic we receive the most questions about from shareholders.

### **Nevisense Go – Release and next steps**

I am very pleased to announce that we expect to release the first version of the Nevisense Go platform on October 29<sup>th</sup> 2020. It has taken us a little longer than expected because of the pandemic and the very resource intensive MDR process, which we will discuss below. As previously communicated, this first version will be for the assessment of the skin barrier using inbuilt AI software. It will be fully functional as an impedance measurement device like Nevisense and utilize the same electrode and business model. It will however be simpler, easier to use and significantly less expensive.

This release of Nevisense Go is aimed at Industry partners and researchers within the area of skin barrier, though our aim is for Nevisense Go to eventually support all our clinical applications. Our activities so far lead us to believe that the market potential for research and Industry partners is significant and is a good first step for the product. The product can be used to investigate the skin barrier but is not as of yet linked to any clinical indications (such as eczema or melanoma).

Nevisense Go is the culmination of more than four years of work together with KTH Royal Institute of Technology and our clinical partners SIAF in Davos, but on the other hand is just the very first step for the platform. Our focus is now to continue to develop the platform and to collect clinical data so that we can perform the regulatory work needed to release indications starting next year.

### **COVID-19 and the Market**

The pandemic had a significant effect on our customers in Germany and New York during the second quarter, and also slowed our rollout with Advanced Dermatology and Cosmetic Surgery (ADCS) somewhat. We saw however, increased interest in our products from the beginning of June and the return of orders from existing customers. This is very positive, though in general for

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the industry, customers have remained hesitant to invest in new devices. Overall, the third quarter appears back on track, and this is driving our hope that we will achieve one of our goals for 2020 - profitability in the Germany market on a local basis.

The bottom line is that after a very tough period the market, customers and patients are returning.

### **New applications and MDR**

SciBase is entering a phase where we move from a single indication (melanoma) to multiple indications by adding non-melanoma skin cancer (NMSC) and skin barrier assessment. All indications are based on the same base Electrical Impedance Spectroscopy (EIS) + AI technology, the same electrode technology, and the same business model.

The release of new applications covering these indications is closely intertwined with the introduction of the new EU medical industry regulations, MDR. A company wanting to sell in Europe must have MDR in place if they wish to approve new indications, even if MDR only becomes mandatory from May 2021.

Our NMSC application is an add-on software module for Nevisense and as such will be targeted at the same customer group as melanoma. The product is complete and is awaiting approval under MDR. The initial clinical data evaluation has been positive. When released, we expect many customers to add this functionality and hope that the combination also helps us attract new customers. Though NMSC usually has a lower risk profile than melanoma, there are many more patients with NMSC than with suspected melanoma – in Sweden for example the ratio is at least 10 to 1.

Skin Barrier assessment is actually a group of applications that are linked to diseases connected to the skin barrier. We see uses for our technology in the prediction, improved diagnosis, and management of atopic diseases such as atopic dermatitis (eczema) and food allergies. These are very common diseases, and we see a large potential. The first step as discussed above is the release of Nevisense Go for barrier measurement and we are targeting Industry partners and researchers where we are collecting data to support new barrier applications.

### **US progress**

It was very pleasing to see the publication of two new studies in JAAD and SKIN last week from Professor Darrel Rigel's team in New York. The reader studies evaluated the impact of Nevisense information on clinicians' decision-making. Nearly 600 US clinicians performed over 25,000 evaluations comparing management decisions first using visual evaluation only, and then with the addition of Nevisense information. The results were impressive – an average improvement in sensitivity of 14% (ability to detect melanoma) and an average improvement in specificity (ability to correctly classify as benign) of over 10%.

We have installed 6 systems in clinics in Florida and Michigan with our partner Advanced Dermatology and Cosmetic Surgery. We have several further installations planned and our hope is that we can move this first phase forward over the coming weeks.

We see the current period as the beginning of the next phase in the development of SciBase as a company. We will continue to build on our melanoma business not only in Germany, but also in the US. We will start the transition from Nevisense to Nevisense Go and in doing so broaden our customer focus. And finally, we will start the transformation from a 'single product company' to a

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company with multiple legs to stand on with the addition of NMSC and Barrier. We are making considerable progress and have laid the foundation for accelerated future growth.

Best Regards

Simon Grant, CEO

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**About SciBase and Nevisense**

*SciBase AB is a Swedish medical technology company, headquartered in Stockholm that has developed and sells a unique point-of-care device for evaluation of skin disorders such as skin cancer and atopic dermatitis. Its first product, Nevisense, helps doctors to detect malignant melanoma, the most dangerous type of skin cancer. Further development has led to Nevisense also being used as a tool to assess the skin barrier and inflammation. SciBase was founded by Stig Ollmar, Associate Professor at The Karolinska Institute in Stockholm, Sweden. Nevisense is based on substantial research and has achieved excellent results in the largest clinical study ever conducted on the detection of malignant melanoma. Nevisense is CE marked in Europe, has TGA approval in Australia and an FDA approval (PMA) in the United States. Nevisense is based on a method called Electrical Impedance Spectroscopy (EIS), which uses the varying electrical properties of human tissue to categorize cellular structures and thereby detect malignancies and abnormalities. SciBase is listed on First North Growth Market ("SCIB"). Further information is available at [www.scibase.com](http://www.scibase.com)*