

## Closing the valuation gap driven by 90% likelihood of achieving US reimbursement – which is a license for medtechs to print money

Obtaining payment for medtech products from government bodies and private insurance companies is generally not a clear-cut route, and breaking into the US market is key for medtech companies to drive sales growth. Challenges in this area are common reasons why early-stage commercial medtech companies become stranded; consequently, some investors avoid these early-stage companies prior to them showing traction in the payor process. The flip side to this exact same coin is the good news; the stock market rewards medtech companies handsomely when they break through, unlock payor coverage, and deliver consecutive commercial advances translating into steady sales growth.

We believe SciBase has built the necessary enablers to accelerate its topline growth and embark on a positive trajectory in the same direction as local peers such as Sensime and Redsense Medical. With a market value of SEK 200m in contrast to Sensime's and Redsense Medical's values of approximately SEK 1.3bn and SEK 660m, respectively, there are clearly numerous essentials with deep value in SciBase's case that are being overlooked. We believe the commercial prospects of SciBase are suppressed behind a thick wall of painful memories.

### US-launch anchored with the largest dermatology network and a 90% likelihood of achieving reimbursement

- Commercially de-risked roll out of Nevisense 3.0 with Advanced Dermatology and Cosmetic Surgery (ADCS) group- the premier dermatology network in the US with over 150 practices aiming to "bring more science into Dermatology" through the adoption of Nevisense.
- SciBase has been granted a Category III CPT® code by American Medical Association. Once in effect, estimated in July 2021, the code becomes automatically available to all providers, including Medicare and Medicaid advantage providers. The code is an important step towards securing payment coverage in the US and broaden market adoption. There is a high likelihood that CMS MACs will assign reimbursement to the code in initially selected states (NY/tri-state area and Florida); we estimate a 90% likelihood on the basis of 1) recent enactment of CMS legislation to provide coverage of CPTIII (40%); 2) Nevisense being a PMA product with extensive documentation on clinical efficacy and utility (15%); 3) a high level of need in the Medicare population (10%); 4) solid record of payments from private payers and generation of claims from local providers, being accelerated in collaboration with ADCS (15%); and 5) support from KOLs and providers (10%). We ascribe the last 10% to execution risk.

We initiate coverage with an Outperform rating and a target price of SEK 7.5, corresponding to an equity value of SEK 413m non diluted. Our target price is derived from a DCF valuation of the initial opportunity in melanoma and non-melanoma skin cancer in the key markets Germany and US, limited to initially selected states. We have not baked in any upside from other applications under way.



## OUTPERFORM

### Initiating Coverage

Target price: SEK 7.5  
Current price (close 12/11): SEK 3.66  
Implied upside potential: 105%

#### SciBase at a glance

SciBase develops unique point-of-care devices for the evaluation of skin disorders such as skin cancer and atopic dermatitis, based on Electrical Impedance Spectroscopy combined with Artificial Intelligence. The first product, Nevisense, helps clinicians detect melanoma. Further development has led to Nevisense also being used to assess the skin barrier and non-melanoma skin cancer. Nevisense is CE marked in Europe, has TGA approval in Australia and FDA approval (PMA) in the US for melanoma detection.

#### Share price development (index= Nov 12, 2019)



#### Key Data

As per 2020-11-12

Ticker	SCIB
Share price (close)	SEK 3.66
Free float	82.7%
Market cap	SEK 200m
Website	www.scibase.com
Average daily volume	SEK 0.39m

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## A value gap is to be closed between SciBase and local peers

Usually, the stock market rewards early-stage commercial medtech companies on the back of consecutive commercial advances translating into steady sales growth. Demonstration of commercial advances signals traction and de-risks the profile of the company, which is typically followed by institutional ownership and a positive stock growth trajectory. Redsense Medical (REDS: Spotlight) and Sensime (SEZI: FN) serve as two recent examples with such development and we grant them a bravo for their successes.

When examining essential factors determining medtech companies' likelihood of achieving longer-term commercial success such as depth of innovation and platform applicability with clear competitive advantages; clinical and health-economic evidence; regulatory approval and barriers; reimbursement landscape; partners etc. – it is noteworthy that SciBase is at least as attractively positioned as compared to Redsense Medical and Sensime. Despite SciBase's advancements over the past year, it is evident that the market sentiment is stuck in the past, still assessing the case in accordance with its legacy which does not reflect the reality of the SciBase's attractive position today.

We believe the commercial prospects of SciBase are suppressed behind a thick wall of painful memories. In this report, we will give a comprehensive case for why we believe one should set aside legacy and emotions for the benefit of evidence for how SciBase is closing the valuation gap to its local comparable peers.

### The Investment Case

We believe, SciBase has built the necessary enablers to accelerate its topline growth and embark on a positive trajectory in the same direction as Sensime and Redsense Medical. However, with a market value of SEK 200m in contrast to Sensime's and Redsense's values of approximately SEK 1.3bn and SEK 660m, respectively, there are clearly numerous essentials in SciBase's case being overlooked.

SciBase's engine for growing sales is its AI and Electrical Impedance Spectroscopy (EIS)-based technology platform, where the first application of the point-of-care diagnostic Nevisense for melanoma detection has picked up significant momentum; positioned for expansion in the two key markets driving growth, Germany and the US. Pre-COVID-19, the 3rd generation of Nevisense generated 6 consecutive quarters with sales growth, primarily driven by increased adoption in Germany. In parallel, SciBase has built up initial US traction at private clinics, having positive progress of reimbursement of manual insurance claims.

### German market is penetrated at about 15% and growing to SEK 50m at full penetration of the achievable market

The majority of SciBase's annual sales of SEK 9m (2019) stem from Germany, from privately insured patients for which SciBase's EIS technology, Nevisense, is successfully reimbursed. This *achievable* market, defined as the privately insured patients and the cases where Nevisense is clinically applicable, represents a total of SEK 50m in sales/year in our conservative estimate. We estimate that SciBase currently has a market penetration of about 15% and should within five years grow their share to at least 50%,

corresponding to SEK 25m in sales per year; sales from self-pay is an upside to that figure. The growth in Germany going from current levels up to SEK 50m at full penetration will primarily be driven by the launch of Nevisense to assess non-melanoma skin cancer (NMSC). The new clinical application is ready for launch in key EU markets subject to MDR registration of SciBase which we expect by the end of Q1 2021.

Non-melanoma skin cancer (NMSC) represents a significant growth driver; NMSC is common with patients numbering ten times that of melanoma, and the customers are the same as those targeted today for melanoma detection, thus enabling a faster roll-out and penetration and as such, growing the use in both melanoma and NMSC. There has been a clear customer demand for this application in Germany where there is off-label use and reimbursement already in place for the EIS procedure with Nevisense.

**The most important growth driver ahead is successful penetration of the US market**

With roll-out recently initiated with US' largest dermatology practice network, Advanced Dermatology and Cosmetic Surgery (ADCS), and a high 90% likelihood of CMS MACs<sup>1</sup> attaching reimbursement to the recently granted a Category III CPT® (CPTIII) code in selected states, SciBase is ticking off the boxes to begin a deep penetration of the US market under Medicare coverage and achieve a successful launch. Focusing primarily on the initial key states – the New York/tri-state area and Florida – the achievable market as regards Medicare and private insurance coverage is estimated to USD 40-50m/year. Achieving a 50% market penetration over a 10-year period, i.e. rendering about SEK 200m in annual sales from these initial states, is highly reasonable with roll-out through practices provided Medicare coverage and private insurance coverage. Subject to Medicare coverage in selected states, estimated in early July 2021, private insurers and other payers are likely to follow. In parallel, local coverage and successful progress with ADCS is also likely to trigger additional partnerships with other dermatology practice groups, following ADCS's lead. The rest of the US provides additional upside, where California is another important state.

On top of the initial opportunity in melanoma and NMSC presented above – is skin barrier assessment, representing a substantial market opportunity and where we see high potential for partnerships with Big Pharma. Furthermore, the portable Nevisense Go expands the applicability of SciBase's EIS technology outside specialist clinics.

Obviously, SciBase's ability to execute and drive steadily increasing operating leverage is critical for fully closing the gap in valuation. However, the valuation gap is presently unproportionally large. We believe the stock is way too cheap to be ignored and investors seeking a growth story should re-imagine SciBase's investment case.

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<sup>1</sup>Center for Medicare and Medicaid Services (CMS), the federal body that manages the Medicare and Medicaid programs and provides oversight of Medicare contractors. CMS relies on a network of MACs (Medicare Administrative Contractors) to serve as the primary operational contact between the Medicare program and health care providers. The MACs have been awarded a geographic area or "jurisdiction" to regionally manage policy, medical claims and reimbursement under Medicare. Local Coverage Determinations (LCDs) are decisions made by a MAC whether to cover a particular item/service in a MACs region.

## A closer look at the key enablers positioning SciBase for growth

### The third-generation device is re-designed and fits into clinical workflow

- Nevisense 3.0, the third generation of the Nevisense system for early melanoma detection has since its introduction in late 2018 in Germany and the EU been the catalyst for year-on-year quarterly sales growth for six consecutive quarters until the impact of COVID-19. Sluggish uptake of previous product generations has largely been due to the fact that these did not fit into clinical workflow. However, Nevisense 3.0 has been optimized for this purpose – validated through the markedly increasing adoption of the device in Germany and partnership with US' largest dermatology chain, ADCS, for roll out on the US market. After a second quarter hampered by COVID-19, the company sees the market returning and achieves local profitability in Germany in the third quarter.

### Technical and regulatory risk should be deemed as eliminated

- Nevisense is approved in the US for detection of Melanoma through the PMA pathway – FDA's most rigorous process for approval of new medical devices for the US market. Hence, technical and regulatory risks should be deemed as eliminated. Nevisense remains the only FDA approved system for melanoma detection in the US.
- Clinically validated with comprehensive package of robust clinical and health-economic documentation demonstrating the clinical value of Nevisense for accurate and objective detection of melanoma. Has German reimbursement for privately insured patients through an analog code, meaning that payment is connected to the EIS procedure; the code can therefore be applied for new applications such as NMSC as well as melanoma detection. Clinical guideline for the use of Nevisense in the evaluation of lesions with suspicion of melanoma has been published in Germany, backed by the German dermatology society for skin cancer prevention and therapy, Onkoderm, which also includes a reimbursement recommendation. The launch of Nevisense 3.0, together with inclusion in German guidelines, contributed to sales growth of more than 30% in 2019 in Germany, driven by a 50% increase in the number patients tested.

### US-launch anchored with the largest dermatology network and a 90% likelihood of achieving reimbursement

- Commercially de-risked roll out of Nevisense 3.0 with ADCS – the premier dermatology network in the US with over 150 practices aiming to “bring more science into Dermatology” through the adoption of Nevisense. If that isn't a testament to the clinical value of Nevisense, then we don't know what is.
- Furthermore, SciBase has been granted a CPTIII code by American Medical Association (AMA). Once in effect, estimated in July 2021, the code becomes automatically available to all providers, including Medicare and Medicaid advantage providers. The code is an important step towards securing payment coverage in the US and broaden market adoption. There is a high likelihood that CMS MACs will assign reimbursement to the code in initially selected states (NY/tri-state area and Florida); we estimate a 90% likelihood on the basis of 1) recent enactment of CMS legislation to provide coverage of CPTIII (40%); 2) Nevisense being a PMA product with extensive documentation on clinical efficacy

and utility (15%); 3) a high level of need in the Medicare population (10%); 4) solid record of payments from private payers and generation of claims from local providers, being accelerated in collaboration with ADCS (15%); and 5) support from KOLs and providers (10%). We ascribe the last 10% to execution risk.

### Market expansion through launch of pipeline indications

- Nevisense 3.0 for non-melanoma skin cancer (NMSC): ready for launch in Germany pending MDR registration of SciBase which we expect by the end of Q1 2021. NMSC presents a significant growth driver aimed primarily at Germany to drive sales. NMSC is very common with patients numbering ten times that of melanoma, and the customers are the same as those targeted today, thus enabling rapid roll-out and penetration and as such, growing the use in both melanoma and NMSC. There has been a clear customer demand for this application in Germany where there is off-label use and a positive case for reimbursement already in place as the EIS procedure is successfully reimbursed for privately insured patients.
- Nevisense Go for barrier assessment. Nevisense Go represents the next generation product platform of SciBase's technology. The product is flexible and portable, easier to use, increases operational cost-effectiveness, and expands SciBase's technology to new areas outside clinics. The primary focus near-term is to roll out the product for skin barrier assessment, where SciBase is first in the world to introduce an AI-algorithm for assessment of skin barrier. The product targets initially researchers and industrial partners, where first sales to an undisclosed "major industrial player" are being delivered. We believe Big Pharma has a great interest in the area given increasing therapeutic attempts and blockbuster sales of therapeutics such as Dupixent®, and we see tremendous potential for partnership with Big Pharma.

To conclude: SciBase has worked systematically to build up and organize a robust growth engine around a highly innovative platform technology, set to materialize commercial prospects and drive growth.

### How deep is the value gap between SciBase and peers?

Two great companies that we salute and regard as peers to SciBase in terms of commercial stage maturity are Redsense Medical and Sensime. Redsense Medical (market cap approx. SEK 660m) is right now enjoying higher demand created by extraordinary factors beyond the company's proprietary achievements: 1) The Trump administration's initiative to create new financial incentives and payment structures to promote kidney disease prevention, where one key effort was to encourage in-home dialysis and transplants over in-center treatment; and 2) the COVID-19 pandemic, accelerating transition to in-home dialysis.

Sensime (market cap approx. SEK 1.3bn), is relative to Redsense and SciBase earlier in their commercialization process with regard to the US market. We focus primarily on the US market in this comparison, as it is by far the most important market for medtech companies to succeed in to drive long-term sales growth. Sensime received 510(k) approval in October 2019 and has communicated financial goals; it "shall reach at least SEK 200 million in revenue in 2023, corresponding to a sales increase of 100% vs. 2022". This is surely an ambitious goal based on 2019 net sales of SEK 6.7m.

Cellavision's sales ramp up may serve as benchmark when assessing the probability of Senzime's financial goals coming true. Cellavision's revenue ramp up from SEK10 m beyond the SEK 100m mark took 7 years.

See the table below for a head to head comparison. Legacy and emotions aside; if you fail to find deeper value in SciBase's case by now, please do not continue reading this report.

	<b>Senzime</b>	<b>Redsense Medical</b>	<b>SciBase</b>
<b>Main Product/Technology</b>	TetraGraph®, a digital system based on electromyography for monitoring patients undergoing anaesthesia with neuromuscular blocking agents. To prevent residual neuromuscular blockade and related complications.	Redsense system, based on technology utilizing fiber optics to monitor for potential blood loss from the hemodialysis access site in patients undergoing hemodialysis treatment.	Nevisense, first application of the AI and Electrical Impedance Spectroscopy (EIS)-based technology platform for an objective and accurate detection of melanoma.
<b>Regulatory EU/US</b>	CE-marked 510(k) – Oct 2019	CE-marked, MDR registered 510(k) approval, 2007-2015	CE-marked, MDR underway PMA approved 2017, recent 3.0 version approved Apr 2020.
<b>Reimbursement</b>	Providers receive bundled per 'treatment' payment for surgeries (should cover all costs related to the procedure.)	Providers receive bundled per treatment payment for dialysis services (incl drugs and all costs related to the service)	Use of Nevisense for melanoma application obtained specific CPTIII code by AMA
<b>Commercial strategy/ Partners</b>	Distributors and sales organisation in US.	Partnerships with distributors and healthcare providers.	Local sales team Germany. Distributors, partnerships with providers/practice groups such as ADCS in US. Focus partnerships for other applications.
<b>2019 Full year net sales</b>	SEK 6.7m, incl. SEK 1.8m license payment from Japanese partner Fukuda Denshi. (SEK 3.2m, incl SEK 2.4m license payment from Fukuda Denshi)	SEK 13.3m (SEK 7m)	SEK 9.3m (SEK 6.9m)
<b>Net sales rolling 12 mos. Q4 2019- Q3 2020</b>	SEK 8.5m (SEK 6.7m)	SEK 17.2m (SEK 11.9m) Profitable Q1 2020	SEK 9.3m (SEK 8.5m) Locally profitable Germany Q3
<b>Market cap</b>	SEK 1 285m	SEK 657m	SEK 200m
<b>Cash</b>	SEK 76m	SEK 6m	SEK 22m
<b>Technology value (EV)</b>	SEK 1 209m	SEK 651m	SEK 178m

Source: Information obtained from companies' websites and financial reports. Technology value (EV) defined as Market cap - latest cash balance (Q3 2020). Market cap as per 2020-11-12 (capitaliq.com). Cash as per 2020-09-30, company financial reports

## AI and EIS – based technology platform, with first application launched in the US market and a 90% likelihood of achieving reimbursement

SciBase's unique technology platform is based on Electrical Impedance Spectroscopy (EIS), a relatively new patented technology developed for use on skin for over 20 years at Karolinska Institute. EIS works by transmitting a harmless electrical signal through the skin (epidermis and dermis) at several depths and frequencies and measuring the electrical response, influenced by certain properties of tissue integrity and structure. EIS measures human tissues' resistance to the flow of alternating currents of various frequencies, reflecting the pathophysiological status of the tissues as normal and abnormal tissues may differ with regard to cell size, shape, orientation, compactness and structure of cell membranes. As such, the technology has potential to be applied

and developed for use in a wide range of skin disorders. Combined with advanced Artificial intelligence (AI) algorithms, the EIS analysis is translated into an output specific for the clinical application.

The first application of the proprietary AI and EIS-based technology is the point of care diagnostic product Nevisense for accurate and objective detection of melanoma, supporting standard of care visual examination – a highly subjective procedure correlated to the skill of the physician which frequently results in misdiagnosis. Optimized to fit into clinical workflow, the third generation of Nevisense (Nevisense 3.0) has since its introduction in late 2018 in Germany accelerated adoption.

### **A positive case for broad US reimbursement, on track for adoption from 2021 onwards**

In our view, the traction demonstrated in Germany with the latest generation of Nevisense provides an outlook for future development in the US – THE key market to succeed in to accelerate sales growth. Initial US traction has been built up in the New York/ tri-state area with the predecessor to Nevisense 3.0 at private clinics, generating repeat orders from well-renowned customers as Advanced Dermatology PC, among others. The US customers have positive progress with the manual insurance claims process as the majority of claims to private insurance companies are reimbursed. Payers are typically careful in providing coverage for procedures that do not have an established code; thus, the high approval rate is a very positive indication, substantiating the likelihood of broader payor coverage to follow.

SciBase focuses initially on the US northeast tri-state area and Florida, and on establishing broad reimbursement coverage. As private equity investment drives a consolidation of US dermatology practices into groups across the US, the company can achieve a wide penetration of the market, without building a larger local sales organization, through collaborations with practice groups, such as the one with ADCS. Several groups are being targeted, and progress with a leader in the field such as ADCS in combination with Medicare coverage in selected states is likely to trigger a positive spread across other groups. Provided that Medicare coverage of the CPTIII code is in place next year in selected states, while roll-out of Nevisense 3.0 is progressing with ADCS across their >150 practices, SciBase should witness a rapidly increasing adoption translating into topline growth from next year onwards.

The designated CPTIII code will be officially live in the coding system from 1 July next year meaning that it becomes automatically available to all providers, including Medicare and Medicaid advantage providers, opening up Nevisense for key target population of 5m seniors in Florida and 3.5m seniors in NY. When the code is "effective" customers will be able to easily submit claims for reimbursement through existing billing systems. This will help track utilization which will support the company's effort to achieve broader coverage. There is a high likelihood that CMS MACs will assign reimbursement to the code in these initially select states; we estimate a 90% likelihood on the basis of 1) recent enactment of CMS legislation to provide coverage of CPTIII (40%); 2) Nevisense being a PMA product with extensive documentation on clinical efficacy and utility (15%); 3) a high level of need in the Medicare population (10%); 4) solid record of payments from private payers and generation of claims from

local providers, being accelerated in collaboration with ADCS (15%); and 5) support from KOLs and providers (10%). We ascribe the last 10% to execution risk.

SciBase has a comprehensive package of robust clinical and health-economic documentation demonstrating the clinical value of Nevisense for accurate and objective detection of melanoma. Relative to other smaller Scandinavian medtech companies that are establishing themselves in the US, SciBase's data package is outstanding. In order to further support payor coverage, drive acceptance among specialists and key decision makers in the US market, the company has reinforced its data package with peer reviewed data from US reader studies<sup>2,3</sup>, evaluating 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. This is the first time such studies have been published with Nevisense, and they were carried out across three different clinician groups (Dermatologists, Physician's assistants and residents) with a range of experience levels. The results demonstrate clearly that Nevisense improves both clinicians' ability to accurately detect melanoma and clinical management decisions. This US demonstration of clinical utility will be of high value to achieve broader payor coverage, and to support the use of Nevisense by mid-levels and less-experienced Dermatologists.

#### **Roll-out with ADCS progressing in parallel with reimbursement, setting the scene for synergistic growth effect**

Shortly after FDA approval of Nevisense 3.0, April 2020, the company announced collaboration agreement with ADCS - the premier dermatology network in the US with over 150 practices of care located across 14 states aiming to "bring more science into Dermatology" through the adoption of Nevisense. If that isn't a testament to the clinical value of Nevisense, then we don't know what is. The agreement will provide ADCS practices with Nevisense 3.0, the only FDA approved melanoma detection system, for the analysis of patients' atypical moles at point-of-care. Under the agreement, Nevisense 3.0 will initially be installed in 20 clinics to evaluate practice workflow integration, followed by expansion within ADCS's large network of practices. The initial pilot is ongoing and we expect an update on progress from all 20 clinics in early 2021. Subject to positive outcome, the installation of Nevisense will expand across ADCS +150 practices. From 2021 is when we expect meaningful contribution to SciBase's topline. The expansion across >150 practices in combination with local coverage in selected states is a recipe for rapid adoption, synergistically accelerating growth; both Medicare coverage and positive outcome from the initial evaluation and subsequent rollout in ADCS's network is also very likely to trigger the interest of other dermatology practice groups, following ADCS's lead.

While the commercial roll-out progresses, ADCS and SciBase will also collaborate on scientific research and the evaluation of new products addressing other skin conditions.

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<sup>2</sup> Litchman, Graham H. et al. (2020) Impact of Electrical Impedance Spectroscopy on Dermatologists' Number-Needed-to-Biopsy Metric and Biopsy Decisions for Pigmented Skin Lesions. *Journal of the American Academy of Dermatology*. <https://doi.org/10.1016/j.jaad.2020.09.011>

<sup>3</sup> Litchman, Graham H. et al. (2020) Integrating Electrical Impedance Spectroscopy into Clinical Decisions for Pigmented Skin Lesions Improves Diagnostic Accuracy: A Multitiered Study. *SKIN The Journal of Cutaneous Medicine*. <https://doi.org/10.25251/skin.4.5.5>

**Nevisense remains the only FDA approved system for melanoma detection in the US**

For the detection of Melanoma, Nevisense is classified as a class III medical device in the US (elsewhere class IIa), requiring pre-market approval (PMA). The PMA process includes studies with FDA oversight due to the increased risk posed by the device or lack of similarity to previously approved devices or techniques. During this process, SciBase has conducted the largest study ever conducted in melanoma detection devices. The study involved 1,951 patients at 22 different sites in the US and Europe. Due to the resource-intensive and difficult process, only 20-30 companies per year complete the PMA process, whereof most are larger companies. SciBase is rare in the sense of being one of only a handful of Swedish companies that has undergone and completed a PMA process successfully. Nevisense remains the only FDA approved system for melanoma detection in the US. Hence, technical and regulatory risks should be deemed as eliminated.

**Razor-razorblade business model**

SciBase operates with a razor-razorblade business model which indicates high scalability and possibilities to reach attractive margins. The model relies on customers purchasing the Nevisense (tablet and probe) initially, and then purchasing disposables (electrodes) regularly, creating a recurring revenue stream. Consequently, the revenue stream is dependent on the implementation of Nevisense in the clinical setting, in conjunction with the health-economic benefits that the device will establish, if integrated into the systems as a new standard of care, and essentially, granted reimbursement.

**Driving growth: new applications launched to expand customer base and increase usage**

**Nevisense 3.0 for non-melanoma skin cancer (NMSC):** ready for launch in key EU markets such as Germany pending MDR registration of SciBase which we expect by the end of Q1 2021. The application is primarily aimed at Germany to drive sales. NMSC is very common with patients numbering ten times that of melanoma, and the customers are the same as those targeted today, thus enabling rapid roll-out and penetration, growing the use in both melanoma and NMSC in Germany. There has been a clear customer demand for this application in Germany where there is off-label use and a positive case for reimbursement as the EIS procedure is successfully reimbursed for privately insured patients.

**Nevisense Go for skin barrier assessment.** Nevisense Go represents the next generation product platform of SciBase's technology. The product is portable and flexible, easier to use, increases operational cost-effectiveness and expands SciBase's technology to new areas outside clinics. The primary focus near-term is to focus the product for skin barrier assessment, where SciBase is first in the world to introduce an AI-algorithm for assessment of skin barrier. The product targets initially researchers and industrial partners, where first sales to an undisclosed "major industrial player" are being delivered. First product sales to research were delivered under Q3 2019.

The skin barrier application assessment introduces a key long-term growth driver. The application represents a group of diseases connected to the skin barrier – a new ‘hot’ emerging field in research and industry, where SciBase’s technology has potential to be applied in the prediction, improved diagnosis, and management of very common atopic diseases such as atopic dermatitis (eczema) and food allergies<sup>4</sup>. Given the emerging focus in the area among Big and Specialty Pharma companies, triggered by commercial gains generated by blockbuster drugs such as Dupixent®, we predict that SciBase’s technology will be of high interest for them to integrate and we therefore see high potential for partnerships. Underpinning our argument further, is the fact that SciBase’s EIS technology can be applied to investigate and develop transdermal drug delivery<sup>5</sup>.

The challenge is that the method used to measure skin barrier function, called Trans Epidermal Water Loss (TEWL) can not be used in daily clinical practice as it is time consuming and very sensitive to environmental and patient artifacts.

As discussed above, Nevisense Go for skin barrier assessment targets initially research and industrial partners. As such, it has currently no clinical indication, and it is presently not classified as a medical device. While the main advancements of this application will presumably be conducted in collaboration with partners, we also believe that SciBase will allocate resources to conduct sponsor-driven studies to support the advancement of clinical applications.

## Competitive landscape

Overall, SciBase benefits from favourable competitive positioning in all applications, and we cannot identify any product in development or on the market that would pose a serious threat.

For detection of melanoma, the competitive marketplace has changed in the last 2-3 years and Nevisense is the only device available now in the US approved for detection of melanoma. There are researchers that appear and publish a small study every now and then, but the need for large studies like SciBase’s pivotal study and a PMA has so far stopped all potential competitors.

The closest and most active ‘competitor’ is DermTech (DMTK: NASDAQ CM, market cap SEK 2.2 bn), using non-invasive gene-expression testing to detect melanomas. The test is licensed under CLIA and can be used for laboratory testing. DermTech’s product uses adhesive patches to sample RNA for suspicious lesions that are sent to DermTech’s laboratory for RNA extraction and rtPCR, and the results are then sent back to the dermatologist after five- ten days. While DermTech has several advantages, we believe that Nevisense outshines these and offer higher value for clinical use. This is also supported by the fact that ADCS actively chose Nevisense to improve melanoma

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<sup>4</sup> Rinaldi, AO, Morita, H, Wawrzyniak, P, et al. (2019). Direct assessment of skin epithelial barrier by electrical impedance spectroscopy. Allergy. <https://doi.org/10.1111/all.13824>

<sup>5</sup> Morin, M., Ruzgas, T., Svedenhag, P. et al. (2020) Skin hydration dynamics investigated by electrical impedance techniques in vivo and in vitro. Sci Rep. <https://doi.org/10.1038/s41598-020-73684-y>

detection. The fact that DermTech is progressing rather shows the need to introduce objective methods for melanoma detection.

Limitations/disadvantages of the test and DermTech:

- Not point-of-care – requires laboratory analysis and many clinicians instead feel it is just as easy to do a shave biopsy.
- Process takes time as it requires 5 tape strips to be taken and sent to laboratory
- Test takes up to ten days to receive an answer
- No reimbursement to Dermatologist
- Challenges to collect enough skin material for an adequate analysis.

Advantages of the test and DermTech:

- Reasonable sensitivity and good specificity, but limited data.
- The laboratory side has reimbursement
- US-based with high marketing activity
- good funding level through Alpha Capital Corp

For NMSC and skin barrier assessment we cannot identify any approved direct competitor. Trans Epidermal Water Loss (TEWL) is used in research to measure skin barrier, but it cannot be used in daily clinical practice as it is time consuming and very sensitive to environmental and patient artifacts.

## Outlook

Below follows near-term events that we forecast for SciBase and Nevisense.

- Q1 2021: MDR registration, triggering launch of NMSC in Germany. Launch in other EU markets will be evaluated.
- Q1 2021: Pilot phase with ADCS completed, followed by roll out across its +150 practices and translation into sales for SciBase
- H1 2021: First partner for skin barrier assessment
- Q3 2021: CPTIII code live and negotiations with CMS MACs to achieve local coverage of code in at least one of the selected states finalized.

## Risk Analysis

This section provides an overview of the company's risk profile and how we deem it positioned with regard to key risks pertaining to early commercial medtech companies. We focus primarily on SciBase's initial strategic focus in melanoma and NMSC. Visibility into Nevisense Go and skin barrier assessment remain quite limited, and we look forward too following updates providing further details into the company's short to long-term outlook.

Risks	Risk mitigation identified
Team and BoD	Vast experience in medtech and international commercialization among management and BoD. Backed by Scientific Advisory Board composed of world-leading dermatology experts. In addition, established KOL-network including high level KOLs in melanoma and barrier.
Technical risk	Should be deemed as eliminated: <ul style="list-style-type: none"> <li>• FDA approved device for melanoma detection through the PMA pathway.</li> <li>• NMSC ready for launch upon MDR registration of SciBase, expected by the end of Q1 2021. High demand in Germany.</li> <li>• Robust data package.</li> </ul>
Clinical risk	Nevisense 3.0 optimized to fit into clinical workflow, validated through German adoption and commercial roll-out in the US with ADCS. Wide adoption will be dependent on gradual reimbursement unlocking, see below.
Commercial risk	<p>Main risk in this case. SciBase's ability to execute and drive steadily increasing operating leverage is critical for fully closing the gap in valuation. Successful penetration of the US market is key to accelerate growth in the years ahead. Adoption is dependent on unlocking broad reimbursement, starting with Medicare coverage in key selected states. We see a high likelihood that CMS MACs will assign reimbursement to the code in these initially select states; we estimate a 90% likelihood on the basis of;</p> <ol style="list-style-type: none"> <li>1) recent enactment of CMS legislation to provide coverage of CPTIII (40%);</li> <li>2) Nevisense being a PMA product with extensive documentation on clinical efficacy and utility (15%);</li> <li>3) a high level of need in the Medicare population (10%);</li> <li>4) solid track record of payments from private payers and generation of claims from local providers, being accelerated in collaboration with ADCS (15%);</li> <li>5) support from KOLs and providers (10%).</li> </ol> <p>We ascribe the last 10% to execution risk.</p>
IP risk	<p>Extensive coverage through 63 approved patents divided into six families and an additional two families in process. Approved patents provide coverage until at least 2030, excluding extension. Patent applications in process extends coverage, once granted, until at least 2028.</p> <p>The most significant protection, however, is the clinical data collected and trials performed as basis for PMA and approvals in EU and Australia, providing high barriers to entry. In addition, the technology is inherently difficult to copy as it benefits from &gt;20 years of development, with extensive experience and knowhow retained in the company.</p>

Source: Vator Securities

## Valuation

### Outperform rating and target price SEK 7.5

We initiate coverage with an Outperform rating and target price of SEK 7.5 per share. Our target price is based on a DCF valuation of the initial opportunity in NMSC and melanoma in the key markets US and Germany with Nevisense 3.0. While Nevisense Go expands SciBase's technology to new areas outside the clinics and Skin barrier represents a larger opportunity than melanoma and NMSC combined, visibility into the short- to long-term outlook remains quite limited. We therefore currently consider these new applications as upsides to our target price for the 12 months ahead.

### We forecast sales of SEK 248m in 2031

Our financial outlook is based on the company's initial strategic focus with Nevisense 3.0, i.e. melanoma detection in selected states in the US and melanoma and NMSC assessment in Germany. Our forecast is built on usage, i.e. electrode sales. We do not include installation of new systems as we calculate these revenues to make up 2% of total net sales at the end of the forecast period.

#### US

- Focus initially on New York/tri-state area and Florida. Local medicare coverage from 2021, followed by a gradual increase in coverage by private insurers.
- According to guidance, about 30% of the adult population is covered by CMS/Medicare in New York/tri-state area and Florida. There are approximately 5-6m skin checks performed annually by dermatologists, whereof Nevisense is clinically applicable in 20% of cases.
- Price per electrode is USD 45.
- Achievable market at full penetration estimated to about USD 45m/year. We believe that a market penetration of 50% over the forecast period is highly achievable with roll-out through practice groups.

#### Germany

- Focus on privately insured patients.
- According to guidance, approximately 750k skin checks per year performed by dermatologists where Nevisense is applicable in 20% of cases.
- Price per electrode EUR 35.
- Launch of NMSC in 2021, growing usage in melanoma and NMSC. Achievable market at full penetration estimated to slightly above SEK 50m/year. We believe that SciBase will grow their share from about 15% to 50% by 2024, reaching a relatively conservative estimate of 60% of the achievable market by the end of the forecast period.
- We estimate that 10% of total sales from Germany stem from self-pay.

#### Other

- We estimate a modest cost increase based on primarily partner strategy for commercialization. We include an investment of SEK 20m during 2021 into production processes to expand capacity.
- Investments in research & development during the period 2021-2023 is forecast to amount to approximately SEK 20m before leveling out at approximately SEK 2m per annum thereafter.

- Based on our assumptions we model two further equity issues in 2021 and 2022 of SEK 50m and SEK30m respectively in order to maintain sufficient liquidity.
- Gross margin through gradual economies of scale reaching 73% over the forecast period.

The table below summarizes SciBase's financial development based on aforementioned assumptions. We expect a slight turndown in net sales for 2020 due to the effects of COVID-19. The increasing cost base results from additional sales & marketing costs as well as additional headcount as the company expands. The gradual decline of research & development expenses to some extent limits the total increase in total operating costs as detailed below.

P&L (SEK million)	FY18A	FY19A	FY20E	FY21E	FY22E	FY23E	FY24E	FY25E	FY26E	FY27E	FY28E	FY29E	FY30E	FY31E
<b>Net sales</b>	<b>6.9</b>	<b>9.3</b>	<b>9.0</b>	<b>17.9</b>	<b>35.0</b>	<b>55.4</b>	<b>71.6</b>	<b>89.6</b>	<b>105.4</b>	<b>132.4</b>	<b>152.3</b>	<b>199.2</b>	<b>223.7</b>	<b>248.0</b>
COGS	(3.3)	(4.2)	(4)	(8)	(14)	(20)	(25)	(30)	(33)	(40)	(44)	(56)	(60)	(67)
<b>Gross Profit</b>	<b>3.6</b>	<b>5.1</b>	<b>5</b>	<b>10</b>	<b>21</b>	<b>35</b>	<b>47</b>	<b>60</b>	<b>73</b>	<b>93</b>	<b>108</b>	<b>143</b>	<b>163</b>	<b>181</b>
<i>Gross margin</i>	52%	55%	55%	57%	59%	63%	65%	67%	69%	70%	71%	72%	73%	73%
Sales and marketing costs	(24)	(23)	(21)	(22)	(22)	(23)	(24)	(24)	(25)	(26)	(26)	(27)	(27)	(28)
Personnel costs	(9)	(8)	(10)	(10)	(11)	(11)	(12)	(13)	(13)	(14)	(15)	(16)	(17)	(19)
R&D expenses	(10)	(8)	(10)	(9)	(7)	(4)	(3)	(3)	(3)	(3)	(3)	(2)	(2)	(2)
Other operating costs	(5)	(2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
<b>Total operating costs</b>	<b>(48)</b>	<b>(42)</b>	<b>(40)</b>	<b>(41)</b>	<b>(40)</b>	<b>(38)</b>	<b>(39)</b>	<b>(40)</b>	<b>(41)</b>	<b>(43)</b>	<b>(44)</b>	<b>(45)</b>	<b>(47)</b>	<b>(49)</b>
<i>Operating costs as % of Net Sales</i>	693%	449%	449%	228%	114%	69%	54%	45%	39%	32%	29%	23%	21%	20%
<b>EBITDA</b>	<b>(44)</b>	<b>(37)</b>	<b>(35)</b>	<b>(31)</b>	<b>(19)</b>	<b>(4)</b>	<b>8</b>	<b>20</b>	<b>31</b>	<b>50</b>	<b>64</b>	<b>98</b>	<b>116</b>	<b>132</b>
<i>EBITDA-margin</i>	n/m	n/m	n/m	n/m	n/m	n/m	11%	22%	30%	38%	42%	49%	52%	53%
<b>Net income</b>	<b>(44)</b>	<b>(40)</b>	<b>(37)</b>	<b>(33)</b>	<b>(25)</b>	<b>(8)</b>	<b>3</b>	<b>16</b>	<b>28</b>	<b>47</b>	<b>61</b>	<b>95</b>	<b>114</b>	<b>129</b>
<i>Profit margin</i>	n/m	n/m	n/m	n/m	n/m	n/m	5%	18%	27%	35%	40%	48%	51%	52%

Source: Vator Securities

## Discounted Cashflows

We use a discount rate (WACC) of 12.3%, as well as a 2.0% terminal growth rate (in line with GDP growth) and a 90% life cycle adjustment of terminal value. The risk-free rate is -0.06%, based on the Swedish Government ten-year bond, and the risk premium is 11.6%, based on a size and market risk premium of 4.0% and 7.6% respectively. Lastly, we use an equity beta value of 1.10. We have also included a net present value of the cumulative tax shield. With our estimates and DCF input variables, our DCF model indicates an equity value for SciBase of approximately SEK 413m, equivalent to SEK 7.5 per share (based on approximately 54.8m outstanding shares).

DCF (SEKm)	FY18A	FY19A	FY20E	FY21E	FY22E	FY23E	FY24E	FY25E	FY26E	FY27E	FY28E	FY29E	FY30E	FY31E
EBIT	(44.0)	(39.4)	(37)	(33)	(25)	(8)	4	17	28	47	62	96	115	130
Paid tax	0.0	0.0	0	0	0	0	0	0	0	0	0	0	0	0
NOPLAT	(44.0)	(39.4)	(37)	(33)	(25)	(8)	4	17	28	47	62	96	115	130
Adj. for non-cash items	0.0	2.8	2	2	5	5	4	3	3	2	2	2	2	2
Changes in NWC	0.0	0.0	1	1	1	1	2	3	3	4	6	5	6	4
Capex	1.5	1.1	2	20	1	1	1	1	1	1	1	1	1	1
<b>Free cash flow</b>	<b>(45.5)</b>	<b>(37.7)</b>	<b>(38)</b>	<b>(52)</b>	<b>(21)</b>	<b>(6)</b>	<b>5</b>	<b>16</b>	<b>27</b>	<b>45</b>	<b>57</b>	<b>92</b>	<b>110</b>	<b>1 229</b>
Discount factor	-	-	1.06	1.19	1.34	1.50	1.69	1.89	2.13	2.39	2.68	3.01	3.38	3.38
<b>Net Present Value - Free Cash Flows</b>	<b>n/a</b>	<b>n/a</b>	<b>(36)</b>	<b>(44)</b>	<b>(16)</b>	<b>(4)</b>	<b>3</b>	<b>9</b>	<b>13</b>	<b>19</b>	<b>21</b>	<b>31</b>	<b>32</b>	<b>364</b>

	SEK million
<b>Terminal value</b>	<b>1 229</b>
Life cycle adjustment TV	90%
<b>Adjusted Terminal value</b>	<b>1 106</b>
<b>Net Present Terminal Value</b>	<b>327</b>
<b>Net Present Value FCF</b>	<b>27</b>
<b>NPV of FCF incl. TV</b>	<b>355</b>
Tax shield value, NPV	37
Interest bearing net debt	(22)
<b>Equity Value</b>	<b>413</b>
Number of shares, non-diluted, million	54.8
<b>SEK/Share</b>	<b>7.5</b>

Source: Vator Securities

## Key personnel

**Simon Grant**, CEO. Simon Grant holds an BSc (hons) in Electrical Engineering. He has vast experience in the medical device industry, especially with diagnostic devices where he has focused on commercialization of new technologies. Throughout the years, Simon has held senior managerial, sales, and marketing positions in medtech startups, such as Neoventa and Synectics Medical. He has also worked in established multinational companies such as Medtronic. Simon's scope has always been on international focus and he has been based in Scandinavia, the US, and Asia.

**Michael Colerus**, CFO. Michael Colerus holds an MBA from Uppsala University. He was the CFO for Aerocrine AB and took them public in 2007 on Nasdaq OMX Stockholm. He was also active in building Aerocrine's US company and sales force. Prior to his CFO positions, he was the Business Controller for various business areas within Pharmacia & Upjohn.

**Per Svedenhag**, VP Business Development and Marketing. Per holds an MSc in Electrical Engineering from KTH Royal Institute of Technology, Stockholm. Per has more than 20 years of experience working with product management, marketing and business development in the medtech industry and has previously worked at, inter alia, Gambro Engström, Racal-redac Ltd., Siemens-Elema AB, XCounter AB (publ) and Innoventus Project AB.

**Tobias Bergenblad**, Global Sales Director. Holds a two-year degree in Finance from the Edinburgh Business School Marketing. Joined in 2015 after 12 years in international MedTech and LifeScience industry working with product launches and business development. He held several positions in sales and marketing with companies Hudson RCI, Maquet Critical Care and Aerocrine AB. Previous job was International Sales Director for Aerocrine AB where he successfully ran the ASIAPAC region.

**David Melin**, Director Product Development. David holds a degree of MSc in Mechanical Engineering focusing on Mechatronics from the Royal Institute of Technology, Stockholm, and has previous experience of product development and test automation as a consultant.

**Niklas Jakobsson**, Director Quality Assurance & Regulatory Affairs. Holds a MSc in technical physics and electronics from Linköping University. He has 20 years of experience from the medtech industry, including positions within R&D, Production and Quality management for a number of different medtech companies; many of which have been active on the US market. Niklas previously held the position of Quality manager at Ginolis AB in Uppsala where the electrode was manufactured before it was transferred to SciBase.

**Linn Olsen**, Production & Supply Chain Manager. MSc in Industrial Engineering. Has more than 15 years of experience from both the medical technology and high-tech industry areas, where she has focused on production, quality, and supply chain. Her background includes several roles at cardiac pacemaker manufacturer St Jude Medical where she worked as Quality Engineer, Production and Development Engineer and as Manager for Leads Manufacturing. Her most recent role has been as the Operations

Project Manager and Operational Excellence Manager at the positioning technology company Trimble.

## Board of Directors

**Tord Lendau**, Chairman of the Board. Tord holds an upper-secondary education in engineering from Linköping University. He has extensive experience as a CEO in different medtech companies and from board assignments in both Swedish and international listed companies and owner-managed companies. Among other things, Tord has been the CEO of Synectics Medical Inc, Synectics Medical AB, Dantec AS, Artimplant AB, VP of Medtronic and Division Manager for Sandvik MedTech. Tord has an upper-secondary education in engineering and unfinished studies in industrial engineering from Linköping University. In addition to his board work, Tord Lendau has been on multiple boards in the US, Holland, South Africa Korea etc.

**Diana Ferro**, Board Member. Diana holds an MBA from the University of Hamburg and various follow-on educations among them an exam in medical marketing from UCLA (the University of California Los Angeles). Diana is today the CEO of Medskin Solutions Dr Suwelack AG with over 130 employees in Europe, the US and Japan. She has an extensive experience from various senior positions within the Pharmaceutical industry in both the US and Europe.

**Thomas Taapken**, Board Member. Holds a PhD in organic chemistry from the Technical University of Berlin and has also studied economics, chemistry and physics at the University of Göttingen. He is an independent adviser and has over 20 years of experience from senior management positions within the life sciences sector and as a venture investor. He has held positions as CFO of Medigene AG (publicly listed in Germany) as CEO and CFO of Epigenomics AG (publicly listed in Germany) where he led the company's efforts in gaining regulatory approval for the company's lead product with the FDA and oversaw its subsequent introduction into the US market and formerly as CFO at Biotie Therapies (formerly listed on Nasdaq Nordic) and its predecessor company Elbion AG.

**Barbro Fridén**, Board Member. Barbro is a licensed physician from Umeå University and a MD from the University of Gothenburg. She has extensive experience as a hospital director and is a specialist in obstetrics and gynecology with a subspecialty within reproductive medicine. Barbro Fridén has among other things been CEO of Sheikh Khalifa Medical City, United Arab Emirates, CEO of Sahlgrenska University Hospital, Division Director of Astrid Lindgren Children's Hospital and Medical Director of Fertilitetscentrum AB in Stockholm and Göteborg, Sweden.

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I, Felicia Rittemar, the author of this report, certify that notwithstanding the existence of any such potential conflicts of interests referred to below, the views expressed in this report accurately reflect my personal view about the companies and securities covered in this report.

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