

NEWSLETTER / JULY 2012 ISSUE

Attractive investment Medical technology in the DACH region profits from favorable conditions

What makes the medical technology sector in the DACH region so successful and thus attractive for investors? It's the combination of a large and growing market, a high level of innovation, a transparent and predictable regulatory environment and attractive exit options.

Attractive growth market

The global medical technology market is estimated at 300 billion euro and continues to grow. The primary driver of this increase is the aging population in the industrial world, which results in a steadily increasing demand for innovative products among purchasers. An additional factor consists of the expanding middle class in emerging economies.

The region at the cutting edge

A strong medical technology sector with a highly productive supplier network has developed in the DACH region over the course of many decades. This has its technological origins in precision engineering. The development activities of these companies have traditionally been very dynamic and are supported by attractive government aid programs as well as public research and education facilities. These positive conditions result in a high level of innovation, which is of course particularly crucial to the success of medical technology. Therefore German medical technology companies achieve almost a third of their turnover with products that are less than three years old.

Favorable framework conditions

The attractive regulatory environment also plays an important role. For example, Shay Mandle, whose group represents more than 600 medical technology businesses in the USA, has concluded that the

European approval system works better and more reliably than the American one. According to the most recent figures, the European approval procedure is ten times less costly and an average of three years shorter. This results in a clear competitive advantage for companies located in Europe. They introduce their products to the market more quickly and inexpensively and can thus achieve turnover and profit earlier in the game.

Outstanding exit options

In addition to this, the large medical technology companies are very active in acquiring innovative young companies in this field, paying attractive prices honoring the large market potential. The dynamic M&A activities provide investors with attractive exit opportunities. Especially in times, in which American competitors can't use their home field advantage due to regulatory hurdles, these companies increasingly look to Europe, where new technologies that are still awaiting approval in the US are already undergoing clinical trials or even being introduced to the market.

The combination of strong demand, a high level of innovation and favorable market access and exit options makes the DACH region not only the largest European market, but also an attractive environment for investors.



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Contents

Articles Pages 1 and 2

Reinhilde Spatscheck:
Attractive investment

Ulrike Hinrichs, BVK:
Supporting innovations –
improving framework conditions

Interview with Prof. Malte Kelm:
"Clinical research is tremendously important
for future progress"

New investments Page 3

SHS acquires Spiegelberg

SHS invests in Miracor Medical Systems

Existing investments Pages 4,5 and 6

4a medicom GmbH launches clinical pilot
study of the GlucoPEARL system for simplified
self-administered blood glucose monitoring

Fresh capital for Micropelt

LipoFIT takes new paths in
human diagnostics

Strong profitable growth at phenox

Sartorius Stedim Biotech and c-LEcta reach
sales agreement

Interview with Jon H. Hoem,
CEO of Miracor Medical Systems:
PICSO®: cutting edge
technology that saves lives
New CFO at LipoFIT

Inside SHS Page 7

SHS contribution to the
strategy process "Innovations in Medical
Technology"

Successful launch of the
"CEO days"



Supporting innovations – improving framework conditions

Our association has been intensively involved in the discussions and consultations pertaining to the legal framework conditions for equity capital and innovations at the federal level in the past. We expressly welcome the federal government's current initiative to improve the framework conditions for venture capital in Germany. Especially the improvement of the fiscal framework conditions for venture capital planned for this legislative period show that the federal government has recognized the urgency of this issue and the need for action. Germany needs growth and growth needs innovation! Venture capital can be a decisive factor in financing innovation. Venture capital can provide the funds necessary to ensure long-term growth. Therefore it is important to reduce the number of constraints and hurdles required for successful innovation financing. The planned improvement of the fiscal framework conditions for venture capital can be a significant initial step toward achieving this.

Ulrike Hinrichs is Managing Director of the German Private Equity and Venture Capital Association (BVK)

"Clinical research is tremendously important for future progress"

Interview with Prof. Malte Kelm, Director of the Clinic for Cardiology, Pneumology and Angiology at the University Clinic in Düsseldorf

Professor Kelm, you face medical limitations on a daily basis when treating patients. What do you consider to be the greatest unsolved problems in cardiology?

"There are four main medical areas, in which patients and physicians would like to see progress. These include heart failure treatment, valve replacement, coronary heart disease and myocardium treatment. It is also important to strike the increasingly difficult balance between appropriate therapy, costs and ethics. But medicine alone can not provide this. It requires consensus in society."

How important is research for future progress in clinical cardiology?

"Clinical research is tremendously important for future progress. In comparison to the rest of Europe, the research funding in Germany is still quite good even though the competition for resources has increased considerably. However, it is increasingly hard for physicians to bridge the gap between the clinic and clinical research."

The implementation of new treatment approaches is often driven by young technology companies with the support of venture capital. How important to success is the close interaction between clinics and development companies?

"From my perspective, the intensive collaboration between clinicians and clinical research is essential for young technology companies in order to meet actual medical needs with a new product. The interaction between medical professionals and engineers is extremely important, but an understanding for the other side does not always exist. The companies not only have to possess engineering know-how, but develop medical competency. Then the interaction between patients, clinics and companies runs more smoothly."

Implementing research results in the daily clinical routine is time-consuming and consists of many hurdles. How do you think research results could be integrated more quickly and efficiently in clinical application? What would you change?

"Recently there has been a trend toward assessing clinical trials with Medtech products in a way similar to pharmaceuticals trials. This is definitely not productive. The two sectors generally differ too much to use the same approach. It would be good to rethink this trend. In general it would make sense to accelerate approvals with the involved authorities. In my opinion this should be possible without having a negative impact on the quality of the decisions."



SHS acquires Spiegelberg

SHS acquired the partner's interest in Spiegelberg (GmbH & Co.) KG (Spiegelberg) in August 2011. The medical technology company based in Hamburg develops, produces and sells highly specialized catheters and measurement probes for neurosurgical applications in the brain as well as antimicrobial products to protect against hospital infections.

Spiegelberg is a well-known supplier of technology for intracranial pressure (ICP) measurement and external ventricle drainage (EVD). With its Silverline® an-

timicrobial products, Spiegelberg provides especially promising technology. Its fungicide and bactericide silver coating in particular make an important contribution to the fight against hospital infections. A clinical trial carried out with the University Clinic in Cambridge showed that the use of Silverline catheters almost cuts the infection rate in half.

Spiegelberg has a turnover of 2.5 million euros, has 30 employees and is profitable. SHS acquired the shares together with the Join & Venture GmbH of

the medical technology entrepreneurs Dr. Heinz Fischer and Frank Sodha.

"We are very pleased to have gained SHS as equity investors, who have demonstrated the highest level of competency and experience in the field of medical technology. This combination opens up new resources, synergy effects and sales potentials which will help us continue our profitable growth", says Dr. Andreas Spiegelberg, founder and Managing Director of Spiegelberg (GmbH & Co.) KG (Spiegelberg).

SHS invests in Miracor Medical Systems

In September 2011 SHS invested in the Vienna based medical technology company Miracor Medical Systems GmbH (Miracor). Together with other financial partners, SHS as lead investor has provided a total of seven million euros in the current round of financing (series B). Miracor develops and markets PICSO® (Pressure-controlled Intermittent Coronary Sinus Occlusion) therapy technology, which can significantly reduce the amount of damage caused to the myocardium following a heart attack or resulting from cardiac insufficiency. RED HERRING recently listed Miracor as one of the 100 most innovative and promising companies in Europe.

Miracor was founded in 2008 with the goal of providing patients suffering from Acute Coronary Syndrome (ACS)

and cardiac defects as well as heart surgery patients with better treatment methods and tissue regeneration after heart attacks. PICSO® technology consists of installing a balloon catheter in the coronary sinus, which then expands on a regular basis to temporarily suppress the outflow of venous blood. The slightly increased pressure in the blood vessel has a similar effect to a massage on the vascular wall and stimulates the release of neurotransmitters, which results in partial regeneration of the myocardium. Conventional treatment of heart attacks has merely focused on preventing future damage to the heart and supporting blood circulation.

"We are happy to have found an experienced growth investor for our company in SHS. We will be using the funds from

this round of financing to prepare the use of the PICSO® system for market launch", says Jon H. Hoem, Managing Director of Miracor.



PICSO® treatment helps reduce the amount of damage to the myocardium following a heart attack.



4a medicom GmbH launches clinical pilot study of the GlucoPEARL system for simplified self-administered blood glucose monitoring

The University Clinic in Graz, Austria is currently conducting a clinical trial, in which 600 diabetes patients will be testing and evaluating the GlucoPEARL system. This clinical pilot study will test the functionality of the GlucoPEARL blood glucose monitoring system and data will be collected with regard to its accuracy and precision. This clinical pilot study serves as preparation for CE certification of GlucoPEARL.

The GlucoPEARL system developed by 4a medicom GmbH integrates

the lancing device, the lancet and test strips all in one unit. This permits patients to measure their blood-sugar levels in a single step. The benefits of the product are that it is practically painless and easy to use. This is of great importance, particularly for the fast-growing group of older diabetics. Because the device is designed as a safety product, it also offers hospital personnel effective protection against infections.

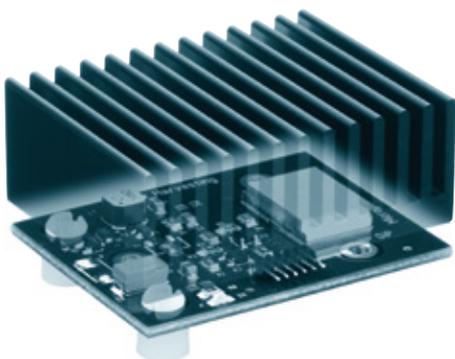
4a medicom GmbH with its headquarters in Traboch, Austria was found

ded in 2006 with the objective of significantly simplifying what up until then had been complicated self-administered blood glucose monitoring. Many diabetics depend on determining their blood sugar level several times a day and therefore blood sugar self-testing is attractive to a large and continually growing market.

The GlucoPEARL system for simple blood collection and diagnostics is a platform technology which can also be used to determine other blood parameters.

Fresh capital for Micropelt

An inexpensive alternative to batteries: thermoharvesting devices convert excess heat into energy.



Micropelt GmbH is celebrating completion of a new round of financing amounting to 6.5 million euros. It is being used for the market launch and development of the global sale of the energy harvesting specialist's thin film thermoelectrics, which are now available in high volume. The British Ludgate Environmental Fund (LEF) has invested five million euros, the Japanese Mitsubishi UFJ Capital (MUCAP) has invested one million euros and 0.5 million euros have been contributed by Micropelt GmbH's current investors IBG/Goodvent, KfW, L-Bank and SHS.

Micropelt's micro-energy harvesting technology helps to significantly improve resource and energy efficiency espe-

cially in building technology, industry and transport applications. Among other things, it is used to replace batteries in electronic heater thermostats, sensors for industrial processes and machine function monitoring.

This latest round of financing gained additional momentum due to the mass production launched in Halle, Germany in June 2011 as well converter ICs adapted especially to Micropelt thermogenerators by market leader Texas Instruments. Micropelt chairman of the board, SHS partner Hubertus Leonhardt, is looking forward to the new international partners: "This will help us to more rapidly realize Micropelt's innovative potential around the world."



LipoFIT takes new paths in human diagnostics

Good diagnostics are the key to successful treatment. However, there is still a lot of room for improvement in this area. Test results are often ambiguous and those suffering from illnesses are often not diagnosed reliably. Therefore research is being carried out around the world into methods which can be used to understand patients systemically rather than based on certain indicators only. LipoFIT is taking precisely this path: This new company founded from the Institute for Biophysics at the University of Regensburg, Germany uses the ability of nuclear magnetic resonance (NMR) to comprehensively measure fluids such as blood samples.

LipoFIT uses this to generate a dynamic map of the metabolism and thus allows for precise statements as to cancer development for example.

The first clinical results of this approach are so promising that LipoFIT has now launched a series of tests as part of clinical testing: The spectrum ranges from the assessment of coronary heart conditions, diabetes and kidney damage to oncology. The results achieved thus far have also gained the interest of several large pharmaceuticals and diagnostics companies, who would like to work with LipoFIT. In addition to the clinical development of tests, the first products are about to be launched on the market.

Sartorius Stedim Biotech and c-LEcta reach sales agreement

Sartorius Stedim Biotech and c-LEcta have reached an agreement pertaining to the worldwide sale of the c-LEcta *Serratia marcescens* nuclease for biopharmaceutical applications. The endonuclease is produced by way of genetic engineering in bacillus. Endonucleases are used in numerous biopharmaceutical production processes in order to increase their efficiency by reducing viscosity and removing nucleic acids. The new product is intended for the biopharmaceutical industry and is now available via all the usual sales channels from Sartorius Stedim Biotech under the product name DeNArase.

Dr. Marc Struhalla, Managing Director of c-LEcta GmbH, sees great opportunities in the partnership with Sartorius Stedim Biotech: "Our new patented technology allows us to provide the nuclease at the highest quality. We are certain we have found the right sales partner in Sartorius Stedim Biotech for successful global marketing of the product in the biopharmaceutical industry."

Strong profitable growth at phenox

SHS invested in the company phenox from Bochum Germany in 2010. phenox develops and sells instruments for the neurointerventional treatment of strokes. The company has developed very positively and grown considerably since then. The increasing recognition of this new minimally invasive treatment due to convincing international studies and outstanding treatment success are helping the company considerably in this

regard. The German magazine DER SPIEGEL wrote of a "dramatic step forwards" due to this technology (DER SPIEGEL, March 26, 2012, Pg.116).

The company will be placing further products on the market in 2012: an aneurysm implant, which prevents breakage of cerebral vessels (hemorrhagic stroke) as well as an implant that bridges weak points in cerebral vessel junctions.



PICSO®: cutting edge technology that saves lives

Interview with Jon H. Hoem, CEO of Miracor Medical Systems GmbH

Mr. Hoem, what medical approach does your company take?

Hoem: "Miracor Medical Systems has developed unique technology called PICSO® (Pressure-controlled Intermittent Coronary Sinus Occlusion) for use in treating acute heart attacks and other heart conditions. The PICSO® technology prevents the outflow of venous blood from the myocardium. This blockage causes an increase in pressure in the myocardium, which has a positive effect after heart attacks. Clinical data shows the positive effect of PICSO® in patients subjected to revascularization as part of percutaneous coronary intervention (PCI). This is intended to stop the progression of damage to the myocardium in time and promote blood circulation again so as to prevent subsequent damage.

Our goal consists of developing an entirely new platform for the PICSO® technology, the so-called Miracor PICSO® Impulse System, which consists of a console and an associated catheter. We are planning commercialization of PICSO® for 2013 and have already received CE certification in Europe. We estimate that approximately 30% of all patients with acute coronary conditions can benefit from this new treatment method, which equals more than 350,000 patients in Europe and the USA alone."

What is Miracor's strategy with regard to partnerships?

"After founding Miracor, we decided to outsource console and catheter develop-

ment to respectable European development firms, which enabled a very rapid development process and an early pre-clinical proof-of-concept.

By the same token, the company has always maintained full control of the quality assurance measures and continually expanded its patent and IP positioning based on this new technological development. We currently hold ten PICSO® patents from the console, the catheter and the SW Wien algorithm to the US treatment method."

Was it difficult to set up financing for the company?

"In the past four years, Miracor has successfully completed the series A and B financing totaling 20.4 million euros in capital from renowned venture capitalists and Austrian funding (aws, FFG). Thus far our rounds of financing have been perfectly timed. Our series A round was closed in May 2008 just three months prior to the severe financial crisis and the series B round was supported by the aws Double Equity Program. For the series C round, we are focusing on both European venture capitalists as well as strategic investors from the USA to lift the company to the next level."

Where do you see your companies in five years time?

"From today's point of view, two different exit strategies could come into consideration for Miracor in a couple of years. One option consists of selling Miracor to one of

the large players in the field of cardiology such as Medtronic, J&J, Boston Scientific or Abbott Vascular following proof-of-concept of the clinical and commercial concept with initial commercial success. We see the other option as consisting of drumming up additional funding ourselves for introduction in the USA, possibly by way of an IPO, if the company has become profitable by that time."

How significant do you think scientific research is for young aspiring companies in general?

"When I look back, I find it fascinating to see all that the small but dedicated Miracor team has achieved with the potential groundbreaking PICSO® technology. Within just a few years, we have bridged the gap between a visionary research concept and a commercial product. As a small company financed by venture capital, one of the greatest challenges lies in the translational development from the concept to the machine ready for sale. To sum it up, I think that research fundamentally plays an important role in establishing a company and that important aspects such as the development of quality systems and the ability to actually implement these innovative concepts on a sustainable basis in practice are among the most important value enhancement activities of small aspiring Medtech companies."

This interview originally appeared in PHARMAustria, May 2012



New CFO at LipoFIT

As of June 1st, LipoFIT has a new CFO. Hans-Henning Doerr has taken on this job from Peter Böhnert, who will focus entirely on his job at AMW GmbH. Doerr graduated from the European Business School in business administration and worked for a listed corporation for many years, most recently as financial director. He also served as the chief financial officer of a listed company and has supported companies in IPOs.

SHS contribution to the strategy process "Innovations in Medical Technology"

With its nationwide strategy process "Innovations in Medical Technology", the German government is facing the challenges and opportunities of medical technology in an all-encompassing strategy. Ways are to be found to further accelerate the innovation processes in medical technology and strengthen the competitiveness of the German medical technology industry. Dr. André Zimmermann, partner at SHS, helps design the processes as an expert in the field.

Successful launch of the "CEO days"

The managing directors of the SHS portfolio companies met on October 21st and 22nd at Haigerloch castle near Tübingen. The agenda of the so-called "CEO days" included presentations on the subjects of product approval, sales, strategic partnerships and exit. The speakers included:

- Dr. Michael Scholl (Homburg und Partner)
- Dr. Kerstin Ebock (Orrick Hötlers & Elsing)
- Prof. Wolfgang Blättchen (Blättchen Financial Advisory GmbH)
- Dr. Harald F. Stock (CEO Grüenthal GmbH)

- Dr. Claus Michelfelder (CMC Consulting)
- Dr. Frank Pitzer (CEO Roche NimbleGen Inc.)

In addition to gaining new insight, the managers used the opportunity for intensive networking and exchange. The feedback was positive from all participants. "The exchange with the other CEOs and Life Sciences experts from the SHS network provided me with many valuable ideas for our business. I am looking forward to the next meeting", says Jon H. Hoem, Managing Director of Miracor Medical Systems GmbH.

Company details

SHS NEWSLETTER
is published by
SHS Gesellschaft für
Beteiligungsmanagement mbH
Bismarckstraße 12
D-72072 Tübingen, Germany

Editorial office: SHS Gesellschaft für
Beteiligungsmanagement mbH,
Ira Wülfing Kommunikation GmbH

Design: Sophie Wolfbauer

