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Bringing through Clinical Trials Technology for Wireless Intracorporal Pressure Measurement, Implandata Ophthalmic Products GmbH will Provide a Better Way for Doctors to Monitor their Glaucoma Patients

Healthcare Medical Devices (Private)

Implandata Ophthalmic Products
GmbH

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Max G. Ostermeier, MBA Co-Founder and Chief Executive Officer

BIO:

Mr. Ostermeier is co-founder and General Manager of Implandata Ophthalmic Products GmbH. He has extensive experience in the commercial development of technologically advanced products, in building operational capabilities for aggressively growing companies and in creating businesses, attracting potential acquirers in the global market. As serial entrepreneur he was founder and General Manager of a German medical device start-up, developing a new to the world portable medical device

for rapid detection of intracranial bleedings, which was acquired by a US based company in 2007. Mr. Ostermeier was also co-founder and CEO of a medical technology company with innovative neuro surgical products whose technology was acquired 4 year after foundation by a leading US medical device company. Prior to that he was instrumental in creating for a globally leading fine chemistry company their biotech entity, where he served as General Manager and Vice-President until this company was divested.

Company Profile:

Implandata Ophthalmic Products GmbH is a medical device start-up company, located in Hannover, Germany. The venture capital funded company owns the most superior and robust technology for wireless intracorporal pressure measurement, developed in collaboration with Fraunhofer Gesellschaft e.V., Germany, which is Europe's largest application-oriented research organization.

The first products for ophthalmic applications are currently in the regulatory approval process, demonstrating compliance with relevant standards. We expect CE mark and initial market launch soon, followed by regulatory approvals for the US market and subsequent marketing in North America.

Implandata Ophthalmic Products GmbH will transform glaucoma care via dramatically better disease information at significant less effort:

Ophthalmologists will be able to understand the patients' individual intraocular pressure also in between office visits. This allows immediate adjustment of therapy regiment upfront, before further vision loss occurs to the patient • Patients can do pressure readings by themselves and under normal life conditions. This helps them to adhere to therapy and reduces frequent office visits, as patients can be monitored and managed remotely. Researchers and clinicians all over the world will develop fundamental understanding about glaucoma and the role of intraocular pressure, as 24h intraocular pressure monitoring will reveal crucial information, which was not obtainable in the past. This will help them to develop better and more efficient therapeutic glaucoma strategies. The company's activities are executed by an experienced and highly motivated management team and supported by seasoned investors and world class advisors. The company collaborate with the most prestigious sites and institutes in order to present the most advanced and utile products to the patients and medical community.

Interview conducted by: Lynn Fosse, Senior Editor CEOCFO Magazine

CEOCFO: Mr. Ostermeier, what is the focus and basis for Implandata? **Mr. Ostermeier:** Actually, we develop ophthalmic surgical products which are for improved diagnoses of glaucoma patients, resulting in improved disease treatment and better quality of life for glaucoma patients and their families.

CEOCFO: What is the basic technology that you are working with today?

Mr. Ostermeier: The basic technology originates from the automotive industry. You may know about tire pressure sensors. Those are used to measure the air pressure inside a tire. These sensors have to work wireless because you cannot have a cable going into a cars tire for power supply or data read out. We have taken that technology and advanced it to a telemetric long-term micro implant, so that it could be used for measuring intraocular pressure, or generally any pressure inside the body. However. our very first application is for measuring intraocular pressure, which is important for glaucoma patients. Glaucoma patients do have elevated intraocular pressure, which over time causes damages to optic nerve, resulting in incurable blindness. Currently there is no technology available to measure intraocular pressure over the course of 24h or in between office visits, why ophthalmologists demand a product for better monitoring of intraocular pressure at these patients for a long time.

CEOCFO: Why did you decide to start in the area that you did if it could be used anywhere in the body?

Mr. Ostermeier: Measuring intraocular pressure seemed to be the area where telemetric pressure sensors are most desirable and will find immediate application. Glaucoma is a very emotional disease and it is a chronic disease which needs to be managed for the rest of a patient's life. The risk of patients getting incurably blind due to uncontrolled intraocular pressure is very real and threatening. Ophthalmologists want better monitoring of intraocular pressure, so that they can titrate therapy prior to vision loss. And patients want peace of mind that their eye pressure is fine and well under control, reducing the risk of experiencing visual impairment or blindness.

CEOCFO: What steps have you taken and where are you in the process?

Mr. Ostermeier: The core piece of our technology is a tiny pressure sensor, which is located on an integrated circuit. It is a microchip with small pressure membranes. It took us

longer than expected to get that microchip working. Once we had accomplished that, we started preclinical testing in animals, followed by first in human implantation approximately three years ago. After additional testing, we felt comfortable to start with the CE registration process in 2011, which requires clinical studies. Studies are progressing as planed, why we expect CE mark in 2013, which will allow us to start commercialization of our first product in Europe and many other areas in the world.

CEOCFO: Have the doctors been looking for a better way or is it something that they are going to be happy to know is available?

Mr. Ostermeier: Doctors have been desperately looking for a product like ours for a long time, for a better way to monitor their glaucoma patients. The problem with glaucoma management today is not therapy. There are many therapeutic options. You can use drugs, usually eye drops or combinations of various eye drops.

Doctors have been desperately looking for a product like ours for a long time, for a better way to monitor their glaucoma patients. - Max G. Ostermeier, MBA

> There are also surgical approaches to decrease intraocular pressure. But right at the moment you don't know which option works best for which patient, currently it has to be found out the hard way. The big problem in glaucoma management today is that diagnosis is not good. Intraocular pressure, which is the early indicator for the disease can be only measured at the doctor's office and it is only a snapshot, representing the pressure at the second measured. There is no knowledge how the pressure is doing over the course of 24h or in between office visits. That is why many patients are progressing though they are under therapy, because the right treatment for that patient was not chosen, resulting in additional vision loss. By having more comprehensive information about the patient's individual pressure condition, doctors will get an immediate feedback if a chosen therapy works for a specific patient, or if therapy needs to be adjusted or optimized. This will allow

them to make the right decision at the first place, preventing vision loss of the patient. And it allows them to monitor patients tightly, as response to medication changes over time, which requires adjustment of medication

CEOCFO: Is the medical community aware of what you have been doing? Mr. Ostermeier: Yes. We are already working with key opinion leaders in the US as well as in Germany. One of the most prolific clinicians and researchers in glaucoma, Robert N. Weinreb from University of California San Diego is heading our Scientific Advisory Board and is also founding shareholder of our company. We are also working with MEEI Harvard Medical School in Boston, with Wills Eve Center in Philadelphia and we are going to work with Duke Eye Center in North Carolina. Once our products get to the marketing stage we will expand and strengthen our visibility to the outside community.

CEOCFO: What is your funding situation for Implandata? Do you have what you need to get to commercialization?

Mr. Ostermeier: We did a seed round two years ago. And

we just accomplished a first Series A closing in December last year. We are about to do a second Series A closing in the next few weeks. That will give us enough funding to accomplish CE mark and to start a pilot study in the US. We are also working on an IDE for getting a US study started in early 2013. However, to further expand our business and to start product approval studies in the US, we will look for more money around the middle to late 2013.

CEOCFO: What is the market opportunity in dollars?

Mr. Ostermeier: We are targeting a market size of approximately a couple of hundred million USD a year. Glaucoma is the second leading cause of blindness in Europe and North America. In certain Asian countries, it is the leading cause of people getting blind. Globally 80 million patients have the disease today and every year there is an additional 5-6 million new patient's world wide. Incidence will even go up,

because of aging of population in many territories, since glaucoma is a disease which typically affects elderly people.

CEOCFO: What is it about the team at Implandata that shows you can be successful at commercialization where many people often are not?

Mr. Ostermeier: We have a complementary management team. We are working with the leading glaucoma scientists and clinicians. We do have a very strong technology background and internal and external experts for product development. Myself, I have a business background; I am an MBA by education. I have worked for the last fifteen years in the life sciences industry. I worked for a US/German biotech company, which then was sold to Sigma-Aldrich. In the last ten years I founded three medical device companies which we brought to a

successful exit. This is now my fourth medical device company I am working on. We know what is important to get a company to the stage where it can be successfully sold to one of the big companies in the ophthalmic area.

CEOCFO: Why should investors pay attention to Implandata today?

Mr. Ostermeier: In general, the ophthalmic device industry is very well known for aggressive buying of new technologies. Large companies like Alcon, Bausch + Lomb or AMO have spent a lot of money in the last ten years buying new products. For example in refractive surgery or for cataract surgery. And now they are all looking very keenly into the business opportunities surrounding glaucoma. Why to pay attention to Implandata: First of all, the market is very open to adopting new and exciting technologies, offering attractive exit opportuni-

ties for start-up companies. Second. we are addressing a vast medical need and by this a quite substantial market. Third, there is not a lot of competition right now. We have a clear competitive edge against other projects in that area with a pretty strong IP. Fourth, we own a solid and validated technology. We have plenty of animal data and solid human data. Fifth, clear regulatory pathway and fast time to market: We are already working on the CE mark for getting regulatory approval for Europe and most other countries in Asia. And our FDA process has been started. So in summary. I think it is a pretty exciting area to work. For the investor, there is a good chance to yield a good return, since the ophthalmic industry is prominent for making acquisitions of new technologies.



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