

THE WALL STREET TRANSCRIPT

Connecting Market Leaders with Investors

Implantica AG (STO:IMP-A-SDB)



DR. PETER FORSELL is CEO and Founder of Implantica AG. Dr. Forsell was the Executive Chairman of Obtech Medical AG, the team's previous successful medical technology business which commercialized the SAGB, an adjustable gastric band to treat obesity that Dr. Forsell developed. The total gastric banding market peaked at 42% market share of all obesity surgery. Dr. Forsell has gained extensive experience during this long journey on how to lead and develop a business from inception to a successful global enterprise. Obtech was later sold for a significant amount to Johnson & Johnson. As CEO of Implantica, he is focused on guiding Implantica to the next level. Dr. Forsell is an internationally renowned surgeon and the brain behind Implantica's decade of patent and development work focusing on how to move advanced technology into the body. He developed Implantica's wireless energizing and eHealth platforms. He is the inventor and originator of most of Implantica's

products and the large patent portfolio of >1,000 patent cases. This includes RefluxStop™, a device obtaining a CE mark after a very successful clinical trial that will cause a potential paradigm shift in the treatment of acid reflux. Dr. Forsell is a specialist in surgery at the Karolinska Hospital, and he obtained his medical degree at the Karolinska Institute in Stockholm, Sweden. He has also studied basic law, tax and finance.

SECTOR — HEALTH SERVICES

TWST: Tell us about the company Implantica and why you decided to found it.

Dr. Forsell: The Implantica journey actually began quite a while ago when I developed the adjustable gastric band and created a business around that, which was very successful. After six years, we sold the business to Johnson & Johnson for a substantial amount of money. With the funds that I received from J&J for the gastric band company, I reinvested in Implantica. I've invested approximately \$150 million in Implantica to date. Prior to selling the gastric band business, we had taken 28% of the global market excluding the U.S. because we had not yet received regulatory approval to sell in the U.S.

TWST: How has the company evolved over the years?

Dr. Forsell: What I learned from the previous business is the importance of having a strong, well-protected product pipeline. I also realized that there is a huge gap in available medical device products and potential patient needs that could be met with technologically advanced treatment solutions. In order to address these unmet needs, we developed two platform technologies — a wireless energizing platform in order to charge a battery directly through intact skin and allowing for remote-controlled action, and then also an eHealth platform in order to be able to measure how the treatment is going, measure various parameters from inside the body and send them to the caregiver. The health care provider

should be able to view the patient's measurements and also readjust the treatment and change the treatment from a distance.

We then spent years to see how we could improve health care with these platform technologies. We went through treatment field after treatment field, and we looked at all the existing patents, all the existing treatments to see how we can improve them. After performing market analysis, product analysis, prototyping and so on — a three year process — we managed to create an enormous amount of patents, nearly 2,000 patent cases. We have more than 300 inventions and have selected more than 40 products in the pipeline, most of them based on the platform technologies, but some are totally passive like RefluxStop. There are many treatment fields, like acid reflux, for example, where we are able to improve treatment without the need for a complicated electrical implant, just a passive device.

TWST: You mentioned RefluxStop — and that procedure has been successfully performed in the U.K.

Dr. Forsell: Yes, absolutely, we currently perform the RefluxStop procedure in Germany, Switzerland, Austria and the U.K., and should soon start in additional key international markets. We have four-year outcomes data from our original CE marking clinical investigation, and it is extremely effective. We are getting more and more of the top surgeons in the field on board for this new treatment.

Acid reflux is actually the largest medical treatment field in the world. One billion people are affected at least every week by acid

reflux and maybe half of those suffer every day. They have pain — the acid comes up from the stomach to the lower esophagus. The primary treatment for acid reflux today is drugs, so-called PPIs. The problem with PPIs is that while they reduce the amount of acid in the stomach fluid, they do not get rid of the reflux. You still have your reflux, and the problem with acid reflux is that it can cause cancer. About 48,000 people die annually from esophageal adenocarcinoma in Europe and the United States alone — an enormous amount of deaths, mainly just because of acid reflux.

The problem with the drugs is that they don't affect the cancer risk, therefore no one has been able to show any effect of PPIs on the risk of cancer. It's necessary to treat the acid reflux; it is not enough to treat only the symptoms of it. You need to get rid of the acid coming up to the esophagus and get rid of it completely. With RefluxStop we treat the cause of acid reflux, and that's why 98% of our patients in our study have normal pH — people are completely treated. If you take PPI users and test them to see if they are treated, between 33% and 39% still have acid reflux, still have bad pH in their lower esophagus when measured objectively.

In contrast to RefluxStop, existing surgical methods have been focused on encircling the food passageway to treat acid reflux. In order to avoid stomach acid coming up, the food passageway is encircled to attempt to close the lower esophagus, often resulting in problems swallowing. Fundoplication can lead to gas bloating and the inability to belch and vomit — your abdomen gets swollen and distended. When swallowing, we swallow lots of air all the time, which is normally regulated out nicely through the opening in the lower esophageal sphincter, but this doesn't work anymore if it is constantly compressed.

“The RefluxStop device offers an alternative mechanism for treating acid reflux compared to existing surgical options. We have identified the cause of acid reflux, and therefore, we not only treat acid reflux better, we also got rid of the complications such as swallowing problems and gas bloating because RefluxStop doesn't affect the food passageway.”

As a surgeon, I worked 10 years with these patients, and they are generally not happy with the existing types of anti-reflux surgery. Five years after surgery, approximately 50% of the patients have gas bloating. Since the side effects of existing anti-reflux surgery are so unpleasant, the total number of anti-reflux procedures have reduced dramatically over the last 40 years.

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TWST: And can you explain how the RefluxStop procedure works?

Dr. Forsell: Absolutely. The abdomen and the chest are divided by a large muscle called the diaphragm. The diaphragm moves up and down when breathing. In the chest, when breathing, you get pressure variations; the pressure comes and goes with your breathing movements.

These pressure variations leak out through the opening in the diaphragm where the esophagus passes through. If the muscle that separates the esophagus from the stomach, called the lower esophageal sphincter, or LES, comes too close to the opening in the diaphragm, and

you start to get problems with acid reflux. This is because the lower esophageal sphincter muscle does not have enough power to stay closed if it is too close or even above the diaphragm — in which case it is called a hernia. This is why people have acid reflux. By restoring and maintaining normal physiology in the body with the LES far below the diaphragm, no reflux will occur.

RefluxStop works by reinforcing the upper part of the stomach — the fundus — to interact with the diaphragm for a new dynamic treatment of acid reflux. The RefluxStop device is placed on the outside of the top fundus wall of the stomach via laparoscopic surgery. The RefluxStop device physiologically maintains the LES in the abdomen, acting like a mechanical stop against the diaphragm, keeping the LES in its original anatomically correct position, far below the diaphragm. In this way, the RefluxStop restores normal anatomy with the LES remaining in the abdomen, which in itself prevents acid reflux.

RefluxStop furthermore dynamically interacts with the diaphragm muscle parallel to the LES and the hiatus opening in the diaphragm, leaving the food passageway unaffected. Therefore, side effects associated with standard anti-reflux surgery are reduced by avoiding encircling of the food passageway.

Nissen fundoplication was developed by Dr. Nissen in 1956, and it involves taking the top part of the stomach and wrapping it around the lower esophagus, applying pressure on the closing sphincter. There is another surgical intervention available, a product from Johnson & Johnson called LINX™ Torax Medical Inc. Magnetic Band. It is a magnetic band, and similar to fundoplication, it supports the closing between the lower esophagus and the stomach to prevent acid from regurgitating up into the esophagus.

Originally, everybody believed that the cause of acid reflux is that the closing muscle is weak. We have shown that there is nothing wrong with the closing muscle, it is the position of the closing muscle or LES that is the problem.

If you compare the results from the FDA trial of the Johnson & Johnson product, LINX, to the RefluxStop CE mark trial, you see that the results are like night and day. The most objective acid reflux test is measuring pH in the lower esophagus over 24 hours; 42% of LINX patients failed this test, 10 times more failures than in the RefluxStop study. In addition, 68% of the LINX patients had swallowing problems. This indicates that it is not possible to only support the closing of the lower esophageal sphincter to prevent acid reflux because then it causes swallowing problems.

RefluxStop is a completely new generation of treatment and has all the attributes to become the new standard of care in acid reflux treatment. With the continued outstanding long-term patient outcomes, we believe we can help millions of patients get access to RefluxStop therapy while also growing RefluxStop as a multi-billion dollar business opportunity for the investor community. There are 1 billion sufferers in this treatment field, and now we have something that really works. When looking at our three-year results, all patients took PPIs for their acid reflux

before surgery, and none of the patients took PPI at a three-year follow-up, which is an indicator of a very successful treatment. None of the three patients who left the study before the three-year follow-up took PPIs at the time of terminating the study. These are extraordinary results compared to what exists on the market today.

One example of the positive response RefluxStop has received, is from the FDA. We have made great progress in the approval process in the U.S. The FDA has agreed to accept a Premarket Approval Application — PMA — based solely on our existing long-term European data, which if approved, would allow for U.S. market entry without a premarket U.S. clinical trial. We view this totally unique favorable treatment from the FDA as an endorsement of RefluxStop's excellent clinical trial results.

TWST: How soon might we see this in the U.S.?

Dr. Forsell: We are preparing the PMA application right now. We intend to file during the next 12 months and then the FDA handling time is approximately eight to 10 months. If we are lucky, we should see RefluxStop in the U.S. market in the near future.

TWST: How important is this overall to your growth and development as a company?

Dr. Forsell: The U.S. market is very important to us, and we are incredibly excited and looking forward to entering that market. That said, we have done an IPO on the NASDAQ First North Premier Growth Market in Stockholm and have been able to raise significant funding for the next several years. Therefore, we are in good shape. As you know, we are also developing the eHealth products, and I can tell you about some of the other products as well.

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TWST: Please do.

Dr. Forsell: We also have a totally unique new product to treat obesity. Obesity surgery today is focused on making a small food storage and a narrow outlet. Basically, a big portion of your stomach is removed and thrown in the trash — a major physiological alteration and a big burden for the body. What we have done is develop a system to treat people's appetite, which is done in the same way as the body controls appetite naturally. When people eat, their stomach becomes full with food and at some point, stretch receptors in the top part of the stomach send a signal to the brain, indicating that it is full. Then you don't eat anymore.

Our device, AppetiteControl, is designed as a small implant that looks like an octopus with arms, and it will be placed on the outside of the stomach. The food passageway will not be opened, the anatomy will not be damaged, but only a bit of stomach tissue will be sutured over each arm. When one of the arms moves, it stretches the stomach wall, which will activate a signal to the brain, the same way that occurs naturally. We will imitate exactly how people feel full in reality.

We have also developed a special food sensor, which shows what people are eating and how they are eating. The doctor will then be able to sit at a distance and adjust the parameters of the device to enhance weight loss since this will be an eHealth product. All information is designed to be transported to the doctor virtually. He can view the patient data online and decide how much to adjust a patient's food intake. He can decide this patient

should eat solid food six times for lunch to optimize weight reduction, for example, and will fine-tune the implant and interact over years at a distance.

This is one example of how eHealth can provide a new modern treatment. There are approximately 650 million obese people worldwide, and this is a particularly large problem in the U.S. Compared to existing obesity surgery, where a portion of the stomach is cut away, our solution is again designed to be like night and day and has a huge market potential.

Implantica is focused on two treatment areas, digestive surgery and urology. In the urology treatment field, we are developing a product for people who leak urine. Urinary leakage is a very large treatment field with up to 10% of all women leaking urine. Our treatment solution, UriControl, is designed to be used with a remote control, a smart device providing open and close technology.

Another product is for people who can't urinate. More than one-third of these patients have a spinal cord injury and one-third have multiple sclerosis, where they cannot urinate. Paraplegics are not able to urinate on their own and instead in order to urinate they need to put a catheter in their own bladder approximately five times per day. This is a very burdensome life, and we're talking about 100 million people here.

Implantica has developed a system with our eHealth platform and our smart charging implant that is designed to empty the bladder with a remote control. This technology will be such a relief for all these sufferers, and we would envision applying for FDA approval with the humanitarian or breakthrough program. These are examples of what can be accomplished with the eHealth platform combined with the wirelessly charging technology.

Another product in our pipeline is for people who have a stoma. They often suffer removal of a portion or all of their large intestine, maybe due to a disease such as colitis, in which case their small intestine is taken out through the abdominal wall, and their fecal matter is collected in a plastic bag attached to the abdominal wall. It is a business of nearly \$3 billion just for such plastic bags. With our StomaRestore solution, these sufferers wouldn't need to wear plastic bags anymore. Our technology is designed to restore normal anatomy by creating a reservoir and connecting to the anus. With open and close functionality the reservoir is designed to be emptied on command, combining electrical stimulation to train and always keep a healthy muscular intestinal wall.

This is another example of how we can really change people's lives. But of course these products will take a little bit longer to bring to the market. We're actively working on the development of the eHealth products.

The product currently commercially available is RefluxStop, which has great potential. We have a multi-billion dollar opportunity within our reach: a treatment field with a tremendous unmet need and over 1 billion sufferers. RefluxStop is a unique invention that treats the cause of acid reflux without causing the complications of existing anti-reflux surgical procedures. We have very positive feedback from leaders in the gastrointestinal field endorsing the superior clinical effect of RefluxStop.

We have excellent four-year results from our clinical trial. The FDA is allowing us to use existing European clinical investigation results in a PMA application indicating support for our product. RefluxStop is designed to treat acid reflux better than existing treatment solutions, supported by an approximate 10 times lower incidence of 24-hour pH monitoring failure in our CE mark study as compared to the FDA trial of our main device competitor and PPIs as indicated by Becker et al. *Alimentary Pharmacology & Therapeutics* 2015.

This is incredibly important given that esophageal adenocarcinoma has the fastest rising incidence rate of any cancer with approximately a tenfold increase among men over the last 40 years despite the introduction of PPI 34 years ago.

TWST: Just shifting gears a bit, is COVID still impacting your business operations at all?

Dr. Forsell: COVID has affected our business. Many hospitals closed down all elective surgeries during the pandemic, and it was impossible to conduct clinical trials or registry studies during this time. It is difficult to find electronic components for our pipeline products. Look at the car industry, there is a long waiting time to buy a new car because of lack of electronic components. However, Implantica is in good shape due to the solid financing raised at the IPO.

TWST: So you're having supply chain issues on top of the pandemic issues?

Dr. Forsell: For the pipeline products — the smart implants — the pandemic issues are supply chain issues for electronic components. For RefluxStop, there is not a supply issue because RefluxStop has no electronic components. With RefluxStop we have enough supply for a large expansion. The COVID situation has been more about hospitals closing down elective surgeries; however, that has now subsided, and we are seeing the situation starting to normalize. With RefluxStop, we see a huge expansion going forward.

“Implantica’s eHealth technology is totally unique. You can change device parameters at a distance and thus control treatment at a distance. We recently completed an extensive eHealth patent filing of 25,000 pages just covering our eHealth technology. Implantica will be in the absolute front line of eHealth development when that is launched.”

Our top priority for RefluxStop is to accelerate our market access efforts to obtain adequate reimbursement and coverage to unlock the multi-billion dollar commercial opportunity in key markets. Our market access strategy includes a commercial development team to develop RefluxStop’s go-to-market strategy to advance market access with reimbursement, clinical evidence generation, publications, marketing and commercial roll-out. It is clear that market access is our biggest enabler to capture the broader RefluxStop commercial opportunity.

We are at the stage where it’s all about the need for governmental bodies or insurance companies to pay for the device. Health care systems around the world are becoming increasingly complex and demanding when it comes to covering and paying for new medical technologies. The medical necessity of a new treatment is assessed and ensuring “value for money” when approving new technologies is vital.

For any health care provider — e.g. hospitals — certainty in reimbursement with high coverage has a significant impact on the willingness to adopt any new technology. Therefore, securing timely and adequate market access is our top priority and a critical goal for the Implantica team

to achieve. Our long-term vision for RefluxStop is to establish it as a new evidence-based standard of care for acid reflux treatment and unlock the multibillion potential for the RefluxStop business case.

TWST: What are your top goals and objectives for the next year or two?

Dr. Forsell: Implantica’s top objectives for the next two years include filing the PMA with the FDA using our existing European clinical data and to get approval in the U.S. This is the main goal. The second is, of course, to obtain reimbursement in the U.S. We have a really excellent team of market access people who are spearheading the reimbursement effort in Europe and the U.S.

To achieve positive market access decisions and the faster adoption in clinical practice, superior clinical outcomes against standard of care are needed both from randomized clinical trials and real-world observational studies. To that end, the Implantica team has already commissioned a well-designed real-world observational registry study and we are planning a large multi-national randomized controlled trial.

A top goal is to launch an RCT in France under their Forfeit Innovation program, expanding to additional European countries and eventually the U.S. to support the reimbursement process. Then of course, we are focusing on other key markets like Japan. We have been approved to receive support from Jetro, a Japanese government-controlled company that supports various special technology companies in entering the Japanese market, funded by the Japanese government. We are now starting the process to gain regulatory approval in Japan. In addition, we will focus on gaining regulatory approval and reimbursement in Canada.

We are focussing on commercializing RefluxStop step by step, obtaining approval both from a regulatory and reimbursement point of view in more and more countries. It will for sure be an expansion of business year by year now going forward, which is the goal for RefluxStop.

An additional objective is to advance the development of the pipeline products and the eHealth platform in particular. Implantica’s eHealth technology is totally unique. You can change device parameters at a distance and thus control treatment at a distance. We recently completed an extensive eHealth patent filing of 25,000 pages just covering our eHealth technology. Implantica will be in the absolute front line of eHealth development when that is launched. We will then focus on elevating other potential flagship products from our portfolio, such as urinary products UriRestore and UriControl, and also AppetiteControl, controlling appetite, the goal to get them approved and launched.

TWST: What are some of the biggest challenges you’re facing right now?

Dr. Forsell: For the moment, we are very happy that COVID is finally over, and for now, it’s more relief than challenge we feel. We are optimistic — we have more and more adoption by leaders in the surgical field, and we are planning to initiate several large and small clinical and research studies to further validate and demonstrate unique benefits of RefluxStop therapy. For the moment, it’s all quite positive.

TWST: What separates Implantica from its competitors?

Dr. Forsell: For RefluxStop, what separates Implantica's solution from existing surgical methods is that RefluxStop restores and maintains the natural physiologic anatomy to treat acid reflux. Existing surgical methods on the other hand encircle the food passageway to try to keep the LES closed in order to treat acid reflux. The RefluxStop results speak for themselves. It is designed to treat acid reflux better without causing the complications of swallowing difficulty and gas bloating that occur with existing surgical procedures. In terms of PPIs, RefluxStop actually treats the cause of acid reflux as opposed to simply relieving its symptoms. We believe that RefluxStop is designed to, if widely adopted, have a dramatic effect on the incidence of esophageal adenocarcinoma, the primary cause of which is acid reflux.

In terms of our eHealth platform technology, we have a unique technology with the ability to treat from a distance. This is a potential blue ocean market and with our extensive patent coverage and developments in progress, we see an exceptional potential.

TWST: What's the most important thing you would want a potential investor to know about the company?

Dr. Forsell: Our first product, RefluxStop actually has a multi-billion opportunity in a marketplace of 1 billion people with a superior treatment effect, proven clinical results and without the complications of existing therapies. Since RefluxStop has all the attributes to become the new standard of care, it's most likely just a matter of time. Furthermore, we have two platform technologies and a very large patent covered pipeline, which also are very interesting for those investors who are more mid term.

TWST: And as we conclude, is there anything you wanted to mention that we haven't discussed?

Dr. Forsell: I would like to mention that the enthusiasm Implantica has for its product pipeline is shared by surgeons in the treatment fields. For example, we had a company called GfK Ltd.

in the U.K. survey of surgeons about our pipeline products and for AppetiteControl, we asked, "Would you start to use this product right away?" Eighty percent said they will start right away with this product and also said that this may potentially account for majority of the obesity surgeries in future, if it's proven long term. For UriControl to treat urinary incontinence, basically two-thirds of the surgeons may consider switching right away to this device, because it can potentially offer so many advantages.

The good thing with UriControl is that it may already fit within the existing reimbursement coding and payment pathway in some countries — in the U.S., for example, for some of the existing urinary incontinence treatment options, they pay \$13,000; in Canada, C\$18,000, and so on. That will provide a solid foundation for reimbursement planning for UriControl and hopefully help accelerate the overall market access approval process.

When we enter the market with our eHealth platform, this will be a new era. There are so many companies that are focused on eHealth, but they are focused on outside the body — everything is centered around outside measurement of parameters. We are focusing on the inside of the body. We are measuring, have all the intelligence, and treat inside the body. Implantica's eHealth platform is designed to have the ability to provide many more technologically advanced treatment solutions which will meet unmet patient needs and drastically improve patient quality of life, as well as save cost for society.

TWST: Thank you. (CJ)

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