Marc Oczachowski â?? CEO, EDAP TMS, France

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Marc Oczachowski, CEO of EDAP TMS, a French medtech and global leader in therapeutic ultrasound, elaborates on the history of the company while discussing their newest innovation for the noninvasive treatment of prostate cancer. Oczachowski also offers insights on the experiences of a local innovator moving from scale-up to internationalization in France.

Please introduce yourself and EDAP TMS.

My name is Marc Oczachowski, I am from Lyon, and I have been working with EDAP TMS for the last 22 years. My background is a combination of scientific biology and business. Before becoming the general manager of the company in 2004 and later on CEO in 2007, I started my career at the company as a sales manager for our different territories around the world.

EDAP itself is a company that is celebrating its 40-year anniversary in 2019, a testament to our historic capacity for innovation. The company was established by Professor Dubernard from the Edouard Herriot Hospital in Lyon and Pr. Dominique Cathignol who was working with The National Institute of Health and Medical Research (INSERM) to develop shockwave technology for the minimally invasive treatment of kidney stones. In order to ensure that this technology could be commercialized and brought to the market for the benefit of patients, they partnered with an investment firm to create EDAP TMS as it is today.

Since then, we have worked within the same triangle of stakeholders to develop EDAP-TMS: INSERM, the Edouard Herriot University Hospital of Lyon, and ourselves to go from basic research, through clinical research, to the production and commercialization handled by EDAP-TMS. We have a strong synergy between these three activities, all carried out within a regional scale. Thanks to the help of both French national and local institutions, we can manage the entire project from research to clinical and industrial phases.

What are the challenges of bringing this innovation to patients within the French healthcare system?

Although we are a company with 40 years of history, we still think of ourselves in a startup mentality. We are very ahead of trends within our sector and EDAP-TMS constantly creates new concepts in the surgical environment which we consistently bring to the market. EDAP-TMS is a global leader in our experience with energy-based ablation tools. However, bringing this technology to the market can still be a challenge.

For example, EDAP-TMS developed high-frequency ultrasound for the treatment of localized prostate cancer. The first treatment was performed in Lyon in 1993 and we have only recently been granted a temporary, partial reimbursement in France. The process is very complicated with many actors involved to try and make the technology financially viable in hospitals.

Currently, this partial reimbursement is only available in select healthcare institutions for a handful of eligible patients under a clinical study setting. This means not all prostate cancer patients who could benefit from this innovation will have access to the treatment. It took us twenty years to reach the milestone of partial reimbursement, and as we are coming to an end of the five-year probationary period for which the results will be analyzed, we hope to move to the next step in making high intensity focused ultrasound (HIFU) treatment for patients with prostate cancer more accessible in France.

How would you describe the French environment in the context of developing innovative companies into larger scale operations?

In the French management of innovation today, there are many resources for the research and development of projects, but when moving to adoption, there is a large gap which exists. France is very strong in creativity and breeding innovation but lacks in its ability to market these new technologies and is not organized to support the scaleup of companies. Hence, we see many French entrepreneurs struggling to bring their businesses to the next level in the country or choosing to relocate externally to markets like the US. Because of this outward flow, France loses on the investments it makes at the beginning while other countries reap the rewards of success.

How did EDAP-TMS overcome this challenge?

EDAP-TMS has been a publicly listed company on the US NASDAQ stock exchange since 1997. This decision was taken because at the time we were trying to enter the US market with another product, and it was also easier to find funding capital for commercialization activities this way. This was a tremendous help in our efforts to achieve FDA approval, which took ten years and an investment of EUR 20 (USD 22.7) million. As a private company in France, this would have been impossible. At the end of 2015, our first generation of Ablatherm-HIFU was cleared by the FDA and the technology has been well adopted in the market. We were quickly granted temporary reimbursement from the Centers for Medicare & Medicaid Services after 18 months, something that took 15 years in France to achieve. Moreover, we are excited to share that earlier this month, the first hospitals in the US have acquired our innovative recently FDA cleared product Focal OneÂ®, which provides urologists with one of the most precise tools on the market for the targeted, non-invasive ablation of prostate cancer tissue. Specifically, UCI Health Medical Center in California was one of the three medical centers in the country to acquire the device.

How well received has HIFU technology been as a treatment of prostate cancer?

More and more, this innovative technique is becoming valued as the future of patient treatment. Our newest product, Focal OneÂ®, leverages the most advanced therapeutic ultrasound technology as a robot-assisted non-invasive alternative to traditional prostate cancer surgery. Surgical intervention is quite extreme and involves the removal of the prostate and some surrounding healthy tissue during an operation, resulting in many side effects. What we are proud to share is that statistically speaking, there is no difference in effectiveness between radical prostatectomy or radical radiation treatments and active surveillance, as per the Protect Study recently published. However, there is a strong distinction in side effects. Through HIFU methods, patients are able to avoid the impotence and incontinence associated with more invasive treatments.

Focal OneÂ® is a complimentary, alternative tool in the middle ground between active surveillance and radical treatments such as prostatectomy. We designed the machine as a solution to patients who are choosing the surgical option less and less, and as a complementary tool to surgeons. Focal OneÂ® is entirely automated and together with urologists who chose the points and intensity of treatment based on high-resolution multiparametric prostate MRI fused with ultrasound images, a targeted treatment can be delivered to patients on a personalized basis.

What is EDAP-TMSâ?? internalization strategy?

EDAP-TMS has cultivated a strong international network of fully owned subsidiaries in several major markets. We have a large team of about 45 people in Japan working as a hub for the Asian market. We are still progressing on attaining PMDA approval for HIFU and Focal OneÂ®, however, we hope to reach this milestone within the next few years. Japan is our second most important market after France, accounting for nearly 25 percent of EDAP-TMSâ??s revenues. EDAP-TMS has a favourable market share for our lithotripsy business for kidney stone shockwave therapy with 150 devices installed throughout the country. Moreover, because of our solid foothold in Japan, we also offer regulatory services to help other companies in their PDMA process and also act as a distributor for urology devices which accounts of approximately half of our revenues in the market.

EDAP-TMS also has a subsidiary in South Korea which we restructured in 2017. The affiliate was very small, and we were subcontracting to a cousin company for sales and distribution services, but today all activities are carried out internally in our own subsidiary. Since 1997, we have also been present in Malaysia to do business in the country itself while simultaneously managing our Southeast Asian distribution network which includes Australia. Malaysia is our operational hub for the region which allows us to be agile, reactive and work to create reliable partnerships with our clients.

In addition, we also have subsidiaries in Germany, Italy and representative offices in the UAE and Russia. Our headquarters in France manage the development and manufacturing of our devices and their marketing and sales in the French territory along with all other markets in which we do not have a direct presence and where we do business through distribution partners. Lastly, we have our US office in Austin â??Texas that we opened in 2012 and which manages the entire Americas as of 2019.

What benefits exist for EDAP-TMS to base its operations in Lyon rather than another city in France?

As I mentioned in the beginning, one of the greatest values Lyon offers EDAP-TMS is the innovative triangle between INSERM, the University Edouard Herriot Hospital and EDAP. The INSERM department, LAPTAU, is Lyon based and has developed alongside EDAP-TMS over the years. There is a strong level of worldwide expertise in HIFU technologies in Lyon and it is imperative we have such a resource close by. The local network EDAP-TMS has developed in the city allows us to be extremely innovative and reactive within our projects.

In terms of recruiting talent, this is always a challenge. However, it is not difficult to convince professionals to come to this region. Lyon is a dynamic city with natural beauty that attracts people from all over the country.

What are your top priorities in the midterm future for the development of EDAP-TMS?

First, we are aiming at developing ourselves worldwide, particularly in the US market following our recent FDA approval and hospital penetration. Secondly, our vision is to solidify HIFU technology as the gold-star standard of treatment for prostate cancer. Finally, we want to expand HIFU to other therapeutic areas such as endometriosis and liver metastases. Our ambition is to develop a box platform with different types of probes using HIFU for use in urology, and many other specialty therapeutic areas. In fact, the FDA registered Focal OneÂ® as an ablation tool for soft tissue rather than just a prostate cancer treatment. This shows that HIFU and Focal OneÂ® are truly the surgical tools of the future, given to professionals to increase the level and complexity of treatments while reducing trauma to the patient.

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