Euro bounce: Europe's medical technology industry employs more than 500,000 people and generates €95bn per year

Europe takes medtech lead

THE REPUTATION OF EUROPEAN COMPANIES WHEN IT COMES TO NEW MEDICAL TECHNOLOGIES AND THE CONTINENT'S ATTRACTIVE REGULATORY ENVIRONMENT IS INCREASINGLY CAUSING VENTURE CAPITALISTS FROM THE US TO STEER THEIR INVESTMENTS ACROSS THE ATLANTIC. **WENDY ATKINS** REPORTS

Regardless of which sector a business operates in, the basics always have to be in place to make an investment worth considering: a favourable tax regime, an enabling regulatory structure, cost efficiency and a skilled workforce all rank highly on the check-list of would-be investors. When it comes to regulatory matters, investors are increasingly reporting that Europe is becoming the most desirable location for the medical technology sector.

Investors in the European medtech market are bullish about prospects in the region for an industry that employs more than 500,000 people, turns over €95bn per year and encompasses some 500,000 different medical technologies.

According to Guy Lebeau, chairman of Eucomed, a body that represents European medtech firms, the industry has a vital role to play in steering European healthcare onto a sustainable path. "There is a growing need for value-based medical technology – technology that marries cost-effectiveness with improved health outcomes. Our industry is stepping up present health systems with value-based innovations that make for healthier patients in both the short- and long-term," he says.

"We're also calling on national governments to do their part. These are tough economic times, but decision-makers are starting to realise that they present an opportunity for new thinking in sustainable health service delivery. This new thinking is leading to investment from overseas and a growing realisation that Europe is emerging as a real leader in medtech innovation."

A valued asset

Many investors point to Europe's regulatory approach as a contributory factor in persuading them of the value of investing in the continent.

John E Milad, investment manager at private equity firm NBGI Ventures, which says it is the only fund in Europe exclusively focusing on the medical technology sector, says: "Europe is a much more permissive and attractive market than the US for innovative companies looking to introduce new medical devices. Under the Medical Device Directive, the EU has a CE [European conformity] marking approach to getting devices approved for human use, which is mainly concerned about establishing safety and having the right processes and procedures in place. This compares with the US FDA [Food and Drug Administration], which often imposes a more onerous burden on innovators in terms of timelines, efforts and costs, and is widely perceived as less predictable."

Mr Milad says this means companies can easily end up spending more than $100m getting a Class III device to market in the US. "That's really challenging in the current capital market where venture funding is scarce and the public markets have pretty much shut down so you can't float to raise your money. This is different from the past where people typically wanted to immediately get new products into the US because it was the world's largest market for medical products and many

inventors were more comfortable with high-burn, high-risk investments. Now, thanks to the attractiveness of the European regulatory environment, Europe can be the natural first market of entry for new devices to more quickly establish clinical adoption and market penetration in a capital-efficient manner," he says.

Mr Lebeau agrees: "The EU regulatory framework on medical devices has brought about positive results over the past 20 years. Our system has been proven to deliver a high level of safety and provides European citizens with access to innovation two to three years before their US counterparts. The EU is in the process of revising the framework with the goals of removing barriers to innovation, ramping up multi-stakeholder engagement and improving coordination among EU member states.

Straightforward approach

Anything that simplifies the regulatory process is welcomed by investors, as recent research from the US highlights. According to a survey of 156 venture capital firms by the Medical Innovation and Competitiveness Coalition, a partner organisation of the National Venture Capital Association, the FDA is considered so unpredictable and risk averse that young companies are stopping trying to enter the US market. Some 39% of those surveyed said they have cut their investment in life sciences over the past three years and the same percentage said they will continue to cut back in the coming years, some by as much as 30%.

There is a fear that venture capitalists are beginning to steer their investment dollars away from fledgling pharmaceutical and medical device companies in the US, which could encourage firms to develop and invest in treatments overseas.

"The European approval process is generally less expensive, faster and more predictable," says Jeffrey B Jump, president of medical device company Biosensors International. "The CE mark mandate instead of the FDA's safety and efficacy approach puts responsibility in the hands of the doctors rather than the regulators. In addition, the decentralised approach in Europe is less vulnerable to 'regulatory capture', in which the influence of large industry players can lead to de facto market entry barriers, to which smaller, less well financed companies are especially vulnerable... Compared to other regulatory frameworks around the globe, the EU seems to have found a reasonable balance between patient safety and innovation."

However, questions are being asked about how well the EU regulatory system works. "We've seen increased interest from some quarters in adopting a regulatory system that models [itself on] that of the US FDA, which would increase development costs and delay time to market for many devices," says Mr Jump. "Of course, given the macroeconomic environment, governments and healthcare providers are instead looking for ways to reduce costs, and this has actually helped drive downward price pressure."

> HEALTH SYSTEMS ARE LOOKING TO TECHNOLOGY TO DO MORE WITH LESS

Medtech hot-spots

Countries such as Switzerland, the UK, France, Ireland and Germany are ranked highly for medtech investment. Eastern Europe is also starting to move up the rankings because of its low labour costs.

Biosensors is one firm taking advantage of what the continent can offer, and has established its European operations headquartered in Switzerland. "We benefit from a central location in the heart of Europe with high-quality infrastructure, a highly skilled workforce, an excellent healthcare system and a government that supports investment in manufacturing and R&D. In addition, the Lake Geneva region boasts a very dense network of life sciences companies and research institutions, which creates opportunities for development partnerships," says Mr Jump.

Mr Lebeau says: "Health systems are looking to technology to do more with less – to add years of healthy life to ageing patients in a way that is sustainable and cost-effective. Any technology that can reduce hospital stays and empower patients through prevention and recovery is going to be popular. The use of e-health solutions such as telemonitoring, as well as the shift from hospital to community care, are examples of an evolution in the way Europe views medical technology and are representative of the enormous opportunities throughout the European health landscape."

Mr Milad adds: "Now is a great time to invest in the European medtech market as the continent is a huge and productive innovation engine that keeps generating a continuous stream of clinical insights and new technologies. There are countless medical needs that have yet to be addressed. Moreover, cost pressures across all health systems drive demand for new approaches... All the raw materials and prerequisites to build innovative companies are abundant in Europe, so all that's really needed are the willing entrepreneurs and sources of funding." ■