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Sensing An Opportunity: Opsens Poised To Enter Growing Cardiac Market

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Mullally: Opsens has made a name for itself in the oil sands, where it has successfully commercialized its fiber optic sensors. But if the company is successful in getting OptoWire approved in the U.S., Europe and Japan by next year, one has to wonder about the future of its SAGD business.

Back when I was a drug rep, I spent a few days shadowing a cardiologist and was fortunate to spend some time in the cardiac catheterization lab (cath lab). Those were the heady days of drug eluting stents, where companies like Angiotech were soaring on the wide utilization of stents for coronary artery disease. Things in the cath lab have changed a lot since then.

“Inappropriate stenting” has captured headlines as the media and more importantly payers are increasingly scrutinizing stent use. However, I was surprised to learn that technology now exists, known as fractional flow reserve (FFR), to quantify the likelihood of a cardiac vessel, and thereby the patient, benefiting from a stent. I was even more surprised to learn that a tiny Quebec City based company, **Opsens (TSXV:OPS)**, known more for its role in the oil sands, believe it has an improved FFR technology that could make them a major player in this growing cardiology market.

Opsens was founded on proprietary fiber optic sensor technology. The company targets niche markets where highly sensitive pressure, and sometime temperature, measurement is required. The company has made a name for itself in the oil sands where it has successfully commercialized its fiber optic sensors for measuring down hole pressure and temperature in steam assisted gravity drainage (SAGD). Its SAGD business, as well as

a few other niche industrial applications, has generated relatively consistent \$6 – \$8 million in annual revenue. This revenue has helped the company to develop their fiber optic technology for new markets without having to hyper-dilute its stock. One such new market is FFR, where the company is poised to make regulatory submissions in Europe and the U.S., with the goal of commercial launches in 2015.

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FFR is used during coronary catheterization to measure the ratio of distal pressure to aortic pressure. It is intended to complement the current gold standard coronary artery diagnostic tool, angiogram, by providing quantitative data on the degree of stenosis (narrowing) of a vessel. FFR was first developed and launched by a Swedish medical company, Radi Medical Systems, which was acquired by U.S. medtech giant St. Jude Medical (NYSE: STJ) in 2008. Although provocative technology, FFR lacked the robust clinical outcome data to drive broad adoption, until 2009 when Radi / St. Jude presented the FAME study results. The study results, published in the prestigious New England Journal of Medicine, demonstrated superior cardiac outcomes for patients when FFR was used in combination with an angiogram and stent versus an angiogram and stent alone.

The FAME study was a catalyst for the FFR market, providing the mortality and morbidity evidence needed for broader adoption by interventional cardiologists and payers. The study also crystallized Opsens’ plan to focus its R&D efforts on FFR. Before 2009 the sleepy FFR market had not attracted many companies. This was partly due to the small size of the market (U.S. market estimated at \$75 million in 2009) and also the challenging intellectual property (IP) landscape. Two companies, St. Jude and Volcano Corp. (Nasdaq: VOLC), had IP for FFR that prevented new market entrants. Both St. Jude and Volcano used electrical sensors for FFR, and this technology was at the core of their IP. Opsens saw an opportunity to exploit its fiber optic expertise, and set about developing a new approach to FFR based on optical sensors as opposed to electrical-based sensors. The company believes its optical sensor FFR technology, known as OptoWire, has performance, reliability and connectivity advantages versus the incumbent FFR products offered by St. Jude and Volcano. More importantly, the company’s differentiated optical sensor approach allowed it to secure IP for OptoWire, giving it freedom to operate in the FFR market.

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Opsens is at an inflection point with its FFR business, and it could be timely for investors to keep an eye on the company. Opsens should be applying for regulatory clearance in the U.S. and Europe imminently. The company has already signed a distribution agreement for Japan, and a regulatory submission in that territory has already been made. It is therefore foreseeable OptoWire could be commercially cleared for sale in the U.S., Europe, and Japan in the first half of 2015.

The company has yet to sign distribution or partnering agreements for the U.S. or Europe. I have to assume that big cardiac medical device companies, especially those with a presence in the cath lab, such as Abbott and Medtronic, could be interested in a distribution or license agreement for OptoWire. This type of deal would likely yield a healthy upfront payment for Opsens, but big companies can sometimes be unreliable in their commitment to new products for small, albeit growing, markets. Another option likely being contemplated by Opsens is to enter into a number of non-exclusive agreements with smaller distributors. These types of deals generally don't yield much, if any, upfront economics, but the partners are motivated and hungry to sell.

If the company is successful in getting OptoWire approved in the U.S., Europe and Japan by next year, one has to wonder about the future of its SAGD business. SAGD revenues currently fund a large part of their R&D budget, but does it make strategic sense to keep that business if OptoWire is commercial in 2015? The company has a history of successfully exiting /monetizing non-core businesses and applications of its technology. In 2010 Opsens sold its high-power transformer business for \$3.1 million, and earlier this year it licensed its fiber optic technology for circulatory assist devices to Abiomed (Nasdaq: ABMD) for \$6 million (upfront and milestones).

As Opsens progresses with OptoWire, from regulatory submissions, to commercial clearances and new partners / distributors, the relevance of its SAGD business will increasingly come into question. In the meantime, SAGD provides investors with some downside protection, as the company enters this pivotal period with its FFR business.

Disclosure: Cantech Letter Life Sciences Editor Hogan Mullally owns shares of Opsens.

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