

EP Vantage Interview - Merrion partners into the future



[Jonathan Gardner](#)

With two key partnerships with Novo Nordisk to develop oral formulations of insulin and a GLP-1 agonist, small Irish drug developer Merrion Pharmaceuticals believes it is well-positioned to bring forward multiple products using technology to turn parenteral medicines into enteric-coated tablets.

Using a technology purchased from fellow Irish pharmaceutical group, Elan, six-year-old Merrion has also advanced through phase II trials a weekly oral version of zoledronic acid that it is hoping to target for use in bone metastases related to breast, prostate, multiple myeloma, lung and other solid tumours. Merrion expects to partner this leading pipeline candidate in the next 12 months and chief executive John Lynch tells *EP Vantage* there is a "good amount of interest."

Like most drug-discovery firms taking the proprietary delivery route, Merrion's strategy seems to offer a relatively low-risk strategy in that the safety and efficacy data of the base compound is established and the remaining challenge is ensuring that the new product works as well as the old. An endorsement in the form of the two Novo partnerships suggests that the Dublin company is on to something novel.

"We're in a space which is pretty uncrowded," says Mr Lynch. "There are not many people in the area. We have a pretty broad database. We can show success across a huge range of molecules and the technology is intrinsically safe and very simple. Those are huge advantages in attracting partners and going forward."

Trading on strength

The oral zoledronic acid, dubbed Orazol, is aimed at attacking a weakness in cancer care - namely, the need for patients to go to infusion centres when receiving monthly treatments of the blockbuster drug currently sold by Novartis, Zometa. Mr Lynch says the need to schedule appointments and travel to the centres raises compliance issues that can be addressed with a weekly self-administered pill, not to mention reducing the burden on the health care system.

Orazol has completed a phase II trial in 30 patients, with equal efficacy in the primary endpoint, urine NTx, when compared to the monthly infusion of Zometa, as well as strong trends in secondary endpoints. Merrion is planning a phase III trial in 420 patients, as agreed with European regulators. The phase II trial was not powered to find statistical significance, Mr Lynch says, but based on the results would be able to show statistical significance with 70 to 80 patient. So with over 400 patients in the phase III a clear efficacy signal should be detectable.

Analysts from Edison Investment Research have estimated Orazol could be on the market in 2013, although Merrion will only move forward with the Phase III trial once it has secured a partner.

Novo backing

An endorsement in the form of two partnerships with Novo, the biggest producer of insulin in the world, lends some support to Mr Lynch's claims. Novo signed a deal with Merrion to develop an oral insulin in November 2008, followed by an oral GLP-1 agonist deal in January 2009, with total milestones of up to \$116m available. So far the partnership has yielded \$7.3m for Merrion and a €900,000 equity investment.

The Novo partnership leaves the company well-positioned for development. It ended 2009 with €7.22m cash on hand, down slightly from €8.14m the year before, with R&D expenses of €4.41m. Despite the seemingly modest cash balance, Mr Lynch says Merrion has no immediate plans for a fundraising.

This is a sentiment echoed by analysts at Edison, who say that without milestones from Novo Merrion would need to raise funds in 2012 but expects that the company will receive continued fees from the insulin and GLP-1 projects and will partner Orazol in mid-2010.

The research house estimates revenue of €5.82m this year and €5.37m in 2011 and before any Orazol deal,

cash of €534,000 at the end of 2011. This suggests that an Orazol deal is essential if Merrion wants to avoid a fundraising.

Oral diabetes solution

It is the oral insulin and GLP-1 that may be the more closely watched of Merrion's portfolio. With companies like Novo, Amylin Pharmaceuticals and Sanofi-Aventis trying for longer-lasting doses of these injected therapies, oral pills would certainly change how physicians treat diabetes and how patients view the medication ([*EP Vantage Interview - Novo shooting for broad use of insulin degludec, June 30, 2010*](#)).

Not only would it eliminate the issues surrounding self-injection of these drugs, it also eliminates any issues of product stability and storage that might arise from their use in the developing world, where diabetes has a rising prevalence.

For the future, Mr Lynch sees Merrion remaining a partnership-oriented company. The ideal business plan would be to sign up another big pharma partner like Novo with multiple products that can make use of the Merrion oral formulation technology, with single smaller opportunities outside those two partnerships. From there, Mr Lynch says, the company would be able to move forward internal products and eventually add technologies to the company's arsenal.

"At this point we do not have any strategy to market products," Mr Lynch said. "You can essentially put your entire opportunity at risk as you wait for your approval to come through."