

EP Vantage Interview - Gloucester weighs multiple options for future



[Lisa Urquhart](#)

In contemplating its future nothing is off the table for Gloucester Pharmaceuticals. The private Massachusetts-based company is still basking in the afterglow of FDA approval for its first product, Istodax, a treatment for cutaneous T-cell lymphoma (CTCL), earlier this month, but it still has a firm focus on its next steps that could see it either IPO or even sell itself.

While the direction the company will take is still very much up for grabs, speaking to *EP Vantage*, Alan Colowick, chief executive of Gloucester, is clear that decisions will be made by the beginning of next year. "At this point we are not ruling out anything that makes sense for us and having raised that money before Istodax got approved puts us in a nice position to really being able to explore multiple options and doing what makes the most sense," he says.

The cash cushion that will certainly strengthen Gloucester's hand in any discussions is the \$29m raised from five loyal investors who have to date pumped about \$100m into the company and will almost certainly be looking for the exit route that provides the best return on their investment.

Choices, choices, choices

With enough money to last through until the end of 2010, without adding any sales of Istodax which is expected to become available at the start of next year, the group can consider a range of options including the longer-term strategy of staying independent and partnering the drug outside of the US.

Discussions are already underway with what Mr Colowick describes as a "number of potential partners" who are looking at licensing the drug in Europe or folding it into a bigger plan of a global partnership.

Perhaps an indication of just how fluid the group's plans are is that a global partner for the drug, which is also about to enter phase III trials in peripheral T-Cell lymphoma, could include a co-promotion option in the US.

As Istodax is the group's only product and while it is also studying it in solid tumours, with trials in non-small cell lung cancer just initiated, the group would need to extend its portfolio with the in-licensing of new products to be truly viable as an independent company, something that once again Mr Colowick is "considering".

Braving the markets

But it is perhaps the other options that the group is mulling that are providing the most interest to outside observers. One of these is a flotation of the company.

"That is certainly on our list of possible strategic tasks, obviously there is lot we don't control about that option, such as the general market conditions and if there is really a window in the IPO market and is the market receptive to companies without demonstrated revenues," say Mr Colowick.

The fact that Gloucester is poised to start generating revenues and that markets do seem to be more receptive to more mature companies debuting on US stock exchanges, witness this year's launches of Cumberland Pharmaceuticals and Omeros, could mean that if Gloucester did take this route the interest might be there to get an IPO away safely, something that would have been unthinkable even six months ago.

On the block

Unsurprisingly, with the group refusing to rule out licensing agreements or an IPO the other logical exit for investors, a trade sale, is also one of Gloucester's many options.

"There are certainly a number of companies where buying the company makes a lot of sense for them, as apposed to some sort of alliance," says Mr Colowick who again can boast of talks with a number of interested companies.

What could explain Gloucester's popularity and bewildering range of options for its future is the promise that

people see in Istodax, which is only the second ever histone deacetylase inhibitor (HDAC) to be approved ([Event - Gloucester hoping to add to evolving HDAC success story, November 05, 2009](#)).

The group believes that it could be a new standard of care in CTCL, given the sustained duration of response it has demonstrated in trials compared to the current treatments for the disorder. Sales of \$400m in CTCL are forecast by Gloucester, which is also trying to extend its reach in haematological cancers and pivotal trials in PTCL have started with an sNDA expected to be filed sometime next year. Trials in multiple myeloma in combination with Velcade and dexamethasone are also under way and have shown impressive response rates.

Wider opportunity

The opportunity for the drug in solid tumours could really be the driving force for discussions, given that they offer a much bigger market opportunity ([Therapeutic focus - HDAC inhibitors gathering evidence of broader utility, September 11, 2009](#)).

Given its limited resources the group has initially focused its efforts on non-small cell lung cancer in combination with erlotinib (Tarceva). However, a bigger partner or owner could pick up Gloucester's phase II research projects in renal, prostate and pancreatic cancer that have been mothballed in favour of NSCLC.

With such a myriad of options to choose from, while Gloucester's future may not be clear, it is certainly looking very bright.

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