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March 19, 2010

TiGenix reels from surprise US delay

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The dangers of predicting the chances of regulatory success in the US on the basis of European clearance, and vice versa, was highlighted again this week when the FDA asked TiGenix to conduct an additional trial of ChondroCelect, a cell therapy to repair and regenerate knee cartilage, before it would accept a filing for the product.

Having generated significant share price gains last year on the back of European approval and commercial launch of ChondroCelect (*TiGenix rises on landmark European approval, June 29, 2009*), those gains have been wiped out with TiGenix shares sliding 27% since news of the FDA rejection on March 16. Now trading at €3.05, TiGenix shares are back to levels seen 12 months ago before ChondroCelect's pass at the European authorities. The level of disappointment is understandable given that analysts now expect a minimum five-year delay to approval in the US.

Huge disappointment

European approval was gained on the basis of a single pivotal trial which took around five years to complete, which included a three-year follow up. Although the FDA normally requires two positive outcome studies to approve a new therapy, hopes were high that this stipulation would be waived, particularly as the only other comparable product, Genzyme's Carticel, was approved in 1997 with limited supporting data.

As such, one London-based analyst described the US setback as a "huge disappointment", adding: "We were led to believe the company had an agreement with the FDA that the single European study would be enough."

One of the conditions attached to European approval was for TiGenix to conduct an additional confirmatory study of ChrondoCelect, which the company expects to start by the end of the year, so the key issue now is whether this study can be designed in such a way to fulfil the requirements of both the EMA and FDA.

However, even if it can become a dual-purpose trial, the problem is that these studies take a long time to enrol a few hundred patients and long-term outcomes need to be assessed over two to three years.

Cash preservation

Before this week's news, ChondroCelect was estimated to generate annual sales of $118m by 2014, although the bulk of these revenues would have come from the US market. ING estimated 79% of product sales would be derived from the US, in a research note published last August.

So with ChondroCelect unlikely to reach the US market until 2016 or even 2017, the subsequent impact on earnings will be dramatic.

Focus will therefore turn to preserving current cash reserves, €25m ($33.8m) as of the end of 2009, and generating maximum return on European sales.

With a projected burn rate of €17m this year, current cash could stretch into the middle of 2011, but in the meantime European sales are expected to be modest until reimbursement is approved which could happen in the second half of the year.

As such, the company is now walking a tightrope between conserving cash and trying to significantly boost European sales, while making commitments to conduct the confirmatory trial to meet the FDA's surprisingly high clearance bar.

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