Evaluate Vantage

June 14, 2016

The Mesoblast dream is over

Jacob Plieth

The Australian biotech Mesoblast has been living on borrowed time for a few years now, so the surprising thing about today's revelation that Teva had at last pulled the plug on its lead asset, MPC-150-IM, is why this had taken so long.

Mesoblast had heralded the start of Australia's own mini-biotech bull market, and with its shares falling 42% today the dream looks finally to be over. What is more, the group now has a mountain to climb to restore credibility with investors, and needs to find a new partner while an equity offering to fund phase III is likely to send its stock drifting further downwards.

In the meantime Mesoblast is doing the only thing it can: putting a brave face on Teva's decision, which concerned discontinuing MPC-150-IM development for chronic heart failure. Mesoblast's chief executive, Silviu Itescu, called this a "major win", and said MPC-150-IM was a potential multi-billion dollar blockbuster.

Analysts were less convinced, and in an investor call Maxim's Jason Kolbert berated Mesoblast for being evasive and doing a U-turn after previously playing up Teva as a key strategic partner.

Perhaps worst of all, in terms of loss of credibility, was the fact that Mesoblast stock had been suspended since June 3 "pending the release of an announcement". Mr Itescu said this was an Australian stock exchange requirement while the Teva termination was ironed out and the subsequent financing put in place.

But he refused to disclose what the financing arrangement involved, beyond stating that it was in equity and would pay for completion of the phase III trial Teva had started.

"Nobody is happy about being locked out of trading for 10 days," Mr Kolbert retorted. "Should we now assume that $60-100m of stock is going to be dripping onto the market at will to cover the expense?"

Inherited burden

The study tests whether MPC-150-IM, a mesenchymal precursor cell project, can reduce heart failure-related major cardiovascular events versus control. Over 230 of 600 patients are recruited, and it is scheduled for completion in 18 months, said Mr Itescu.

Still, it was a surprise that Teva even began this study, having inherited the Mesoblast project through its 2011 acquisition of Cephalon. The Israeli group had clearly bought Cephalon for its CNS portfolio, and was not interested in cardiovasculars.

It initially stalled for time – perhaps while it considered the financial penalty of axing the deal there and then – before finally starting patient recruitment in 2014.

A subsequent move to cut enrolment from 1,165 to 600 patients looked like Teva giving itself a chance to end the deal early (*Teva's phase III rejig leaves some unanswered questions, August 25, 2015*). The entire cost of the phase III trial was around $150m.

The Australian group, which had US$100m in the bank at the end of March, now turns to finding a new licensee – one not only content to fund the project but also with either an existing chronic heart failure franchise or that is "committed to spending substantial capital to build out such a franchise", said Mr Itescu.

Hopes had risen in April 2015 that a new partner was set to take over from Teva, when Celgene invested $45m in Mesoblast equity, but a six-month option on a formal licensing deal came to nothing. Today Mr Itescu insisted: "We are in discussion with a number of cardiovascular companies."

But it takes optimism to think that, in a distinctly bearish biotech market and with a study whose statistical power has been much reduced, any of these should sign on the dotted line before phase III data are out.

Primary endpoint	Study design	Trial ID
Time to HF-MACE	Double-blind, vs sham comparator; 600 CHF pts (earlier 1,165 pts)	NCT02032004

To contact the writer of this story email Jacob Plieth in London at jacobp@epvantage.com or follow @JacobPlieth on Twitter