## **Biotech Daily**

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## MESOBLAST: THE MARKET WILL TELL

## MARC SINATRA'S BIOGUIDE: MESOBLAST

Mesoblast has been one of the best performing life science companies on the ASX since floating at 50 cents in December 2004.

A track record of beating milestones has seen Mesoblast's share price hit a high of \$1.85 in March this year, before settling back to \$1.65.

With phase II clinical trials nearing, beating milestones will no longer be enough. Clinical and then commercial hurdles must be cleared for shareholders to be truly rewarded.

**Overview:** Mesoblast is an archetypal lean Australian biotechnology company. It was formed to develop adult stem cell derived treatments for orthopaedic conditions based on intellectual property licensed from their self-described sister company, Angioblast. Mesoblast currently owns 33.3 percent of Angioblast which will rise to about 39.2 percent should shareholders approve an additional investment. Mesoblast and Angioblast share directors and employees.

Financials: Market Cap \$102m; Cash \$19.5m; Last quarter cash burn \$2.76m.

## **Directors and management:**

Michael Spooner, executive chairman
Donal O'Dwyer, BE, MBA. non-executive deputy chairman
Byron McAllister, B.Sc, M.Ag, non-executive director
Dr Silviu Itescu, director and chief scientific adviser
Paul Rennie, chief operating officer
Kevin Hollingsworth, chief financial officer and company secretary
Dr Donna L Skerrett, clinical and regulatory affairs
Michael Schuster, project manager

The backgrounds of the directors and managers are diverse and cover many key areas. Although there seems to be a lack of in-house orthopaedics expertise, Mesoblast's scientific advisory board and consultants fill this role.

**Technology:** Adult stem cells have been extensively studied and are used in one currently marketed product and numerous others in development. Adult stem cells are special in that they can develop into variety of different tissues, similar to embryonic stems cells, but, since they come from adult donors, they do not carry ethical concerns. Mesoblast's intellectual property principally protects their ability to purify, in a particular manner, a type of adult stem cell termed the mesenchymal precursor cell. Being able to purify these cells is potentially important given they are found in extremely low concentrations. It is, however, not clear whether this ability will provide a significant competitive advantage.

**Products in development:** Following are the main products Mesoblast has in development and their stated timeline for filing phase II independent new drug applications.

- 1) spinal fusion current quarter;
- 2) bone regeneration end of this year; and
- 3) cartilage repair and regeneration 2007;

In addition, Angioblast intends to submit an application for heart failure in the current quarter.

The regulatory pathway for adult stem cell products is not entirely clear, nor is it clear what the optimal product configuration is likely to be for each indication, making the development path for each product after the phase II trials difficult to predict. The preclinical results supporting each of their products appear solid based on available detail.

**Product markets:** The markets for adult stem cell products for spinal fusion and cartilage regeneration and repair are conservatively estimated at more than \$US1 billion, with the market for heart failure likely to be well over \$US1 billion. The market for bone regeneration is probably much smaller. Competition in many of these markets is likely to be fairly strong, given the products currently available and those being developed. For example, US-based Osiris Therapeutics is clearly the market leader in the area of adult stem cell therapies with a spinal fusion product already on the market and a number of others that will compete directly with Mesoblast's well into clinical trials.

**Verdict:** Based on the research of Mesoblast and others, their products seem to have a good chance of moving successfully through clinical trials, although it is not clear how long it will take to get their products to market. Once on the market, however, they are likely to find the going reasonably difficult.

Based on a market capitalization of \$542 million for Osiris Therapeutics, Mesoblast's current market capitalization of \$102 million seems to represent fair value. When asked for a comment, Mesoblast said it was proud to be competitive with a company five times its market cap.

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