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Daily news on ASX-listed biotechnology companies

Dr Boreham's Crucible: Mesoblast

By TIM BOREHAM

ASX code: MSB; **Nasdaq code (**American depository receipts**):** MESO

ASX Market cap: $646m (401.6m shares on issue); **Share price:** $1.61

Chief executive officer: Prof Silviu Itescu

Board: Brian Jamieson (chairman), Prof Itescu, William Burns, Donal O'Dwyer, Eric Rose, Michael Spooner, Ben-Zion Weiner

Financials: December quarter revenue of $US218,000 (year to date $US579,000); cash burn $US25.53 million ($US46.36 million year to date) and estimated current quarter outflows of $US26.8 million; cash at December 31, 2016 $US33.9 million ($US60.3 million at September 30, 2016). December balance excludes $US21.7 million from Mallinckrodt Pharma in January 2017, for a share placement.

Major shareholders (as of 2016 annual report): Silviu Itescu 17.9%, Cephalon (Teva Pharmaceuticals) 14.6%, M&G Investment Group 12.3%, Capital Research Global Investors 7.6%, Thorney Holdings 5.1%.

A multi-faceted excitement machine in the emerging global stem-cell therapies sector? Or a multi-pronged disappointer with a penchant for burning cash and with little prospect of serious near-term revenues?

Investors can take their pick with Mesoblast, the world's biggest listed player in the art of applying mesenchymal precursor cell (MPC) and mesenchymal stem cell (MSC) therapies to a range of serious and largely untreatable maladies.

Across its portfolio of 796 patents, Mesoblast is targeting cardiovascular disease, inflammatory disorders, such as rheumatoid arthritis, orthopaedic disease and oncological and haematologic conditions.

To the naysayers, Mesoblast's clinical results have not delivered the goods and are dispersed across too many indications. To the true believers, the light on the hill burns brightly if only one or two of its therapies crack their multi-billion dollar markets.

Without getting bogged down in the science, MPCs and MSCs are able to develop into other cells by flowing through the lymphatic and circulatory systems, as well as connective tissues such as bones and cartilage.

As such, they potentially have more useful applications than a Swiss Army Knife and the science is just as cutting edge.

Notably, Mesoblast has regulatory approval for one product – although critics would say just one product – and that was bought from Osiris in 2013 for about $100 million in a mix of cash and scrip.

In 2015, Japan licencee JCR Pharma won full approval from the country's gatekeepers to use the previously Osiris-owned and developed mesenchymal stem cells (MSCs) to treat acute graft versus host diseases (GvHD), an immunological condition following the receipt of foreign transplanted tissue.

The product, Temcell is to deliver unquantified royalty and milestone payments to Mesoblast.

Mesoblast also has three programs in phase-three stage, for advanced (class three) heart failure, chronic lower back pain and acute GvHD.

The heart failure program (MPC-150-IM) involves recruiting 600 patients in the US, with 300 enrolled already. An interim analysis, due in the current quarter will "guide" the company's discussions with the US Food and Drug Administration on an approval pathway.

Similarly, a 360-patient lower back pain trial (MPC-06-ID) is "recruiting well'' with enrolment completed this year. This follows a 100-patient phase-two trial over 24 months which showed a meaningful reduction in pain among the treated cohort.

The acute GvHD trial (MCS-100-IV) is targeted at paediatric patients with a severe immunological reaction to bone marrow transplants. This trial involves recruiting at least 60 patients across 40 centres, with a primary endpoint of an "overall response" at day 28.

A secondary endpoint is survival at day 100 for those with the 28-day response.

In the latest news, Mesoblast last week reported a "durable response" among rheumatoid arthritis patients after nine months having been treated with a single intravenous MPC dose.

The 48 patients in the phase II trial were resistant to the standard treatment, of anti-tumor necrosis factor (TNF) biologics. TNFs are the over-produced proteins causing the inflammation.

In what Prof Itescu dubs “highly encouraging” results, the company noted a “durable improvement in clinical symptoms, physical function and disease relative to the placebo [group]”.

Prospects:

With apologies to Bill Lawry, it’s all happening at the MSB. The trouble is the white-coat brigade is so busy it’s hard to make sense of the busy clinical schedule, although maybe Dr Criterion is just a bit dense.

Mesoblast’s current year timetable includes an interim analysis of the phase III heart failure results by April 2017 and a further read out on the phase II program by the end of 2017.

Also expect nine-month data on the MPC-300-IV program by July 2017, as well as a GvHD update by the end of the year.

Management also promises “potential corporate partnerships” - hopefully the variety yielding up-front dollars and lucrative milestone payments.

The deal with Mallinckrodt includes an exclusive right to negotiate a development partnership for moderate to severe chronic lower back pain and acute GvHD (globally, but excluding Japan and China).

Mesoblast can also tap up to $120 million of equity over the next few years, via an equity facility with the small Melbourne investment house Kentgrove Capital. Ultimately, the funding is sourced from a cabal of high-net worth families.

Dr Boreham’s Diagnosis:

When Mesoblast shares hit $10.04 a share on October 24, 2011, investors were dazzled by the blue sky potential of the emerging science. Few on the institutional side questioned the lofty valuation, with the exception of Macquarie Equities then health analyst Dr Craig Collie.

Then the merde hit the oscillating cooling device.

Apart from slower than expected clinical and commercial progress, the market was underwhelmed by the $US68 million November 2015 Nasdaq raising (and listing), struck at a steep discount to the then value of the ASX-listed shares.

In June last year, the shares fell 28 percent in a day (to $1.52) after partner Teva Pharmaceuticals walked away from backing an expensive chronic heart failure trial.

The problem here is that the deal was struck with Cephalon in 2011, but Cephalon was then subsumed by the Israel-based Teva which has more of a focus on generic drugs.

Fair enough, but management had continued to stress Teva's involvement as a sure thing – right up to the day it wasn't. And despite terminating its partnership, Teva remains a 14 percent shareholder.

Mesoblast shares then drifted to as low as $1.01, before being turfed out of the ASX200 index.

Since its October 2016 nadir the stock has gained favor with a drip feed of promising results and internal efforts to reduce the cash burn.

Dr Boreham has more reservations than the Hilton on this one (the hotel, not Paris). On balance though, the stock looks to have hit its nadir and a smidgen of decent news from the upcoming trials will spur a rerating.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. Nor does Dr Pepper and he runs a multi-billion dollar soft drink conglomerate, so don't be too critical.