Lodge Partners Research
ABN: 25 053 432 769
AFSL: 246271

BUY	12 Month Target	$11.75
	Price	$7.98
	Implied Return	47%

Mesoblast Ltd (MSB)

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Expanding boundaries

This report briefly examines MSB's past financial year, a watershed period for the company which further cemented it as the world leader in stem cell therapies. It also re-examines our valuation model, expanding the geographies it includes and more tightly defining the clinical indications for its products and their addressable market sizes.

Mesoblast (ASX: MSB) delivered a stellar result for shareholders in FY11 (share price up 370%). Key events driving the share price appreciation were:

- The merger of MSB with Angioblast Systems
- The licencing of several applications of its stem cells to Cephalon Inc (in an Australian record deal)
- The release of solid interim results on the performance of its product Revascor™ in the treatment of congestive heart failure

Given the events of the last twelve-months, we have chosen to review our valuation model of MSB from the ground up to ensure its relevance going forward. In doing so, we have re-evaluated:

- The geographies for which we have valued MSB's products
- The clinical indications on which we have valued MSB
- The market sizes for each indication
- The likely pricing of products
- Clinical trial success probabilities for each indication
- Expected market entry dates for each product/indication

Changes we have incorporated into the model include:

- Valuation based on the seven major pharmaceutical markets - France, Germany, Italy, Japan, Spain, UK and the US
- Removal of two indications (fracture repair and eye diseases)
- The addition of two indications (chronic refractory angina and type II diabetes)
- Incorporation of success probabilities for phase II trials and a combined one for phase III trials and regulatory approval
- Adjustments to the expected market entry dates for products/indications. The adjustments are based, in general, on two years for phase II trials, two/three years for phase III trials and one-year for regulatory review/approval.

We also see potential upside, which may come from:

- The announcement of solid data to support the applicability of MSB's stem cells to further diseases, increasing their addressable market
- Positive expert opinions of (and subsequently market reaction to) the full data set from MSB's phase II congestive heart failure trial due to be presented in November 2011
- A further licensing deal in line with the Cephalon deal

Valuation
Following a complete overhaul of our valuation model, we continue to recommend Mesoblast as a **BUY** and place a **12-month price target of $11.75** on the stock.

Company Data

ASX Code	MSB
Shares on issue	280,425,258
Market capitalisation	$2.2b
12 month price range	$1.72 - $9.95
ASX turnover (monthly rolling)	16.7m

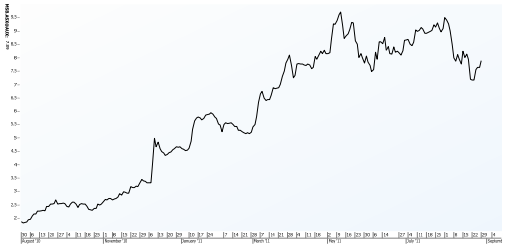
Board of Directors

Brian Jamieson	Chairman (Non-Exec)
Silviu Itescu	MD & CEO
Michael Spooner	Non-Exec. Dir.
Donal O'Dwyer	Non-Exec. Dir.
Kevin Buchi	Non-Exec. Dir.

Major Shareholders

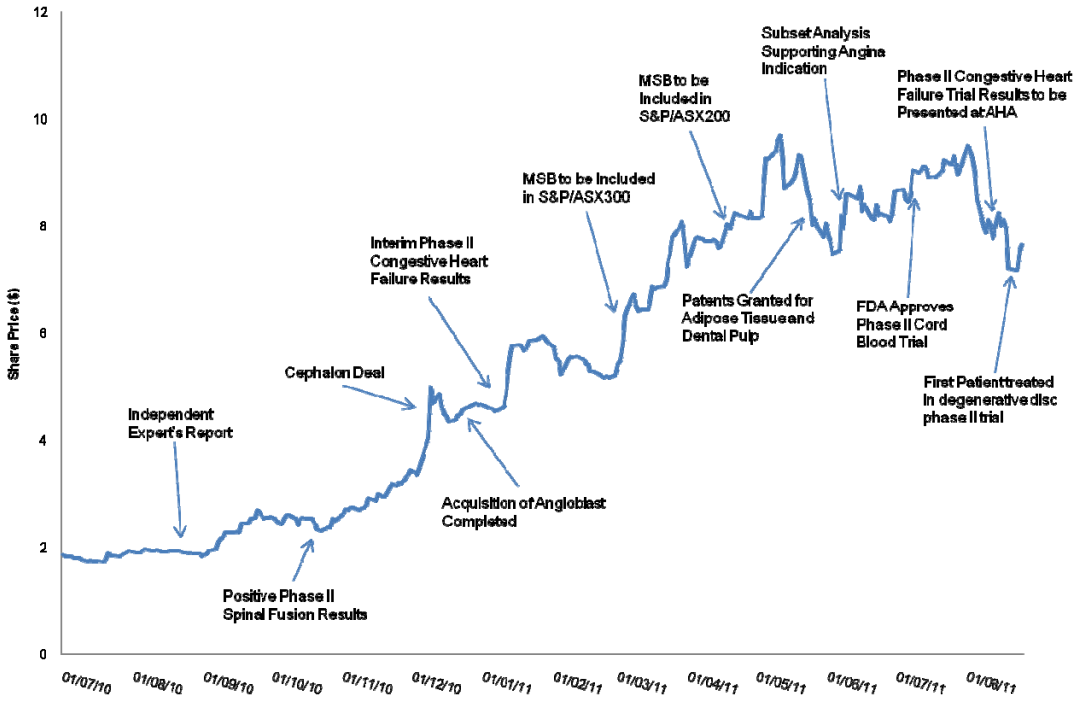
Silviu Itescu	24.3%
Cephalon Inc	19.9%
M&G Investment Funds	8.0%
Thorney Holdings	6.2%

Share Price Chart



Source: Iress Market Technology

Figure 1. MSB Share Price Chart.



Review of Operations

FY11 was a year of substantial progress and change for MSB and one of excellent returns for shareholders. Figure 1 details the major items that have driven the appreciation of MSB's share price.

FY11 results in line with expectations

Last week, MSB announced a Profit Before Tax of $92.2 million, with an NPAT of $90.7 million. These results were in line with expectations and were driven by the receipt of the upfront fee received as a result of the licensing deal with Cephalon. Of particular note was that MSB's current cash reserves of $263 million are expected to fund the company for the next four years, in the absence of further licensing deals.

Staff added

We also noted that the company had been spending considerable time and effort expanding its employee base. Like many biotech companies, MSB had been a quasi-virtual company since its inception, but over the course of the last year grew to the point where such a structure was really no longer suitable. We see this expansion of the employee base as a positive signal and a necessity given the ever increasing range of activities that MSB needs to undertake.

Minor time line slippage

The company stated that the target date for the launch of the cord blood expansion product was 2014, while the phase III trial of Revascor™ for congestive heart failure trial, once commenced, was expected to complete in 2015. Previously, the company had targeted 2013 to have the cord blood expansion product on the market, while it had previously stated that Revascor™, via a congestive heart failure indication, would be on the market in 2015. With the phase III congestive heart failure trial now completing in 2015, it is unlikely that Revascor™ will be on the market sooner than 2016.

MSB expect type II diabetes results to support human testing

The company also said that a study of its stem cells in a diabetic (type II) population of monkeys was continuing. The results from this study are much anticipated and the company also stated they are expected to support the commencement of a phase II human trial for the indication.

Animal trials of MSB's stem cells are also being undertaken for Parkinson's disease and stroke.

Finally, we now expect that a manufacturing strategy centred on Singapore will be re-thought. With the expected approval date of MSB's first volume product likely to be 2016, the company

Manufacturing strategy evolving

does not appear to be under pressure to establish a manufacturing base yet. We believe that while work on scale up and manufacturing processes needs to be occurring, the infrastructure required to support manufacturing does not need to be put in the near term, unless, of course, a particularly attractive opportunity arises.

Valuation – Assumptions and Analysis

Valuation based on seven major markets

We have valued MSB using a project-based, probability adjusted, discounted cash flow model for the seven major pharmaceutical markets - France, Germany, Italy, Japan, Spain, United Kingdom and the United States.

While our general valuation methodology remains the same, the model has been re-built from scratch and various assumptions changed. The assumptions upon which our new model is based are:

- A discount rate of 15%
- 1 AUD = 1 USD
- Equivalent disease prevalence/incidence rates over the seven major markets
- An effective product price across all regions of 71% of the expected US price
- To gain regulatory approval, each product will be studied in one significant phase II trial and one large phase III trial
- All products licensed at the end of phase II studies except for those already licensed to Cephalon
- An upfront payment and a milestone payment upon first major (US Food and Drug Administration or EU European Medicines Agency) regulatory approval for products not currently partnered
- Milestones payable on start of phase III studies and first major regulatory approval for products partnered with Cephalon
- A royalty rate equivalent to 25% of sales revenue via a transfer price to the licensing company for all products
- Table 1 details the indications for which we have valued MSB's stem cell therapies and basic market parameters
- No value has been attributed to applications of MSB's stem cells for eye diseases, bone fracture and neurological conditions

Table 1: Market assumptions for MPC-based therapies

Indication	Est. Market Entry	Est. US Price (USD)	Est. Peak Market Share	Initial Target Market (treatments per annum)
Bone Marrow Transplant	FY14	$20,000	20%	45,000
Congestive Heart Failure	FY16	$10,000	10%	2.9 million
Myocardial Infarction	FY18	$10,000	10%	1.5 million
Refractory Angina	FY18	$7500	5%	2.9 million
Spinal Fusion	FY16	$5,000	15%	1.1 million
Knee Osteoarthritis	FY17	$5,000	5%	7.5 million
Degenerative Disc Disease	FY16	$3,000	15%	2.5 million
Type II Diabetes	FY18	$5,000	15%	11 million

*SOURCE: *Lodge Estimates*

Valuation - Output

Price target $11.75 with diabetes ($9.20 excluding diabetes)

Our analysis yield's a company value of $2.9 billion ($10.25 per share) and a 12-month price target of $11.75 per share. This valuation is contingent upon the announcement of a successful conclusion to a trial of MSB's stem cells in a population of monkeys with type II diabetes. Results from this trial are expected soon and, as previously stated, MSB expects them to support the commencement of a phase II human trial. Should the results not support the commencement of a phase II trial, our target price for MSB would be $9.20, with the BUY recommendation retained at the current share price ($7.98).

Valuation - Upside

MSB believes that its stem cells may have applications in a number diseases for which we have given them no value, such as Parkinson's disease and stroke. Animal studies are currently underway for these indications, as mentioned. Should the results from these studies justify further study in human trials, this would provide upside to our current valuation.

Opportunity for very significant upside to our valuation

In addition, we expect MSB to provide very detailed results when it presents the findings from its phase II congestive heart failure trial in November. The underlying mechanism of action of MSB's stem cells is not well understood. Should the results they present pass expert scrutiny, this fact will become less relevant and a material upward re-rating of the stock may occur.

Finally, while we have assumed that MSB will licence its products, we have not assumed it will be in a deal of the magnitude of the Cephalon deal. If the company were to do another deal in the vein of the Cephalon deal, this would provide upside to our valuation.

Re-Evaluating Our MSB Model

As stated above, MSB has changed substantially over the last year and no longer can it be considered a small Australian biotechnology company. At a current market capitalisation of $2.1 billion, MSB is in the mid-tier of biotechnology companies worldwide and in the league of proven Australian companies, Cochlear and Resmed.

As such, we have chosen to review our valuation model of MSB.

More markets, bigger addressable market sizes

We have expanded the geographic markets targeted by MSB's products to include the seven major pharmaceutical markets – France, Germany, Italy, Japan, Spain, United Kingdom and the United States. Current valuation models have been largely focused on the US. By increasing the number of countries included in the model, obviously, the addressable market sizes for MSB's products are significantly increased.

Estimated prices generally reduced

The prices that MSB will be able to charge for its products have also been examined and adjusted according to the current costs of treatment for a particular condition, the frequency of their anticipated use and the estimated benefit of the respective product. In most cases, this has lead to a decrease in the price we estimate MSB will be able to charge. For example, our old model incorporated a price of US$15,000 for MSB's treatment Revascor™ for myocardial infarction (heart attack). However, the costs associated with the hospital stay for a myocardial infarction patient are around the US$10,000 dollar mark. In this light, US$15,000 for MSB's treatment appears too high. Correspondingly, we have cut our treatment price estimate to $10,000.

Medical products substantially cheaper in non-US markets

Our new model incorporates an effective price for each product. The reason for this is that pharmaceutical prices vary considerably from country to country, with US prices often more than twice that of other countries. We have used an effective price rather than individual prices for each country because of the uncertainty surrounding the geographies in which MSB's products will first be rolled out in and for the sake of simplicity.

A couple of indications removed from our valuation

The indications of long bone-repair and eye diseases have been removed from our valuation. In terms of long bone repair, we simply believe that current and potential future applications of MSB's products are such that long bone-repair simply won't be a priority for the foreseeable future. Regarding eye diseases, this area is becoming increasingly competitive in terms of product development and where MSB's product will fit into future treatment is becoming less certain. As always, should MSB produce additional compelling data on the application of its technology to this area, it will be added back into our model.

A couple of indications added

The indication of chronic refractory angina has been added based on data from an early clinical trial and more recent data from the current congestive heart failure study.

We have attributed significant value to the potential use of MSB's stem cells in the treatment of type II diabetes. This has been done largely based on the positive signals from management. MSB's justification for pursuing type II diabetes is based on results from a

Valuation contingent on Type II diabetes animal trial results

mouse study in which the pancreas of the animals was partially destroyed. In our view, this model is much more applicable to type I rather than type II diabetes. We believe that the ongoing trial of MSB's stem cells in a population of monkeys with type II diabetes will yield much more reliable data regarding the indication. Consequently, we have made our valuation contingent upon positive results from the monkey study.

Trial success probabilities refined

In the past, we have applied a flat product approval probability of 60% to each indication, with some changes on an indication by indication basis depending on trial results. The new model incorporates a probability for phase II trial success and a combined probability for phase III trial success and regulatory approval. All probabilities have been set on a product by product basis.

Expected market launch dates pushed out

Finally, we have re-examined our estimates for year of market entry. Overall, we have taken a conservative approach, pushing out the dates for expected market entry for most products. In general, we have assumed 2-years for phase II trials, two/three years for phase III trials and 1-year for FDA review. Trial design, trial numbers and the number of recruiting trial sites will all impact the speed with which MSB can progress its products. In most cases, it is within MSB's capability to beat our timelines given their cash resources, although the speed at which Cephalon acts on the products it has licensed is largely beyond MSB's control.

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Recommendations are assessments of each Lodge Partners Analyst's view of potential total returns over a 1 year period.

Expected total Return is measured as (capital gain (or loss) + dividend)/purchase price

We have divided our recommendations into three main categories:

Buy: Expected Total Return in excess of 15% over a 1 year period.

Hold: Expected Total Return between 0% and 15% over a 1 year period.

Sell: Expected Total Return less than 0% over a 1 year period.

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