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Mesoblast (MSB)

We have seen the future, and it works

Recommendation
Spec Buy (Buy)
Price
$8.20
Target (12 months)
$16.00 (unchanged)

Expected Return	
Capital growth	**95%**
Dividend yield	**0**
Total expected return	**95%**

Company Data & Ratios	
Enterprise value	**$2,044m**
Market cap	**$2,300m**
Issued capital	**280.4m**
Free float	**100%**
Avg. daily vol. (52wk)	**0.73m**
12 month price range	**$2.52-$10.04**
GICS sector	
Healthcare Equipment and Services	

Disclosure: Bell Potter Securities acted as lead manager in a capital raising in May 2010 and in a selldown of stock in December 2010 and received fees for that service.

Price Performance

	(1m)	(3m)	(12m)
Price (A$)	7.90	9.50	2.62
Absolute (%)	0.25	-16.63	202.29
Rel market (%)	-8.95	-11.08	211.84

Absolute Price

SOURCE: IRESS

MSB has stem cell technologies that work

MSB is commercialising Mesenchymal Precursor Cell (MPC) technology which allows adult stem cells to be extracted from a donor's bone marrow, grown into therapeutic quantities and administered to non-related patients. MSB initially focused on MPCs in orthopaedic and cardiovascular applications but has since expanded into inflammatory and immunological disorders, and diseases of the Central Nervous System. MSB has multiple Phase II trials underway and is initiating a Phase III trial in Bone Marrow Transplant, with a revenue opportunity matching that of Cochlear. With the FDA requiring only one Phase II and a pivotal trial before approving a successful stem cell therapy, the company has the potential to be yielding commercial revenues by late 2013 under a partnering deal with Cephalon, now owned by Teva. That deal, which was inked in December 2010, put >US$200m into the company and has left Teva with a 19.99% stake.

Mesoblast's evolution to a global biologics player takes a major step this month

Bell Potter Securities believes Mesoblast's share price undervalues the cardiovascular applications alone. Much attention will focus on the results of the 60 patient Phase II trial of MPCs in heart failure, to be unveiled at a special session of the American Heart Association's annual meeting on 14 November 2011. The independent analysis, to be presented by Dr Emerson Perin of the Texas Heart Institute, will be the most detailed work to date on what MPCs can achieve in humans. An overview of the Phase II trial released in June 2011 saw outstanding evidence that MPCs can rebuild heart muscle and improve blood flow to the heart muscle, thereby reducing adverse coronary events and hospitalisations. Applications in heart failure, in heart attacks and in chronic angina represent multi-billion dollar market opportunities. We think the heart failure trial results will not only explain the keen corporate interest which has seen Cephalon/Teva and now Lonza commit hundreds of millions of dollars to Mesoblast programmes, but also show how far Mesoblast's science has progressed since 2009.

Investment view – MPCs warrant $16 per share

Considerable clinical and pre-clinical evidence has emerged over the last two years of the effectiveness of MPCs in the treatment of a wide variety of disease conditions, and this evidence has received commercial validation in the Cephalon and Lonza deals. We argue that the evidence not only justifies the recent share price appreciation, but suggests the potential for Mesoblast stock to continue climbing towards our $16 share price target. In this note we look at five emerging pieces of the Mesoblast story which we regard as confirmatory of the effectiveness of MPCs and their long-run commercial potential: a) Evidence of the mechanism of action; b) Evidence of clinical effectiveness in heart failure; c) Evidence of superiority versus other stem cell approaches; d) Evidence of progress on manufacturing and e) Evidence of strong market demand.

Mesoblast – We have seen the future, and it works

Mesoblast, which did its IPO on the ASX in late 2004, has matured considerably from a scientific, clinical and commercial perspective over the last two and a half years, and this has been reflected in the run-up in the share price from ~80 cents in May 2009 to the recent all-time-high closing price of $9.99. Since 2009 considerable clinical and pre-clinical evidence has emerged of the effectiveness of Mesoblast's Mesenchymal Precursor Cells (MPCs) in the treatment of a wide variety of disease conditions, and this evidence has received commercial validation in the major partnering deal which Mesoblast completed with Cephalon in December 2010 and in the manufacturing partnership which was initiated with Lonza in September 2011. We argue that the evidence not only justifies the recent share price appreciation, but suggests the potential for Mesoblast stock to continue climbing towards our $16 share price target. In this note we look at five emerging pieces of the Mesoblast story which we regard as confirmatory of the effectiveness of MPCs and their long-run commercial potential:

- Evidence of the mechanism of action;
- Evidence of clinical effectiveness in heart failure;
- Evidence of superiority versus other stem cell approaches;
- Evidence of progress on manufacturing; and
- Evidence of strong market demand.

Evidence of the mechanism of action

MPCs work via the paracrine effect

In October 2010 scientists working with Mesoblast published a paper in the *Journal of Cellular and Molecular Medicine*[1] demonstrating how the company's MPCs could therapeutically treat myocardial ischemia. They found, in a rat model of heart attack, that injection of MPCs into heart muscle promoted left ventricular recovery and inhibited left ventricular dilatation – two indicators of a reversal of heart failure – but did so '*despite poor engraftment of cells*'. This is critical. A common criticism of mesenchymal stem cells is that they do not engraft in target tissue in sufficient quantities to exert a therapeutic effect[2]. With this study there were few MPCs detected in the rat hearts even 24 hours after injection compared to the numbers injected. However the remarkable attenuation of left ventricular dysfunction and remodelling achieved with MPC injections were achievable through injections of MPC-conditioned medium. This suggested that MPCs were working via the 'paracrine effect', in which stem cells release soluble factors that contribute to tissue repair and regeneration, rather than engraft in tissue and then differentiate into that tissue's cells. Unsurprisingly, analysis of the MPC-conditioned medium revealed the presence of IL-6, VEGF and MCP-1, all known to be cardioprotective and pro-angiogenic. We think the *Journal of Cellular and Molecular Medicine* paper answers a key question as to how MPCs work and provides confidence that the therapeutic effect seen in heart failure patients to date is real.

[1] See J Cell Mol Med. 2011 Oct;15(10):2117-29. A full reprint of this paper is available at www.mesoblast.com.

[2] See, for example, Circ Res. 2010 Jun 11;106(11):1753-62. Epub 2010 Apr 8.

Evidence of clinical effectiveness in heart failure

We have previously reported[3] on Mesoblast's 60-patient trial in heart failure patients, which measured three progressively higher MPC doses[4] against standard of care where Left Ventricular Ejection Fraction (LVEF) had dropped below 40[5]. In the trial, 45 patients (who continued on standard of care, ie drug therapy plus, in many instances ICDs) randomised to the three MPCs doses as against 15 to placebo. With each dose, patients received a single injection and were evaluated for heart function recovery at three, six and twelve months. The last patient joined the trial in June 2010 and in January 2011 MSB reported favourable interim data after all patients had reached 6 months follow-up. By that time the average patient had been followed for 18 months and the data below reflects that time period:

- MPCs reduced the number of patients who developed any severe adverse cardiac events over the follow-up period from 93.3% in the control group to 44.4% in the treated patients (p=0.001).
- the number of patients suffering MACE (major adverse cardiac events, that is, death, heart attack, or coronary revascularisation procedures) dropped from 40% to 6.7% (p=0.005).
- the overall MACE monthly event rate went down by 84% compared with controls (p=0.01).

MPCs registered no cardiac mortality over an average 18 months of follow-up

- cardiac mortality[6] dropped from 13.3% to zero. Although that outcome wasn't quite statistically significant because of the small patient numbers (p =0.059), 13.3% suggests the kind of mortality that could be expected of a well-treated cohort of Class II patients at 18 months[7].
- a 22-patient subset analysis of patients in the trial suffering ischemic heart failure with reduced myocardial blood flow showed that MPC-treated patients experienced a 75% reduction in the risk of MACE over a mean follow-up period of 21 months compared with controls that had myocardial ischemia. This result was reported to the market in June 2011.

We think this kind of performance demonstrates reasonably convincingly the strong clinical utility of MPCs in heart failure. We also think the data is remarkable because of two other factors of relevance in the trial – immune response, and patient mix.

MPC outperformance was achieved in spite of the potential for immune response. Over the last two years a body of science has grown up asserting that Mesenchymal Stem Cells, while immunosuppressive[8] and poorly immunogenic[9], are immunogenic nonetheless. This science suggests negative implications for the therapeutic benefits of Mesenchymal Stem Cells. One recent paper, for example, has shown that immunogenicity can occur as allogeneic mesenchymal stem cells differentiate, with consequences for long-term use for myocardial repair[10]. Mesoblast has not published or reported on the immunogenicity issue, since, for conservatism's sake (and not for any concerns over immunogenicity), treated patients only received a single dose of stem cells at baseline. However we argue that the science on stem cell immunogencity unnecessarily discounts the potential of MPCs, since:

[3] See our 27 September 2011 comprehensive update note on Mesoblast headlined 'The Heart of the Matter'.

[4] The animal work has suggested that the effects of MPC in heart failure are dose-related.

[5] A normal heart has a 55-70% LVEF. Around 40% of heart failure patients have LVEFs below 40% - consider, for example, the Echocardiographic Heart of England Screening population study, which found that 41% of definite heart failure patients had an LVEF under 40 (see Lancet. 2001 Aug 11;358(9280):439-44).

[6] As opposed to 'all-cause mortality'. Only around one fifth of heart failure patients die with this condition as a primary cause.

[7] See, for example, Arslan et. al. (Tex Heart Inst J. 2007; 34(2): 166–169), which registered an 11.5% mortality rate for Class II patients at two years where the patients were being evaluated for the prognostic value of the 6-minute walk test. The REVERSE study, which looked at the ability of CRT-D to reverse mild or asymptomatic heart failure, generated 18 month survival of 4.9% for the treated patients but these were only Class I and II patients (Source: *REVERSE at 18 months: Questions about CRT for mild heart failure remain*, theheart.org, 8/9/2008).

[8] See Cell Stem Cell. 2008 Feb 7;2(2):141-50.

[9] See Stem Cells Dev. 2005 Jun;14(3):252-65.

[10] See Circulation. 2010 Dec 7;122(23):2419-29. Epub 2010 Nov 22.

- There is little evidence of MPCs differentiating once injected[11];
- Even if there was an immune response in the heart failure trial, it has not brought about an unfavourable result, suggesting any immunogenicity was not clinically relevant;
- Repeat dosing may not be required for a favourable long-term outcome, which would eliminate concerns about immune response;
- Mesoblast's MPCs sit upstream from Mesenchymal Stem Cells, and are therefore less likely to have co-stimulatory molecules on their surface;
- There is some evidence that the immunoregulatory role of MPCs would enable a reasonable survival length for Mesenchymal Stem Cells even in situations of immune memory[12];
- Potentially tissue typing[13] may be required for a repeat dosing situation should immunogenicity prove an issue, but this would not greatly reduce the convenience and low cost of MPCs as an off-the-shelf therapy.

MPC outperformance was unrelated to the patient mix in each cohort. Mesoblast's heart failure trial recruited patients that were either NYHA Class II or Class III. At baseline there were more Class II patients in the treated group (69% of that cohort) whereas the control group had more Class III patients (60% of that cohort)[14]. This may suggest that the outperformance by the treated group had to do with the control group's sicker patients. However it's worth noting two other baseline elements of interest:

The jury is out as to which arm of Mesoblast's heart failure trial was sicker

- LVEF at baseline was about the same for the two groups (30.4 for treatment, 32.1 for controls);
- BNP - B-type Natriuretic Peptide, which is regarded as a good indicator of heart failure severity[15] - was worse for the treated group (436.8 versus 217.7 for the controls).

In short, it wasn't 100% clear that a preponderance of worse-off patients were in either group. That said, we think that any skew in either group is accounted for by the statistical significance of the interim data. A study result's p value is the measure of the probability that the result was obtained by chance alone. The numbers we quoted above had p values of 0.001 (severe adverse cardiac events), 0.005 (overall MACE) and 0.01 (MACE monthly event rate). This suggested that the strong changes from baseline for both groups had a very low probability of being driven by Dame Fortune. Indeed, these p values are so low that, even if the skew to Class III patients in the control group had been an issue, an 'adjusted' control group would still likely come in well below the 0.05 that is regarded as the top end of statistical significance. We expect that, given the NYHA Class skew, Mesoblast's investigators will conduct *post hoc* analyses to allow a better 'apples with apples' comparison.

Evidence of superiority versus other stem cell approaches.

Looking at the data on other stem cells that have been tried in cardiac applications, we think MPCs stand out. Consider just one measure of cardiac performance, LVEF. In November 2009 Mesoblast reported very favourable six month data on LVEF from its heart failure trial. At six months MPC-treated patients on the lowest dose saw LVEF jump 5.6 points or 20% (baseline 27.8 points) while control patients saw a 4.8 points or 16% decline (baseline 30.5 points). The p value on this measure was 0.05[16]. So, as measured by LVEF,

[11] See the abovementioned J Cell Mol Med paper, which comments that *'...under the present study conditions, mechanisms such as MPC differentiation or fusion are unlikely to account significantly for the observed effects of MPC administration post-MI'.*

[12] See Stem Cells. 2009 Nov;27(11):2865-74.

[13] Testing the cells of prospective donor cells for HLA compatability prior to transplantation.

[14] Source: Presentation entitled "Mesenchymal Precursor Cells for Congestive Heart Failure" by Dr Tim Henry at the Conference on Cell Therapy for Cardiovascular Disease, January 2011.

[15] BNP is secreted from the ventricles in response to changes in pressure that occur when heart failure develops and worsens. Consequently the level of BNP in the blood increases when heart failure symptoms worsen. BNP has prognostic impact with regard to adverse clinical events. See Swiss Med Wkly. 2002 Dec 14;132(43-44):623-8.

[16] See Mesoblast Executive Director presentation to the AGM, 30/11/2009, slide 13.

MPCs appeared to work as an allogeneic stem cell product, in heart failure, with statistical significance. Now compare this finding with six other trials of the last seven years:

- **Autologous bone marrow LVEF at six months, July 2004**. The BOOST study (BOne marrOw transfer to enhance ST-elevation infarct regeneration), a 60-patient initiative of Hannover Medical School in Germany, looked at transfer of autologous bone marrow cells to heart attack patients. It has now published five year data[17]. At the six month point, for which data was reported in 2004[18], the BOOST investigators registered a 6.7 point or 13.4% improvement in LVEF (baseline 50 points) for the treated patients versus a 0.7 point or 1.3% improvement for the controls (baseline 51.3 points). This comparison has statistical significance (p = 0.003).
- **Bone marrow–derived progenitor cells at four months, September 2006.** The REPAIR-AMI trial (Reinfusion of Enriched Progenitor Cells and Infarct Remodeling in Acute Myocardial Infarction), a 204-patient study conducted by scientists at Johann Wolfgang Goethe-University in Frankfurt, looked at a class of stem cells called bone marrow–derived progenitor cells in heart attack patients. This trial has now reported 2 year clinical outcomes data[19]. At four months[20] the trial saw a 5.5 point or 11.4% improvement in LVEF (baseline 48.3 points) for the treated patients versus a 3.0 point or 6.4% improvement for the controls (baseline 46.9 points). As with BOOST, this comparison has statistical significance (p = 0.02).
- **Osiris Therapeutics LVEF at six months, June 2009.** Osiris Therapeutics[21], the most comparable competitor to Mesoblast[22], has published data from a 53 patient trial evaluating the ability of its Prochymal allogeneic mesenchymal stem cell product to improve cardiac function after a heart attack[23]. Here LVEF for treated patients at six months was only 2.2 points or 4.7% higher (baseline 47.3 points) while control patients saw a 0.7 point or 1.6% decline (baseline 45.1 points). This result was obtained using a subset analysis of patients measured with cardiac MRI, but was nonetheless not statistically significant in terms of analysis between groups. Moreover the data using echocardiography, which was what Mesoblast used, was even less impressive[24].
- **Cytori Therapeutics LVEF at six months, May 2010.** Cytori Therapeutics[25] is working on adipose-derived regenerative cells (ADRCs), that is, autologous stem cell transplants where the cells are derived from a patient's own fat tissue. In May 2010 Cytori reported results from a 14-patient Phase II data of the use of ADRCs in heart attack[26] which saw LVEF for the treated patients up 4.0 points or 7.9% (baseline 50.9 points) versus control patients where LVEF declined 1.7 points or 3.2% (baseline 52 points). Like Osiris' data, this result was not statistically significant[27].

Cardio3 may be worth stem cell watchers paying attention to

- **Cardio3 Biosciences LVEF at six months, November 2010**. Probably the most comparable trial to Mesoblast's in the last two years has been conducted by Cardio3 Biosciences[28]. This privately-held Belgian company is commercialising an autologous stem cell therapy called the C-Cure, which is based on discoveries made at the Mayo

[17] See NCT00224536 at www.clinicaltrials.gov. For five year data see Eur Heart J. 2009 Dec;30(24):2978-84.

[18] See Lancet. 2004 Jul 10-16;364(9429):141-8.

[19] See Circ Heart Fail. 2010 Jan;3(1):89-96. Epub 2009 Dec 8.

[20] See NCT00279175 at www.clinicaltrials.gov. For the four month data see N Engl J Med. 2006 Sep 21;355(12):1210-21. REPAIR-AMI made up for the failure of a similar trial called ASTAMI (Autologous Stem cell Transplantation in Acute Myocardial Infarction) a 100-patient study conducted in Norway of autologous bone marrow cells in which treated heart attack patients only enjoyed a 1.2 point gain in LVEF versus a 4.3 point gain for the controls at 6 months (as measured by MRI, p = 0.05, see 'ASTAMI: No benefit of stem cells in MI' by Sue Hughes, theheart.org, 16/11/2005).

[21] Nasdaq: OSIR; Columbia, Md; www.osiristx.com.

[22] It relies on a less-efficient density separation technique to get its starting batches of mesenchymal precursor cells.

[23] See *J Am Coll Cardiol*, 2009; 54:2277-2286. Osiris' trial (see NCT00114452 at www.clinicaltrials.gov) became fully recruited as at March 2011.

[24] At two years Prochymal was still only outperforming its own baseline in terms of statistical significance. It did, however, increase LVEF 6.6 points versus a 3.9 point increase for placebo in the MRI-measured cohorts. See the Osiris press release headlined '*Osiris reports positive two-year data on stem cell treatment for Acute Myocardial Infarction'* and dated 12/2/2009.

[25] Nasdaq: CYTX, San Diego, Ca., www.cytori.com.

[26] See NCT00442806 at www.clinicaltrials.gov.

[27] See Houtgraaf presentation at the 2nd Lugano Stem Cell Meeting, June 2010, as well as the Cytori press release headlined '*Cytori reports stem and regenerative cells from body fat improve outcomes in heart attack clinical trial; plans underway for European multicenter pivotal trial'* and dated 7/5/2010. The LVEF data was gathered using SPECT.

[28] Mont-Saint-Guibert, Belgium, privately held, www.c3bs.com.

Clinic related to the creation of 'cardiopoietic' stem cells from bone marrow-derived Mesenchymal Stem Cells[29]. In a 45-patient trial[30] C-Cure-treated heart failure patients at six months saw LVEF jump 5.2 points or 18.1% (baseline 28.7 points) while control patients saw an increase of 1.9 points or 3.6% (baseline 27.8 points). The p value on this measure was less than 0.0001[31], which was impressive but was obtained through a complicated cell preparation process[32].

- **Athersys LVEF at four months and one year, June 2011.** Athersys[33] is seeking to commercialise a class of mesenchymal stem cells called 'multipotent adult progenitor cells' or MAPCs, which appear to have many of the advantages of MSB's MPCs including the ability to be used allogeneically. That company is currently running a 25-patient Phase I trial of MAPCs in heart attack patients[34]. Four month data showed LVEF for the treated patients up 9.8 points or 23.4% (baseline 41.9 points) for one dose group[35], versus a 1.1 point jump for five 'registry' patients included in the study[36]. By one year the LVEF improvement across all dose groups was up 4.6 points or 11.3% (baseline 40.7 points) whereas the registry patients were up 1.3 points or 3.2% (baseline also 40.7 points)[37]. These results weren't, however, statistically significant in terms of analysis between groups.

We conclude from this analysis that Mesoblast has the superior product:

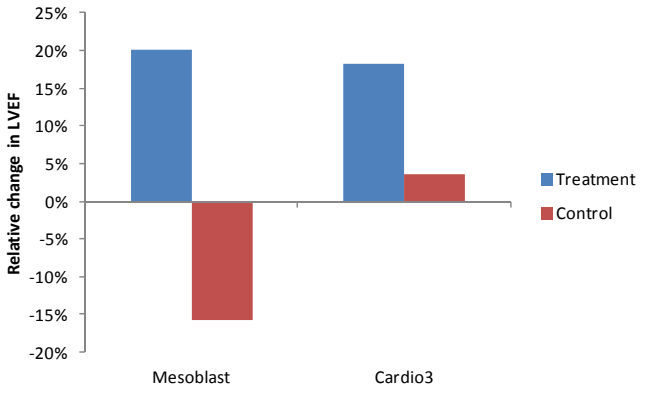
Mesoblast seems to have the superior stem cell product

1) **Mesoblast has superior data overall**, being able to raise relative LVEF – percentage increase from baseline LVEF – at six months with statistical significance by a greater margin than the other products being studied, apart possibly from Athersys's MAPCs at four months, where there was no statistical significance;

2) **Mesoblast has an off-the-shelf therapy**, whereas all the other products other than Athersys' are autologous therapies, with the extra time and expense that this implies;

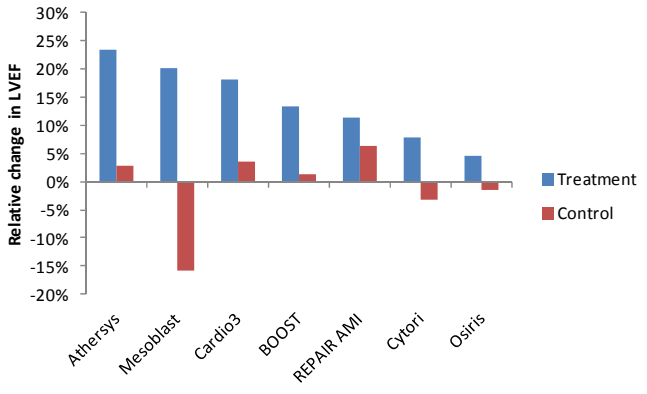
3) **Mesoblast has heart failure data, where the hurdles are higher**, since the ability of heart muscle to bounce back is presumably harder at an LVEF of 30 than at an LVEF of 50. The only other heart failure product described above is from Cardio3, and it's an autologous product.

Figure 1 - As measured by LVEF, Mesoblast's product appears superior in heart failure



SOURCE: MESOBLAST, CARDIO3

Figure 2 – As measured by LVEF, Mesoblast is highly competitive with other cardiovascular stem cell approaches



SOURCE: MESOBLAST, ATHERSYS, CARDIO3, CYTORI, OSIRIS, PUBMED

[29] See J Mol Cell Cardiol. 2008 Oct;45(4):523-9. Epub 2008 Sep 26.

[30] See NCT00810238 at www.clinicaltrials.gov.

[31] See Cardio3 press release headlined '*Cardio3 announces positive outcome of the C-Cure Phase II clinical trial in heart failure patients*' and dated 17/11/2010.

[32] See J Am Coll Cardiol. 2010 August 24; 56(9): 721–734.

[33] Cleveland, Oh, Nasdaq: ATHX, www.athersys.com.

[34] See NCT00677222 at www.clinicaltrials.gov.

[35] The 50 million cell dose group.

[36] See the company's press release headlined '*Athersys announces positive results from Phase I study of Multistem in heart attack patients*' and dated 28/7/2010.

[37] See the company's press release headlined '*One-year follow-up results from Athersys' Phase I Study of Multistem in heart attack patients presented at International Stem Cell Symposium*' and dated 13/6/2011.

LVEF data may allow for some comparisons, but it is adverse coronary events and mortality that really count as endpoints. The reason Mesoblast was recruiting patients with LVEF under 35 into its heart failure trial was that low LVEF is a predictor of subsequent death in heart failure patients[38], and the FDA these days wants to evaluate heart failure therapies on this kind of 'hard' endpoint, whereas LVEF, like NYHA class or the Six Minute Walk Test, is something of a 'soft' endpoint[39]. We are optimistic about MPCs because the data on mortality as well as the other hard endpoint, MACE, has been favourable, not because LVEF has been favourable. It's worth keeping in mind as well that if a drug improves MACE or mortality it may do so by mechanisms separate from LVEF improvement, such as reversal of fibrosis, and the FDA will still approve the product.

Mesoblast's science is being presented at the American Heart Association annual meeting this month

Full Phase II data for heart failure will be available this month. In our view the data announced in January and June 2011 suggest that MPCs are potentially the Next Big Thing in mid-to-late stage heart failure. It's therefore appropriate that full Phase II data[40] will be released at this year's Scientific Sessions meeting of the American Heart Association, which takes place in Orlando, Fl from 12 November to 16 November. The AHA Scientific Sessions is America's premier cardiology meeting, and presenting at Scientific Sessions is a big deal for any company developing a new treatment in the space:

- Around 17,000 professionals attend the meeting, so a presentation helps the data gain a great deal of attention in the cardiology community;
- The imminence of data is often appreciated by the equity market. In August 2010 the LVAD developer HeartWare announced that it would present its US Bridge to Transplant data at that year's AHA Scientific Sessions. The stock was $2.03 at the time, and $2.12 just prior to the meeting. It jumped to $2.21 just after the data was favourably received, and had reached $2.75 by early December.

MSB's trial will be presented in the 'Clinical Science: Special Reports' section on Monday 14 November at 9:15 AM ET by Dr Emerson Perin of the Texas Heart Institute in Houston, which was one of the trial sites[41]. We think the data will provide further evidence of clinical utility in heart failure as well as outperformance compared to other stem cell approaches. We also expect that the data will justify a move straight to a ~1,000-patient pivotal trial from next year (with an interim data point at 500 patients), rather than an enlarged 'Phase IIb', an issue on which Cephalon will have done due diligence prior to its partnering deal with Mesoblast.

Evidence of progress on manufacturing

Mesoblast has established a global manufacturing alliance with Lonza. In September 2011 Mesoblast announced that Lonza, the Swiss contract manufacturer of biological products[42] will become Mesoblast's supplier of stem cells, and will ultimately, at Mesoblast's election, set up a purpose-built stem cell manufacturing facility that Mesoblast will have the option to buy[43]. At present Mesoblast will use Lonza's cell therapy manufacturing facility in Singapore for stem cell sourcing. Lonza is a strong, established company with 2010 revenue of CHF2.68bn, and has done years of due diligence on MPC manufacturing processes[44]. As a consequence the market can have a reasonable amount

[38] See Circulation. 2005 Dec 13;112(24):3738-44. Epub 2005 Dec 5. Zanolla et. al. (Eur J Heart Fail. 2003 Dec;5(6):717-23) note that LVEF and mortality travelled together in various trials of GSK's COREG drug (generic name carvedilol).

[39] Moreover as an indicator of mortality LVEF doesn't always get it right. Consider the V-HeFT II trial of the early 1990s which compared Merck & Co.'s Vasotec drug (generic name enalapril) with hydralazine plus isosorbide dinitrate in heart failure patients. LVEF predicted hydralazine/ isosorbide as being more effective, however Vasotec had better survival numbers. See Circulation. 1993 Jun;87(6 Suppl):VI71-7.

[40] With an average follow-up period of 24 months across the 60 patients.

[41] Abstracts will be available online at the American Heart Association's web site from Friday, 11 November at 4:00 PM ET (ie US East Coast time).

[42] SIX Swiss Exchange: LONN, Basel, Switzerland, www.lonza.com.

[43] We estimate that this will cost Lonza ~US$150-200m, representing a risk that the Swiss company will take on its own balance sheet. This points to the high level of due diligence Lonza has made prior to this deal.

[44] Cambrex had worked on scale-up of MPCs from 2005. Lonza bought the Cambrex business that had done this scale-up work in 2006. Since 2006 Mesoblast has regularly sourced product from Lonza. See, for example, Ghosh et. al. (Arthritis Res Ther. 2010;12(1):R28. Epub 2010 Feb 18) whereSTRO-3-positive MPCs are sourced for experimental purposes from Lonza's plant at Walkersville, Md, inherited from Cambrex.

of confidence that Mesoblast will successfully scale up to commercial-scale manufacturing of stem cells as it moves to bring products on to the market from the middle of this decade.

MPCs are likely to be low-cost to manufacture. While we don't have any hard data on MPC production costs, we believe that the MPC technology has the potential to create high profitability products for Lonza and Mesoblast, since MPCs can be made in one central location under Good Manufacturing Practice and then transported where they are needed, as opposed to having to set up cell manufacturing facilities in individual hospitals. In effect, the product is sold 'off the shelf', allowing economies of scale and progressively lower cost of goods.

Scale up is not likely to be an issue with Lonza on board

MPCs will likely scale-up without extra clinical trials required. A potential issue for any biotech product is what happens to that product when manufacturing is scaled up. Should the product itself change as a result of the new manufacturing process, the FDA may require new clinical trials before it will approve products that are made in the scaled-up facility[45]. Ordinarily producers of biotech products manage this issue through 'potency assays', allowing pre-scale-up and post-scale-up products to be compared. We assume that Mesoblast and Lonza have such assays in place, and have already managed at least one scale-up, as evidenced by the FDA's clearance of the IND for the Phase III Bone Marrow Transplant trial in July 2011. We think that if Lonza and Mesoblast manage all the scale-up issues professionally, the introduction of new production modalities, allowing larger and larger scale manufacturing processes, will not present any regulatory issues.

Lonza has done this kind of deal many times before. For example, manufacturing PEGylated antibody fragments for the Belgian specialty pharma company UCB[46] and the antibody drug Avastin for the American biotech major Genentech[47]. With this kind of experience on Lonza's part we expect that the Mesoblast manufacturing alliance will proceed smoothly.

Mesoblast and Lonza can go down the experience curve together. We expect that Lonza will gradually lower its production costs over time as it has apparently done with antibodies and other biological products. We assume in our modelling of Mesoblast that some of Lonza's cost savings will be passed on to Mesoblast, allowing both companies to raise their margins over time – Lonza its gross margin on sales to Mesoblast and Mesoblast its 'effective royalty' on the average selling price of its licensees.

Evidence of strong market demand

The growth of the market for ICDs and CRT-D points to a large commercial payoff for MPCs. The last ten years has seen the emergence of implantable defibrillation devices as an alternative for later-stage heart failure patients. ICDs, or Implantable Cardioverter Defibrillators, which send electrical signals to the heart to correct irregular heartbeat, began to be increasingly implanted in Class III patients from around 2005[48]. That followed on from the rise of CRT-D devices, which came on the market from 2001, designed to correct conduction defects as well as defibrillate the failing heart[49] and useful in around 20% of heart-failure patients[50]. With both ICDs and CRT-Ds found to be cost effective for the extra

[45] This happened to Genzyme in 2008 when it sought to scale up Myozyme (alglucosidase), a product for the treatment of Pompe disease (which is caused by an enzyme deficiency resulting in muscle damage). Genzyme attempted to move from a 160 litre to a 2,000 litre bioreactor for Myozyme. However the FDA took the view that the new bioreactor glycosylated the protein more than the old bioreactor, to the point where, to all intents and purposes, a different product was being made. In the end Genzyme sought and gained (in May 2010) FDA approval for the drug when sourced from a 4,000 litre bioreactor at Geel in Belgium, since the US site where the 2,000 litre bioreactor was planned also had unrelated quality control issues.

[46] See 'Lonza, UCB Sign Antibody Pact' by Michael McCoy, Chemical & Engineering News, 23/5/2005.

[47] In August 2009 Genentech exercised its option to buy Lonza's newly built 80,000 litre manufacturing facility in Singapore, where the antibody drug Avastin was made, for US$290m upfront and US$70m in milestones.

[48] Traditionally ICDs had been used mainly to treat ventricular arrhythmia or tachycardia. However two large scale trials, MADIT-II in 2002 (See N Engl J Med. 2002 Mar 21;346(12):877-83. Epub 2002 Mar 19) and SCD-HeFT in 2005 (N Engl J Med. 2005 Jan 20;352(3):225-37), established their utility in treating heart failure with low LVEF regardless of the presence or absence of arrhythmia/tachycardia.

[49] Cardiac Resynchronisation Therapy (CRT), also called 'Biventricular Pacing', involves the use of specialised pacemakers to re-coordinate the action of the right and left ventricles of the heart where an abnormality in the heart's electrical conducting system has caused the two ventricles to beat in an asynchronous fashion. CRT-D devices combine these pacemakers with a defibrillator.

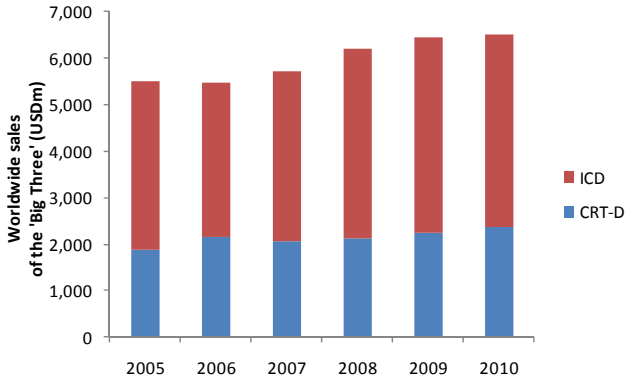
[50] One large study in the UK evaluating the ability of ECG to guide therapy found 20% of suspected heart failure patients had QRS ≥120 ms, indicating a need for evaluation for Cardiac Resynchronisation Therapy (see Eur J Heart Fail. 2007 May;9(5):491-501. Epub 2007 Jan 9).

year or two of life gained[51] the result has been the creation of a >US$6bn market globally for the big American medical device companies Medtronic, St Jude Medical and Boston Scientific. Between 2008 and 2010 that market grew another 5%, based on this evidence of cost effectiveness and an increasing level of comfort on the part of cardiologists as to safety and efficacy. We think MPCs can tap into this same market dynamic:

MPCs will be particularly attractive to NYHA Class III patients

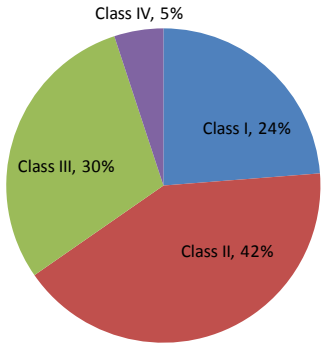
- **There's a lot of heart failure out there.** Heart failure may affect at least 5.7 million adult Americans or 2.4% of the adult population[52].
- **Class III heart failure is a sizeable market in its own right**. We estimate Class III heart failure (experiencing marked limitation of physical activity) constitute 30% of the patient population while Class IV patients (virtually no physical activity without discomfort) are only 4-5%. Without downplaying the opportunity in Class II patients (~40% of the market), we expect that Class III patients and their treating physicians are likely to be particularly attracted to MPCs, because these patients are becoming refractory to conventional drug treatment, and as a consequence are the main drivers for increased ICD and CRT-D implantations, but do not yet qualify for LVADs, which, for cost reasons, are the preserve of Class IV patients. There are probably something like 1.6 million Class III patients in the US alone.
- **The survival data for MPCs has potential to be more favourable than for ICDs**. The interim data suggested the potential for a higher level of life-years gained than for ICDs given that after an average 18 month follow-up period no treated patients had died from cardiac causes. We expect the full data set to provide further clues in this regard.
- **Favourable economics are likely to drive usage in the medium term**. We think evidence of efficacy, as it gathers in the forthcoming pivotal trial and then in Phase IV studies, will combine with favourable healthcare economics, as determined primarily by data gathered *post hoc* on hospitalisation rates[53], to drive demand both for MPCs as well as the new generation (and yet to be widely used) J&J NOGA catheters that deliver them[54].

Figure 3 – Heart failure has grown the market for defibrillators, on which MPCs can piggyback



SOURCE: FOR TOTAL SALES OF DEFIBRILLATION SYSTEMS, ST JUDE MEDICAL, MEDTRONIC, BOSTON SCIENTIFIC. FOR CRT-D SYSTEM SALES, BELL POTTER SECURITIES ESTIMATES.

Figure 4 - Most heart failure is in NYHA Classes II and III



SOURCE: EUR J HEART FAIL. 2004 OCT;6(6):795-800, 821-2; EUR J HEART FAIL. 2010 JAN;12(1):25-31; BELL POTTER SECURITIES.

[51] For ICDs see Circulation. 2006 Jul 11;114(2):135-42. Epub 2006 Jul 3. For CRT-D see J Am Coll Cardiol. 2005 Dec 20;46(12):2311-21.

[52] Source: American Heart Association, *Heart Disease and Stroke Statistics*, 2011 update, Table 9-1. The figures come from NHANEs 2005-2008 data, which is self-reported and therefore potentially under-estimates prevalence.

[53] In 2007 Americans with heart failure still generated close to a million hospital discharges with average length of stay of 5 days (source: CDC, National Hospital Discharge Survey: 2007 Summary) with each hospitalisation costing around US$19,000 (calculated using J Am Geriatr Soc. 2004 May;52(5):675-84, updated using US CPI data on the cost of inpatient hospital services).

[54] As at 2011 no major biologics application had gained FDA approval that required delivery via a NOGA catheter. FDA approval of MPCs would, we believe, considerably increase demand for such catheters. We expect a NOGA catheter would cost around 10% of the reimbursed cost of MPC therapy in heart failure for a single patient.

Sixteen reasons to own Mesoblast

Who is Mesoblast? A Melbourne-based biotechnology company, Mesoblast is creating clinical therapies from a class of adult stem cell called Mesenchymal Precursor Cells (MPCs). The company is currently conducting six Phase II trials of the technology, has completed a seventh Phase II with full data pending, and has initiated its first pivotal trial, in Bone Marrow Transplantation. One other Phase II trial is pending. In many cases there are multi-billion dollar markets to enter in the event of clinical success. Until 2010 Mesoblast focused on the orthopaedic applications of the technology while a 33%-owned associated American company called Angioblast Systems focused on the cardiovascular applications. Mesoblast acquired the Angioblast shares it did not previously hold late in 2010.

We see sixteen reasons why investors should own MSB at current prices:

Mesoblast is the leading company in the stem cell sector by market cap

1. **MSB is part of a wave of the future that is capitalised at only US$3.7bn globally.** Stem cells, which are cells with the ability to develop into many different cell types, or promote the growth of new cells, have demonstrated over the last ten years that they can potentially cure a wide variety of diseases. This makes stem cell technologies such as those owned by MSB increasingly powerful in terms of the upcoming commercial payoff from new drugs. Currently the entire listed stem cell sector of 15 companies is capitalised at ~US$3.7bn[55], reflecting the early stages of what we anticipate will be one of the most commercially significant areas of healthcare in the 21st Century.
2. **There is solid science behind Mesoblast's technology.** Since 2001 Mesoblast has perfected methods for obtaining and expanding its stem cells from donors so that they can be stored and then used in unrelated patients as an 'off the shelf' therapy.
3. **Favourable clinical data is starting to emerge.** Between 2005 and 2007 the company trialled its technology first in 'autologous' applications – ie the patient was given his own stem cells - in the orthopaedics and cardiovascular space. From 2007 it has been successfully trialling them in 'allogeneic' settings where stem cells from a donor are transplanted in an unrelated recipient. The first favourable allogeneic clinical data was obtained from Phase II trials in 2009, markedly boosting the credibility of the MSB story.

The Cephalon / Mesoblast partnering deal was the first major deal in the stem cell space

4. **A major partnering deal with Cephalon has de-risked the company.** In one of the largest biotechnology transactions of 2010 globally, MSB announced, in December, a partnering deal with the American specialty pharma company Cephalon that saw Cephalon 1) take a 19.99% stake in the company 2) partner with MSB on the cardiovascular and bone marrow transplant applications of the MPC technology and 3) agree to help fund new programmes in CNS applications like Alzheimer's and Parkinson's disease. We see this deal as a transforming one for the stem cell space, in that it sees an established pharma company commit substantial resources to stem cell development as a significant part of its pipeline for the first time. It is also transforming for Mesoblast in that it substantially de-risks the company by providing adequate funding for all programmes and strong financial upside. Cephalon's due diligence prior to the deal will also serve as a comfort factor for investors.
5. **Teva's acquisition of Cephalon is a plus for Mesoblast**. The Israeli drug major Teva announced that it was acquiring Cephalon for US$6.8bn in May 2011, and the deal closed in October 2011. We argue in this note that Teva's involvement in Mesoblast is likely to be positive, since that company has a strategy of growing through branded innovator drugs, and is motivated to do so given the various threats

[55] 31 October close on Nasdaq and elsewhere.

faced by Copaxone, its Multiple Sclerosis blockbuster, which loses US patent protection in 2014. We expect Teva will seek to optimise the development pathway for Mesoblast's cardiovascular and CNS programmes, and may also use Mesoblast's technology to bolster its existing franchise in MS.

6. **MSB now has A$256m in cash.** The upfront payment and equity placement associated with the Cephalon deal has left MSB amply funded for further clinical development and negated the possibility of further capital raisings. As at September 2011 the company held $256m in cash.

Mesoblast is currently running or completing seven Phase II trials and is moving towards its first Phase III trials

7. **Multiple trials are now underway with a pivotal now initiating**. As we noted above, MSB is currently conducting or working towards Phase II or Phase III data in eight different applications, mostly cardiovascular and orthopaedic. In each case the MPC technology has been demonstrated to be able to make a difference in what have to date been underserved patient populations. With MSB collaborating on furthering the science of MPCs, we see the potential for other indications to emerge. Significantly, the embryonic stem cell company Geron, which currently has a market capitalisation of US$309m[56], is only entering Phase I now for its stem cell products (although it has made it to Phase II with a cancer vaccine based on the enzyme telomerase).

Figure 5 - Clinical trials being undertaken by MSB

Application	Current Phase	Completion optimistic case	Completion base case	Patients
Posterior interbody lumbar fusion	II	Aug-12	Feb-13	24
Cervical spinal fusion	II	Apr-12	Oct-12	36
Intervertebral disc repair	II	Jan-13	Jul-13	100
Heart failure	II	Data out Nov-11		60
Acute myocardial infarction	II	Feb-14	Feb-15	225
Knee osteoarthritis	II	Jan-12	Jul-12	24
AMD	II	Feb-14	Aug-14	18
Bone marrow transplant	III	May-13	Jul-13	240

SOURCE: MSB, BELL POTTER SECURITIES.

8. **MSB is now a Phase III company with its bone marrow transplant application.** After a successful Phase II trial, MSB's Phase III trial of MPC technology in bone marrow transplantation (BMT) is being readied for commencement, with a cleared IND and a Special Protocol Assessment being sought from the FDA. We see the BMT indication as indicative of substantial upside for MSB. The indication will serve a patient population about as large as that currently served by the Australian medical device major Cochlear Ltd[57], which has a market capitalisation of A$3.3bn[58]. Also, we see the success of the Phase II trial as pointing towards a significant de-risking of the technology.

MSB's heart failure trial has generated solid interim data

9. **MSB's heart failure trial will report Phase II data on 14 November 2011.** With a 60-patient Phase II trial in NYHA Class II and III heart failure patients having generated solid interim Phase II data in January 2011, we expect a favourable outcome from this trial when full data is released at the American Heart Association annual meeting in Orlando, FI, later this month.

10. **MSB has started to build a valuable spinal 'franchise'.** With the MPC technology being successfully applied across a spectrum of spine-related procedures in a Phase II setting, we see substantial value accruing to MSB for this franchise, since it allows a

[56] 31 October 2011 close on Nasdaq.

[57] ASX: COH, Sydney, Australia, www.cochlear.com.

[58] In FY11 COH sold 24,661 cochlear implants globally, representing around 70% of the cochlear implant market. This is around the same as the number of allogeneic bone marrow transplants performed globally each year (Source: National Marrow Donor Program).

potential acquirer to comprehensively access a large and growing segment of the orthopaedics market.

11. **Other applications are growing in importance**. We like MSB's potential in applications such as knee osteoarthritis, AMD/diabetic retinopathy and diabetes, where the animal data looks good.

12. **The path to market is fast.** With the FDA only requiring one Phase II and one pivotal trial before approving a stem cell therapy, we see MSB as requiring a relatively short time before the MPC technology begins to yield commercial revenues.

The FDA only requires two clinical trials per MPC application

13. **The management is commercial.** We have a high regard for MSB's leadership team led by Executive Director Professor Silviu Itescu, who owns 24.4% of the company and is its largest shareholder. We like the commercial approach the company has taken to create shareholder value, as typified by the decision to make orthopaedic applications a key focus in the early days of the company.

14. **We expect substantial news flow in 2011 and 2012.** The next 12 months will feature some strong news flow from MSB, with potential announcements including:

- Initiation of clinical work on diabetes;
- Completion of the spinal fusion trials;
- Heart failure results presented at the American Heart Association meeting in November 2011;
- Progression to a heart failure pivotal trial;
- Completion of the disc repair trial;
- Initiation of Phase II trial in chronic angina;
- Potential completion of the knee osteoarthritis trial;
- Receipt of a Special Protocol Assessment by the FDA for the bone marrow transplant trial;
- The first patient in the bone marrow transplant Phase III;
- The first patient in the Acute Myocardial Infarction in Europe; and
- Animal data on new MPC indications including Alzheimer's and Parkinson's.

15. **There is potential for M&A activity.** We see a number of reasons why Mesoblast may attract further M&A interest from Big and Specialty Pharma:

- *Mesoblast has long-dated patent protection*, with its earliest patent having a 1999 priority date and the most meaningful priority date having been established in 2006, allowing patent protection out to at least the mid-2020s;

Big Pharma likes 'off-the-shelf' business models like Mesoblast's

- *Mesoblast is being set up to enjoy 'pharma-style' economics from its off-the-shelf business model*. The ability to obtain MPCs from one donor and then administer them to an unrelated donor allows Mesoblast's products to be sold like they were small molecules or monoclonal antibodies;
- *Mesoblast would give its partners 'first mover advantage'*. When Roche first acquired a majority stake in Genentech in 1990 (the minorities were taken out in 2009) it effectively acquired first mover advantage in the Next Big Thing in pharmaceuticals – monoclonal antibodies - from which it benefited in a major way from the mid-1990s on. We believe Mesoblast can yield a similar advantage today in stem cells.

16. **The stock is trading significantly below our target price.** We assume the MSB pipeline has value for both the older as well as newer programmes. Our $16.00 target price for MSB is at the midpoint of our base case $11.14 / optimistic case $21.59 per share probability-weighted DCF valuation.

Mesoblast

COMPANY DESCRIPTION

The Melbourne-based Mesoblast (MSB) is a biotechnology company commercialising the therapeutic use of mesenchymal precursor cells or MPCs – a kind of adult stem cell. MSB's MPC technology allows these cells to be extracted from the bone marrow of donors, grown into therapeutic quantities and administered 'allogeneically' – ie, to patients that are not related to the donor - to treat disorders where new bone or tissue growth is required. We like the effectiveness of the technology as against existing therapies, as well as its non-controversial nature. The technology is being applied to a wide variety of orthopaedic and cardiovascular applications with the first commercial products set to emerge from the clinic around 2013. Mesoblast now has A$256m in cash on hand and therefore has no further need to raise capital from the equity markets.

INVESTMENT STRATEGY

We see the major partnering deal with Cephalon inked in late 2010 as providing significant upside since it funds the company's leading programmes in bone marrow transplantation and heart failure. We also see a payoff to shareholders arising from further partnering deals for individual applications as the stem cells prove themselves in clinical trials. We expect a typical licensing deal will yield upfront and milestone payments as well as royalties. The Cephalon partnering resulted in that company owning 19.99% of Mesoblast, a stake that is now held by Cephalon's new owner, the Israeli drug major Teva. We see Teva's need for new branded drugs as a positive for Mesoblast.

VALUATION

We assume the MSB pipeline has value across a range of clinical development programmes. Our $16.00 target price for MSB is at the lower level of our base case $11.14 / optimistic case $21.59 per share probability-weighted DCF valuation. We assume that MSB can be re-rated by the market as the near-term nature of the stem cell opportunity become apparent, and further clinical data emerges.

RISKS

We see the main risk in MSB as being clinical risk – ie that products fail to perform in human trials. Another major risk facing the company is that prospective licensing partners may drive too hard a bargain for MSB shareholders to enjoy a strong return.

Recommendation structure

Spec Buy: Expect >30% total return on a 12 month view but carries significantly higher risk than its sector

Buy: Expect >15% total return on a 12 month view

Accumulate: Expect total return between 5% and 15% on a 12 month view

Hold: Expect total return between -5% and 5% on a 12 month view

Reduce: Expect total return between -15% and -5% on a 12 month view

Sell: Expect <-15% total return on a 12 month view

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