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Mesoblast (MSB)

Phase II success in heart failure

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

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

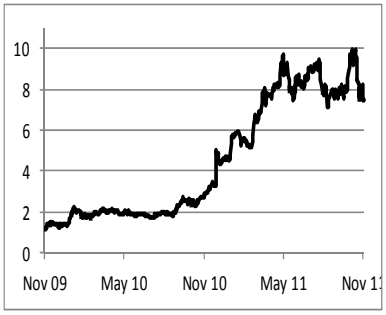
Company Data & Ratios	
Enterprise value	**$2,044m**
Market cap	**$2,300m**
Issued capital	**280.4m**
Free float	**100%**
Avg. daily vol. (52wk)	**0.73m**
12 month price range	**$2.82-$10.04**
GICS sector	
Healthcare Equipment and Services	

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$)	9.48	7.94	2.80
Absolute (%)	-20.89	-5.54	167.86
Rel market (%)	-21.34	-8.35	177.93

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 2014/15 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 has outstanding Phase II data in heart failure

Bell Potter Securities believes Mesoblast's share price undervalues the cardiovascular applications alone. The company has now unveiled the results of its 60 patient Phase II trial of MPCs in heart failure at a special session of the American Heart Association's annual meeting on 14 November 2011. **The data suggests a powerful heart failure treatment, putting the company on track for a Phase III next year**, with a reduction in MACE (Material Adverse Coronary Events) by 78% for the treated patients versus the controls (p=0.011), reduction in cardiac mortality by 89% (p=0.02), and reduction in heart failure-related hospitalisation by 43%. Donor specific antibody response occurred in 6 treated patients, or 13% of that group, without impacting on the efficacy of the cells, meaning that immune response to MPCs was not a serious issue. The favourable clinical outcomes were achieved without needing to move the dial on Ejection Fraction because of favourable 'reverse remodeling' of heart muscle, as indicated by a statistically significant improvement in left ventricular end-systolic volume (LVESV) at the 150 million dose level.

The markets for MPCs in cardio therapies are huge

Applications in heart failure, in heart attacks and in chronic angina represent multi-billion dollar market opportunities. We see a US$6bn market in heart failure alone based on the current take-up of ICD and CRT-D devices in Class III heart failure patients. We think the heart failure trial results 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 we initiated coverage on Mesoblast in January 2010.

Spec Buy recommendation and $16 target maintained

With Mesoblast's cardiovascular and Bone Marrow Transplant franchises and other pipeline opportunities in eye diseases, diabetes & orthopaedics becoming more substantial, we re-iterate our positive outlook on the stock. We value Mesoblast at A$11.14 base case and A$21.59 optimistic case. Our target price of A$16.00 sits at the mid-point of our DCF range.

Mesoblast – Phase II success in heart failure

Mesoblast has announced some very favourable Phase II data from its 60-patient heart failure trial. Mesoblast's trial kicked off in October 2008[1] and measured three progressively higher MPCs doses[2] against standard of care where Ejection Fraction had dropped below 40%[3]. In the trial, 45 patients randomised to the three MPCs doses and 15 to placebo. With each dose, patients received a single injection and were evaluated for heart function at three, six and twelve months. The last patient joined the trial in June 2010 and Mesoblast has now reported 12-month data at this year's Scientific Sessions meeting of the American Heart Association, 12 months being the follow-up time for the last-recruited patient. The mean follow-up period across the trial was 22 months.

- One investigator described the result, in this morning's analyst briefing, as 'an impressive result for 60 patients...as impressive as anything we have seen in the last 10 years'. Later on an investigator suggested that 'even with less favourable data MPCs would still be satisfactory enough for regulatory approval';
- When asked about the next stage in development, Mesoblast CEO Dr Silviu Itescu reiterated Teva comments that it was ready to take MPCs into a Phase III heart failure trial, with the company intending to sit down with the FDA to discuss the endpoints for next year's commencement.

We were impressed with six aspects of the trial result

1 **In what is a statistically significant outcome, people are still alive thanks to MPCs**. In this trial, only one of the 45 treated patients died of cardiac causes over the 22 month follow-up period, as against three of the 15 control patients. This was a reduction in cardiac mortality of 89%, for which the p value was 0.02, suggesting that MPCs were a major factor in improving outcomes on mortality[4].

2 **MPCs kept people out of hospital, with statistical significance**. Compared with controls, MPC treatment reduced the overall risk of Material Adverse Coronary Events (MACE) by 78% (p=0.011), which in today's analyst briefing principal investigator Dr Emerson Perin characterised as the most surprising aspect of the trial given the small patient numbers[5]. In this trial MACE was defined as either cardiac death, revascularisation (ie procedure to reopen blocked arteries, such as stenting or heart bypass, as a result of chest pain) or myocardial infarction (ie heart attack). Heart failure-related hospitalisation came down by 43%. This was not statistically significant due to small patient numbers, but the reduction is still very important in terms of the future healthcare economics of MPCs in heart failure. Moreover Mesoblast reported this morning that the 150 million dose 'completely prevented any episodes of heart failure hospitalization over 18 months of follow-up'. All this is further proof that a single injection of stem cells is quite powerful. It's important to keep in mind that some patients in this trial received their MPCs more than three years ago.

3 **There were no immune system issues with MPCs**. A donor specific antibody response occurred in 6 treated patients, or 13% of that group. So there was an immune response to the cells, as per the findings of recent science on mesenchymal stem cells

[1] After the IND was cleared in June 2008 - see NCT00721045 at www.clinicaltrials.gov.

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

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

[4] The cardiac mortality reduction was not quite statistically significant at the interim data point reported in January 2011.

[5] We think small patient numbers accounts for an apparent lack of dose response across some measures (although the balance of probabilities lies with the 150 million cell dose given its effect on LVESV and six-minute walk) and that larger patient numbers will show a clearer dose response.

and immunogenicity, but that response was weak and did not impact on the efficacy of the cells. Moreover of those six patients, four lost their antibodies in less than one month. There was no effect on therapeutic outcomes from the antibodies, and no clinical-signs or symptoms related to such antibodies. At today's analyst briefing Silviu Itescu also noted that in repeat dosing work in non-human primates there had been no immune response issues observed in terms of its impact on therapeutic effectiveness. We conclude from all this that immune response is not an issue with MPCs. At worse, patients with an immune response could receive a differently typed MPC batch for any repeat dosing should that be necessary.

4 **The favourable clinical outcomes were achieved without needing to move the dial on Ejection Fraction, probably thanks to 'reverse remodeling'.** In this trial Ejection Fraction from baseline to 12 months did not change in MPC-treated patients (mean, 30 to 31%) nor in controls (mean, 32 to 31%). This suggests that the mechanism of action lies elsewhere than in Ejection Fraction, such as reversal of fibrosis and collagen deposition. In the study the treated patients experienced a lower increase in left ventricular end-systolic volume (LVESV), a measure of the size of the failing heart. As hearts fail, they get bigger due to the heart having to pump harder. The investigators noted that at the 150 million cell dose there was a statistically significant reduction in LVESV at six months (p=0.015) over the controls, suggesting that the stem cells were engaging in 'reverse remodeling' of the heart, and that this was what led to the favourable hard data on MACE and mortality without the need to change Ejection Fraction[6].

5 **There was improved functional capacity in treated patients**. The six minute walk test, which measures how far along a flat 30m walkway a patient can walk in a six minute period, is a measure of functional exercise capacity that correlates with survival in moderate heart failure patients. This trial did not generate a statistical significant change in six minute walk test outcomes across all doses, but the 150 million dose did see a trend towards significance (p =0.062) compared to the controls[7].

6 **There was an improvement in NYHA Class**. NYHA Class is often regarded as too subjective a measure of heart failure[8], and Mesoblast's investigators preferred the trend on six minute walk test to the change in NYHA as a more objective measure of functional improvement. That said, MPCs worked quite well on this score. At 12 months, 40% of MPC-treated patients reverted to NYHA class I status compared with only 14% of controls[9]. This suggests that MPCs can meaningfully reverse the course of heart failure in a cost- effective way for a large patient group (Class II, which is around 40% of all heart failure patients) and also suggests competitiveness in Class III (another 30%) where treatment options are limited.

MPCs can now move to Phase III in heart failure. Mesoblast has indicated that it expects its MPCs to move into a Phase III trial in the first half of 2012, with Teva indicating that the Phase II results *'reinforce Teva's commitment to its strategic investment in Mesoblast's adult stem cell technology and to our continued support for the clinical development of Revascor.*' We think this indicates support from Teva to move MPCs into Phase III. We expect that MSB and Teva will proceed to a ~1,000-patient pivotal, with a 500 patient interim analysis point allowing early completion in the event of statistical significance on a composite endpoint of MACE, mortality and hospitalisation. We expect completion of this trial around mid-2014 based on 12-month follow-up from a single injection.

[6] LVESV has been found to be a better predictor of survival after recovery from a heart attack than LVEF. See Circulation. 1987 Jul;76(1):44-51.

[7] We understand that overall the controls actually had higher scores on the six minute walk test at baseline, which would negate any issues that may have arisen from a mismatch of NYHA classes in the treatment and control groups. We deal with the mismatch issue in our 1 November 2011 note on Mesoblast, headlined 'We have seen the future, and it works'.

[8] See Heart. 2007 Apr;93(4):476-82. Epub 2006 Sep 27.

[9] Silviu Itescu noted in today's analyst briefing that the changes are broadly the same if the NYHA mismatch between treatment and control groups are removed.

A strong market awaits a successful launch of Mesoblast's product

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[10]. 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[11] and useful in around 20% of heart-failure patients[12]. With both ICDs and CRT-Ds found to be cost effective for the extra year or two of life gained[13] 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[14].
- **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 Phase II data for MPC 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.
- **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[15], 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[16].

[10] 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.

[11] 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.

[12] 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).

[13] 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.

[14] 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.

[15] 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).

[16] 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$3.6bn 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$3.6bn[17], 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, and this credibility has now taken another step forward with full Phase II trial data in heart failure.

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

[17] 14 November close on Nasdaq and elsewhere.

through branded innovator drugs, and is motivated to do so given the various threats 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$289m[18], 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 1 - 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	III pending	June-2014	October-2014	500-1,000
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[19], which has a market capitalisation of A$3.3bn[20]. 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 Phase II data

9. **MSB's heart failure trial reported favourable Phase II data.** A 60-patient Phase II trial in NYHA Class II and III heart failure patients registered a reduction in MACE (Material Adverse Coronary Events) by 78% for the treated patients versus the controls (p=0.011), a reduction in cardiac mortality by 89% (p=0.02), and a reduction in heart failure-related hospitalisation by 43%. This data was reported at the American Heart Association meeting in Orlando, Florida in November 2011.

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

[18] 14 November 2011 close on Nasdaq.

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

[20] 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).

II setting, we see substantial value accruing to MSB for this franchise, since it allows a 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:

- Completion of the stand-still agreement with Teva on its 19.99% stake;
- Initiation of clinical work on diabetes;
- Completion of the spinal fusion trials;
- 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 BMT trial;
- The first patient in the bone marrow transplant Phase III trial;
- The first patient in the Acute Myocardial Infarction trial 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 2014/15. 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 midpoint 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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