Mesoblast MSB.AX MSB AU

HEALTH CARE & PHARMACEUTICALS

NOMURA
EQUITY RESEARCH

MSB releases final Phase II cardiac trial data

The study achieved its primary endpoint – we await the start of a Phase III clinical trial

November 15, 2011

Rating Remains	**Buy**
Target price Remains	AUD 10.15
Closing price November 15, 2011	AUD 7.75
Potential upside	+31%

Action: Long-awaited Phase II cardiac clinical trial released

Results from MSB's Phase II trial of MPC's Mesenchymal Precursor Cells (MPCs) in patients with moderate-severe congestive heart failure were presented. We note that the primary endpoint of the Phase II clinical trial was to demonstrate safety and activity – this was achieved.

Catalyst: Functional endpoint significant

There was 78% decline in Major Adverse Cardiac Events (MACE). This demonstrated statistical significance at p=0.036. This was the major functional measure in that it is a composite endpoint of cardiac death, need for revascularisation procedure and heart attack. Outputs from pathologic secondary endpoints were mixed, in some cases trending towards significance.

US FDA looks at functional endpoints when deciding on approval

We note that the criteria for US FDA approval are significant functional (not pathologic) improvement. Hence, should MSB's Phase III clinical trial be positive in a functional sense to the same degree as this Phase II clinical trial, then according to FDA guidelines, MSB's MPC product stands a good chance of being approved as a treatment for heart failure.

Valuation: PT A$10.15 – unchanged

MSB confirmed that MSB's partner, Teva (TEVA IL, unrated) is committed to progressing MSB's MPCs to a Phase III trial in heart failure. We believe this sends a powerful signal of Teva's thoughts regarding the potential for a positive Phase III trial outcome, and subsequent approval of MPCs. We assume the start of a Phase III trial in forecasts, hence TP is unchanged.

30 Jun	FY11		FY12F		FY13F		FY14F
Currency (AUD)	Actual	Old	New	Old	New	Old	New
Revenue (mn) 116		31	31	31	31	133	133
Reported net profit (mn) 91		-38	-38	-28	-28	42	42
Normalised net profit (mn) 91		-38	-38	-28	-28	42	42
Normalised EPS 41.79c		-13.50c	-13.50c	-10.08c	-10.08c	14.99c	14.99c
Norm. EPS growth (%) na		-132.3	-132.3	na	na	na	na
Norm. P/E (x) 20.1		N/A	na	N/A	na	N/A	55.3
EV/EBITDA (x) 23.1		na	na	na	na	33.9	33.9
Price/book (x) 4.3		N/A	4.7	N/A	5.0	N/A	4.6
Dividend yield (%) na		N/A	na	N/A	na	N/A	na
ROE (%) 32.7		-7.6	-7.6	-6.1	-6.1	9.0	9.0
Net debt/equity (%) net	cash	net cash	net cash	net cash	net cash	net cash	net cash

Source: Nomura estimates

Key company data: *See page 2 for company data and detailed price/index chart.*

Anchor themes

As the aged population is having more operations, we believe there will be more demand for treatments, which MSB can deliver.

Nomura vs consensus

The difference between our forecasts and consensus relates to our assumptions regarding success of MSB's multiple clinical trials. We forecast a c60% chance of success in Bone Marrow Transplant and Cardiac Failure clinical trials.

See Appendix A-1 for analyst certification, important disclosures and the status of non-US analysts.

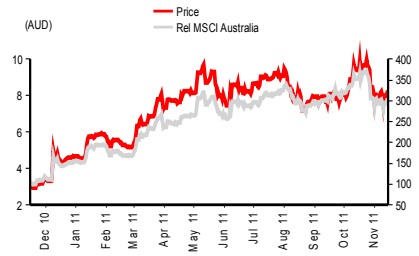
Key data on Mesoblast

Income statement (AUDmn)

Year-end 30 Jun	FY10	FY11	FY12F	FY13F	FY14F
Revenue	**0**	**116**	**31**	**31**	**133**
Cost of goods sold	0	0	-2	-2	-3
Gross profit	**0**	**116**	**29**	**29**	**130**
SG&A -11		-27	-58	-64	-74
Employee share expense					
Operating profit	**-11**	**89**	**-29**	**-35**	**56**
EBITDA	**-11**	**89**	**-28**	**-34**	**62**
Depreciation 0		0	-2	-1	-5
Amortisation 0		0	0	0	0
EBIT -11		89	-29	-35	56
Net interest expense 1		5	8	7	7
Associates & JCEs					
Other income	-4	-2	0	0	0
Earnings before tax	**-15**	**92**	**-22**	**-28**	**63**
Income tax	0	-2	-16	0	-21
Net profit after tax	**-15**	**91**	**-38**	**-28**	**42**
Minority interests	0	0	0	0	0
Other items					
Preferred dividends					
Normalised NPAT	**-15**	**91**	**-38**	**-28**	**42**
Extraordinary items	0	0	0	0	0
Reported NPAT	**-15**	**91**	**-38**	**-28**	**42**
Dividends 0		0	0	0	0
Transfer to reserves	**-15**	**91**	**-38**	**-28**	**42**
Valuation and ratio analysis					
FD normalised P/E (x) na		20.1	na	na	55.3
FD normalised P/E at price target (x) na		25.5	na	na	70.3
Reported P/E (x) na		19.1	na	na	53.2
Dividend yield (%) na		na	na	na	na
Price/cashflow (x) na		16.4	na	na	51.8
Price/book (x) 32.6		4.3	4.7	5.0	4.6
EV/EBITDA (x) na		23.1	na	na	33.9
EV/EBIT (x) na		23.1	na	na	37.2
Gross margin (%) 100.0		100.0	92.7	92.4	97.6
EBITDA margin (%) -199,515	.4	76.8	-90.0	-107.7	46.2
EBIT margin (%) -202,302	.4	76.6	-95.0	-112.2	42.1
Net margin (%) -268,743	.5	77.9	-122.1	-90.8	31.5
Effective tax rate (%) na		1.8	na	na	33.3
Dividend payout (%) na		0.0	na	na	0.0
Capex to sales (%) 1,583	.9	0.4	5.0	4.5	4.1
Capex to depreciation (x) 0.8		3.4	1.0	1.0	1.0
ROE (%) -46.4		32.7	-7.6	-6.1	9.0
ROA (pretax %) -124.2		35.1	-5.9	-7.0	11.2
Growth (%)					
Revenue -97.0		2,113,948.2	-73.3	0.5	328.1
EBITDA na		na	-131.3	na	na
EBIT na		na	-133.1	na	na
Normalised EPS	na	na	-132.3	na	na
Normalised FDEPS	na	na	-132.7	na	na
Per share					
Reported EPS (AUD) -10.51	c	41.79c	-13.50c	-10.08c	14.99c
Norm EPS (AUD) -10.51	c	41.79c	-13.50c	-10.08c	14.99c
Fully diluted norm EPS (AUD) -10.51	c	39.78c	-12.99c	-9.71c	14.43c
Book value per share (AUD) 0.24		1.84	1.71	1.60	1.74
DPS (AUD) 0.00		0.00	0.00	0.00	0.00

Source: Nomura estimates

Relative performance chart (one year)



Source: ThomsonReuters, Nomura research

(%)	1M	3M	12M
Absolute (AUD)	-12.2	2.3	322.2
Absolute (USD)	-14.5	1.8	401.0
Relative to index	-8.6	11.3	327.6
Market cap (USDmn)	2,474.6		
Estimated free float (%)	55.0		
52-week range (AUD)	9.95/1.8		
3-mth avg daily turnover (USDmn)	6.31		
Major shareholders (%)			
Silviu Itescu	25.0		
Cephalon Inc	20.0		

Source: Thomson Reuters, Nomura research

Notes

We forecast revenues for MSB to continue in FY12

Cashflow (AUDmn)

Year-end 30 Jun	FY10	FY11	FY12F	FY13F	FY14F
EBITDA -11		89	-28	-34	62
Change in working capital -1		28	0	0	0
Other operating cashflow	3	-7	-8	7	-17
Cashflow from operations	**-9**	**111**	**-36**	**-26**	**45**
Capital expenditure 0		0	-2	-1	-5
Free cashflow	**-9**	**111**	**-38**	**-28**	**39**
Reduction in investments	4	5	0	0	0
Net acquisitions 0		3	0	0	0
Reduction in other LT assets	0	-22	0	0	0
Addition in other LT liabilities	0	217	0	0	0
Adjustments -5		-201	0	0	0
Cashflow after investing acts	**-10**	**113**	**-38**	**-28**	**39**
Cash dividends	0	0	0	0	0
Equity issue	26	126	0	0	0
Debt issue	0	0	0	0	0
Convertible debt issue					
Others 0		-8	0	0	0
Cashflow from financial acts	**26**	**118**	**0**	**0**	**0**
Net cashflow	**16**	**231**	**-38**	**-28**	**39**
Beginning cash	17	32	263	226	198
Ending cash	32	263	226	198	237
Ending net debt	-32	-263	-226	-198	-237

Source: Nomura estimates

Notes

We assume a successful Phase III bone marrow trial in our forecasts

Balance sheet (AUDmn)

As at 30 Jun	FY10	FY11	FY12F	FY13F	FY14F
Cash & equivalents 32		263	226	198	237
Marketable securities	0	0	0	0	0
Accounts receivable	1	2	3	3	4
Inventories 0		0	0	0	0
Other current assets	0	0	0	0	0
Total current assets	**34**	**265**	**228**	**201**	**241**
LT investments	5	0	0	0	0
Fixed assets	0	1	1	1	1
Goodwill 0		110	110	110	110
Other intangible assets	0	366	366	366	366
Other LT assets	0	22	22	22	22
Total assets	**40**	**763**	**726**	**699**	**739**
Short-term debt	0	0	0	0	0
Accounts payable 2		4	4	5	6
Other current liabilities	0	27	27	27	27
Total current liabilities	**2**	**31**	**32**	**32**	**33**
Long-term debt	0	0	0	0	0
Convertible debt					
Other LT liabilities	0	217	217	217	217
Total liabilities	**2**	**247**	**248**	**249**	**250**
Minority interest	0	0	0	0	0
Preferred stock 0		0	0	0	0
Common stock 88		477	477	477	477
Retained earnings -56		35	-3	-31	8
Proposed dividends					
Other equity and reserves	6	4	4	4	4
Total shareholders' equity	**38**	**516**	**478**	**450**	**489**
Total equity & liabilities	**40**	**763**	**726**	**699**	**739**
Liquidity (x)					
Current ratio	21.01 8.62		7.24	6.20	7.20
Interest cover na		na	na	na	na
Leverage					
Net debt/EBITDA (x)	na	net cash	na	na	net cash
Net debt/equity (%)	net cash	net cash	net cash	net cash	net cash
Activity (days)					
Days receivable	55,780.0	5.5	27.3	32.5	9.1
Days inventory na		na	0.0	0.0	0.0
Days payable na		na	655.9	747.5	659.5
Cash cycle na		na	-628.6	-715.0	-650.4

Source: Nomura estimates

Notes

MSB had A$263mn in cash at end FY11

Phase II cardiac clinical trial released

Results from MSB's Phase II trial of MPC's Mesenchymal Precursor Cells (MPCs) in patients with moderate-severe congestive heart failure were presented at the American Heart Association 2011 Annual Conference. We note that the primary endpoint of the Phase II clinical trial was to demonstrate safety and activity – this was achieved.

Overall, when we analyse the secondary endpoints of the trial, the data highlights to us that the trial was a small one and not powered to achieve statistically significant secondary endpoints. We note the functional endpoints, namely decrease in cardiac deaths and rate of Major Adverse Cardiac Events (MACE), were significant, at p=0.036 and p=0.02, respectively, whilst outputs from pathologic (ie, how the disease progressed) secondary endpoints were mixed, in some cases trending towards significance.

We note that the focuses of the US Food and Drug Administration (FDA – the regulatory body for approval of a biologic or drug) in approving a product are functional measures, like MACE and cardiac death. MSB's Phase II cardiac failure trial had a 78% reduction in MACE that was statistically significant. Hence, should MSB's Phase III clinical trial be positive in a functional sense like the Phase II trial, then according to FDA guidelines, the product stands a good chance of being approved. We note that the independent researchers on the clinical trial call stated that, given the functional results, they believed that MSB already has an approvable product for cardiac failure.

In this note, we:

- Describe the outcomes of the trial in terms of primary and secondary endpoints;
- Highlight the differences between functional and anatomic secondary endpoints, and why this might be the case; and
- Describe what it means for MSB.

What is a Phase II trial?

In a Phase II trial, the drug or treatment is given to a group of people (usually 50 to 100) to see if it is effective and to further evaluate its safety. Some Phase II trials are designed as case series, demonstrating a drug's safety and activity in a selected group of patients. Other Phase II trials are designed as randomised clinical trials, where some patients receive the drug/device and others receive placebo/standard treatment. Phase II studies are sometimes divided into Phase IIa and Phase IIb:

The primary aim of a Phase II clinical trial is to demonstrate safety and activity

- Phase IIa is specifically designed to assess dosing requirements (how much drug should be given).
- Phase IIb is specifically designed to study efficacy (how well the drug works at the prescribed dose(s)).

What do we look for in a Phase II clinical trial?

Apart from the results of the clinical trial in terms of safety and whether the treatment is efficacious, given the relatively (to a Phase III clinical trial) smaller numbers of patients in a Phase II clinical trial, broad conclusions from a Phase II trial are difficult to make. We note that the primary aim of a Phase II clinical trial is to demonstrate safety and activity.

1. Outcomes of the trial in terms of primary and secondary endpoints

The trial demonstrated:

- Ongoing evidence of safety of MPCs when given to patients;
- Statistically significant results for the primary outcome measure, which was safety and feasibility of transendocardial injection of 25mn, 75mn, and 150mn of MSB's MPCs in subjects with heart failure; and
- Some further data regarding the final results.

Set-up of the trial

This was a single-blinded, dose-escalation, cohort study in 60 subjects allocated sequentially to 1 of 3 cohorts. Forty-five subjects were randomised to receive transendocardial delivery of MPC treatment, and 15 subjects were randomized to receive standard-of-care treatment without MPC administration.

Results of the trial – functional measures

Major adverse cardiac events (defined as cardiac death, revascularisation and myocardial infarction [Heart attack]) declined significantly compared to controls. MSB's MPC treatment lowered the rate of major adverse cardiac events over time. The major adverse cardiac event rate declined by 78% during the trial (p=0.036). This compares with 84%reduction reported as a part of the interim data release. We believe the difference between interim and final MACE rates is unlikely to be statistically significant.

There was also a statistically significant decrease in cardiac deaths (p=0.02) in the treatment arm.

Results of the trial – pathological measures

The points to note here include:

- **Dose-dependency of treatment for improvement in Left Ventricular Ejection Fraction** (a measure of the heart's pumping ability): This was not seen through the 12 months of follow-up in any of the 25, 75 and 150mn cell doses. This is seen in the following figure. If the effects change when the dose of the drug is changed, the effects are said to be dose-dependent. As part of the final data release from its Phase II cardiac trial, MSB outlined dose-dependence for aspects of cardiac failure. The data showed a decline in dose-dependency at higher doses. This is in line from data from US-based Athersys (ATHX US, unrated), who are developing a non-embryonic stem cell product for potential use in cardiac disease;

Fig. 1: Changes in pathological parameters

Dose (mn cells)	Change in LVEF at 12 months (%)	p-value	Change in LVESV at 12 months (%)	p-value
Control	(0.4)		3.5	
25	5.2	0.31	13.9	0.39
75	1.1	0.67	0.4	0.66
150	(2.7)	0.47	(7.9)	0.13
Nomura comment	LVEF is a measure of the heart's pumping ability		LVESV is a measure of cardiac remodelling	

Source: company data, Nomura research

- **Dose-dependency of treatment for improvement in Left Ventricular End Systolic volume** (a measure of cardiac remodelling): This was not seen through the 12 months of follow-up, although it was trending towards significance; and
- **Dose-dependency of treatment for improvement in 6 minute walk** (a measure of functional ability): This was not seen through the 12 months of follow-up, although it was trending towards significance.

2. Difference between treatment and placebo arms?

A controlled trial randomisation between treatment and control arms ensures that allocation of patients to treatments is left purely to chance. As a part of a randomised trial, the characteristics of patients that may influence outcome are distributed between treatment groups so that any difference in outcome can be assumed to be due to the intervention.

The independent researchers highlighted that the baseline characteristics between the treatment and control arm were mixed

However, imbalance between groups in baseline variables that may influence outcome (such as age or disease severity) may bias statistical tests. This is a property referred to as chance bias. If there is chance bias, then the implication is that differences in outcomes between groups in a particular trial could by chance be due to characteristics of the patients, not due to the treatment under investigation. Ultimately, this undermines the quality of results of the trial. Today, the independent researchers highlighted that the baseline characteristics between the treatment and control arm were mixed.

Baseline characteristics from the interim results of the MSB Phase II trial

We have enclosed selected elements of the baseline characteristics of the MSB trial below. We note that the trial was small, and hence is more likely to have baseline parameters that favour or do not favour treatment or control arms. We note that as the trial size increases the absolute size of imbalance in baseline characteristics will reduce owing to reduction in sampling error.

Points to note from baseline characteristics include:

Pathological parameters – the treatment arm trending to being sicker in terms of their disease

- **Higher levels of B-type Naturetic Peptide in the treatment arm** – this would suggest that the MPC treatment arm has higher levels of cardiac dysfunction than the control arm;
- **Worse Left Ventricular Ejection Fraction (LVEF) in the treatment arm** - this would suggest that the MPC treatment arm is 'sicker' than the control arm;

B-type naturetic peptide (BNP) is a cardiac hormone specifically secreted from the cardiac ventricles as a response to ventricular volume expansion, pressure overload, and resultant increased wall tension. BNP can be used in the diagnosis of cardiac failure. It is synthesized in bursts, so with chronic and more advanced heart failure; ventricular cells are recruited to secrete BNP in response to the high ventricular filling pressures

Functional parameters – the control arm trending to being sicker in terms of their function

- **Better 6-minute walk in the treatment arm** - this would suggest that the control arm is functionally 'sicker' than the MPC treatment arm. We believe the 6-minute walk test is reflective of activities of daily living; and
- **Better NYHA class in the treatment arm** - this would suggest that the control arm is 'sicker' than the MPC treatment arm, as NYHA Class II has less severe heart failure than NYHA Class II.

Fig. 2: Baseline characteristics of MSB's Phase II clinical trial in Cardiac failure

Parameter (n=% of total)	MPC treatment (n=45)	Control (n=15)	Total (n=60)
Cardiovascular history :			
Acute Myocardial Infarction	38 (84.4)	9 (60.0)	47 (78.3)
Coronary Artery Bypass Graft	21 (46.7)	5 (33.3)	26 (43.3)
Percutaneous Coronary Intervention	33 (73.3)	10 (66.7)	43 (71.7)
	Treatment mean (Standard error of mean)	**Control mean (Standard error of mean)**	
Levels of cardiac failure :			
B-type Naturetic Peptide	436.8 (83.9)	217.7 (38.7)	
NYHA Class I (%)	0	0	
NYHA Class II (%)	69	40	
NYHA Class III (%)	31	60	
NYHA Class IV (%)	0	0	
6 minute walk	401.6 (14.37)	319 (31.35)	
LVEF	30.4 (1.13)	32.1 (1.96)	

LVEF – Left Ventricular Ejection Fraction, NHYA – New York Heart Association
Source: NYC Cardiac Cell Therapy Conference 2011, Nomura research

It may be said that, to some extent, the differences between the treatment and control arms in terms of pathology and function have been seen in the secondary endpoint results from this small clinical trial.

3. What does it mean for MSB?

As a result of the trial result, MSB management confirmed that MSB's partner, Teva (TEVA IL, unrated), is committed to progressing MSB's MPCs to a Phase III trial in Cardiac Failure. We believe this sends a powerful signal of Teva's thoughts regarding the potential for a positive trial outcome, and subsequent approval of MPCs. We believe that Teva, the US FDA and MSB are in the process of determining the make-up of a Phase III clinical trial, with start of Phase III likely in 1QCY12.

We believe MSB will be aiming for a special protocol assessment from the FDA

What will the FDA be looking for? What will they approve?

The FDA states in its cellular therapy for cardiac disease guidance for industry that the industry participant should consider the products' expected mechanism of action and the indication being sought in a choice of study endpoint(s). The insight gained from early phase clinical studies should help guide the selection of a primary endpoint for a Phase III study. For Phase III studies, the primary endpoint should reflect the clinically relevant effect of the product.

The FDA states in its guidance that trials designed to test the cellular products' effect on heart failure may consider endpoints such as:

- Mortality,
- Number of subsequent cardiovascular hospitalisations,
- Cardiopulmonary exercise testing,
- Six-minute walk,
- Change in ejection fraction, and
- The need for various interventions (e.g., an implantable defibrillator, left ventricular assist device, transplantation).

Additional endpoints which may be of value in a blinded study include, but are not limited to, New York Heart Association (NHYA) class or validated patient reported outcome questionnaires. The FDA states that industry may also consider the use of secondary endpoints such as change in left ventricular mass and left ventricular dimensions which are suggestive of reverse remodelling.

The FDA state that Phase III studies should use endpoints such as mortality and cardiovascular or heart failure hospitalisations

Importantly, the FDA state:

"In general, Phase III studies should use endpoints such as mortality and cardiovascular or heart failure hospitalisations, whereas endpoints such as ejection fraction, that have not been validated as surrogates for clinical outcome are not considered to be acceptable as primary efficacy endpoints for pivotal trials. Each of these endpoints should be carefully considered in terms of the long- and short-term risk-benefit ratio of the product."

Hence, the focus for the FDA in approving a product is functional measures, like MACE. We note that MSB's Phase II cardiac failure trial demonstrated statistically significant MACE reduction. Should MSB's Phase III clinical trial be positive in a functional sense (and a larger trial may also demonstrate significance in pathological measures), then according to FDA guidelines, the product stands a good chance of being approved.

What are the options for the Phase III clinical trial depending upon guidance from the FDA?

According to MSB management, Teva and MSB will now meet with the FDA regarding a potential Phase III clinical trial. We believe the potential trial composition options for the FDA in agreeing to a Phase III trial include:

- **A Rolling Phase IIb into a Phase III trial** – In this case, the trial would start as a Phase IIb trial. This would report after c150 patients had been assessed and these patients would then rolled into a larger Phase III trial of c1000 patients. This would allow the FDA to further address any safety concerns early in a Phase III trial;
- **Split Phase III clinical trials** – This would have c500 patients in the US and c500 patients in the EU, thus diversifying investigators (and perhaps cost). All patients would be reported as a part of the Phase III trial result; and
- **A single, large Phase III clinical trial** – This would include c1000 patients in the US.

In developing our valuation for MSB, we already assume start of Phase III clinical trial in 1HCY12. We continue to forecast the start of US revenues for MSB from its MPC product in cardiac failure in FY15F. We enclose a timeline for MSB's cardiac opportunity below.

Valuation and risks

We calculate that the NPV of the potential near-term opportunities developed by MSB is AUD10.15. This is seen below.

Fig. 3: MSB - valuation

Valuation of MSB R&D portfolio	Risk-weighted valuation (A$ps)	Risk weighting of portfolio (in line with Clinical Trial stage) (%)	Opportunity (A$ps)
Chronic refractory angina	$0.57	21.4	$2.66
Acute myocardial infarction	$2.67	21.4	$12.45
Congestive heart failure	$4.17	61.2	$6.82
Bone marrow transplant	$1.63	61.2	$2.67
Spinal Fusion	$0.79	21.4	$3.70
Disc Repair	$0.32	21.4	$1.49
Valuation	**$10.15**		$29.79

Source: Nomura estimates, PubMed

In generating our DCF valuation, our assumptions include:

- **Equity beta** – due to its inherent risks, MSB will have a higher beta than most other industrial companies. We assume that the company's equity (and asset) beta is 1.80, in line with the average beta for higher-risk biotech opportunities.
- **Nominal long-run growth rate** – given the potentially high growth rate of this business, and in line with those of other high-growth companies in the market, we assume a nominal long-run growth rate of 5% and a real long-run growth rate of 2.5%.

Risks to our investment view

There is still a good deal of uncertainty around MSB's viability in most of its prospective markets. Pre-clinical trials, although positive, give no firm indication of a product's true viability, and full foresight on future market conditions is difficult to obtain. In its favour, MSB's base product is found naturally in the body, and we see little reason to believe that injections of concentrated numbers would cause serious health issues or be relatively less effective in doing their natural job. Cancer concerns arising from the use of embryonic stem cells have not been mirrored in the use of adult stem cells. Problems associated with overgrowth of bones or tissue in sensitive areas are more likely, but less of a concern. If this becomes an issue, we believe that potentially it could be controlled by appropriate dosage and thus would affect the product's viability only marginally. To date, all preclinical and Phase II trials have shown good indications for the product's viability.

We believe that there is potential simply because no other product can directly rebuild the components of organs, tissue, bone, and muscle. As it stands, there have been no significant adverse effects or health issues and all Phase II or pre-clinical trials indicate a product with market viability. Its distinctive technology platform and clinical progress probably also places it in the strongest position for its markets relative to its stem-cell competitors. Therefore, we believe this is an attractive investment opportunity for investors with a higher risk appetite.

Appendix A-1

Analyst Certification

I, David Stanton, hereby certify (1) that the views expressed in this Research report accurately reflect my personal views about any or all of the subject securities or issuers referred to in this Research report, (2) no part of my compensation was, is or will be directly or indirectly related to the specific recommendations or views expressed in this Research report and (3) no part of my compensation is tied to any specific investment banking transactions performed by Nomura Securities International, Inc., Nomura International plc or any other Nomura Group company.

Issuer Specific Regulatory Disclosures

Mentioned companies

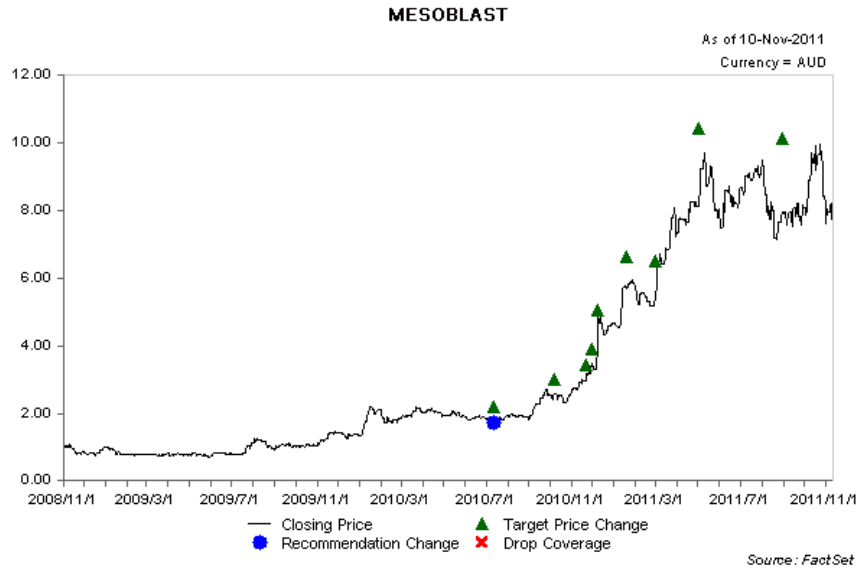
Issuer name	Ticker	Price	Price date	Stock rating	Sector rating	Disclosures
Mesoblast	MSB AU	AUD 7.75	15-11-2011	Buy	Not rated	

Previous Rating

Issuer name	Previous Rating	Date of change
Mesoblast	Not Rated	12-7-2010

Mesoblast (MSB AU) **AUD 7.75 (15-11-2011)** Buy (Sector rating: Not rated)

Rating and target price chart (three year history)



Date	Rating	Target price	Closing price
31-Aug-2011	10.15		7.95
03-May-2011	10.45		8.19
01-Mar-2011	6.51		5.42
18-Jan-2011	6.66		5.76
08-Dec-2010	5.08		4.05
30-Nov-2010	3.92		3.46
22-Nov-2010	3.44		3.19
08-Oct-2010	3.01		2.60
12-Jul-2010	2.21		1.74
12-Jul-2010	Buy		1.74

For explanation of ratings refer to the stock rating keys located after chart(s)

Valuation Methodology We calculate that the NPV of the potential near-term opportunities developed by MSB is A$29.79. We believe the probability of MSB getting its product onto market depends on its clinical trial stage. Hence, our risk-weighted valuation is A$10.15.

Risks that may impede the achievement of the target price There is still a good deal of uncertainty around MSB's viability in most of its prospective markets. Pre-clinical trials, although positive, give no firm indication of a product's true viability and full foresight on future market conditions is difficult to obtain. In its favour, MSB's base product is found naturally in the body, and we see little reason to believe that injections of concentrated numbers would cause serious health issues or be relatively less effective in doing their natural job.

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STOCKS

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Explanation of Nomura's equity research rating system for Asian companies under coverage ex Japan published from 30 October 2008 and in Japan from 6 January 2009

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