Mesoblast MSB.AX MSB AU

HEALTH CARE & PHARMACEUTICALS

NOMURA EQUITY RESEARCH

Closing in on a Phase III trial

We revise our view of the probability of success of MSB's clinical trial program

May 3, 2011

Rating Remains	**Buy**
Target price Increased from 6.51	AUD 10.45
Closing price May 2, 2011	AUD 8.15
Potential upside	+28.2%

Action: TEVA to buy CEPH -- de-risks development of MSB's pipeline

Teva (TEVA US, unrated) and Cephalon, Inc. (CEPH US, unrated) have announced a definitive agreement under which Teva will acquire all of the outstanding shares of Cephalon. As CEPH is a partner to MSB, we believe this deal de-risks the further development of MSB's specialty Pharma product pipeline, and provides MSB with a large global partner that has been progressively moving from generic into speciality Pharma.

Catalyst: Final results from CHF trial due in 4QCY11

In 2009, MSB began a Phase II Congestive Heart Failure (CHF) Clinical Trial. In the interim results, major and serious adverse cardiac events declined significantly compared to controls. We continue to believe that should this trial continue to demonstrate significant results, this would be a major positive for the stock. We expect the end of the clinical trial in June 2011. The hard end-points achieved to date will likely form the basis for the primary end-points for a future Phase III trial in heart failure patients. We continue to forecast the start of US CHF revenues for MSB in FY15.

Valuation: MSB should also start a Phase III trial in 3QCY11 for bone marrow transplantation

We revise our view of the probability of success of MSB's clinical trial program. In our scenario analysis of the opportunities for MSB, we calculate that the NPV of the potential opportunities developed by MSB is A$17.14. Once MSB begins a Phase III trial, we believe the probability of MSB getting its product onto market increases from 21.4% to 61.2% (according to Tufts data). Hence, our risk-weighted valuation increases to A$10.45 (=0.61xA$17.14). We set this as our target price.

30 Jun	FY10	FY11F		FY12F		FY13F	
Currency (AUD)	Actual	Old	New	Old	New	Old	New
Revenue (mn)	0	116	116	154	154	183	183
Reported net profit (mn)	-15	67	67	94	94	116	116
Normalised net profit (mn)	-15	67	67	94	94	116	116
Normalised EPS	-0.1	0.3	0.3	0.3	0.3	0.4	0.4
Norm. EPS growth (%)	na	na	na	9.1	9.1	22.4	22.4
Norm. P/E (x)	na	N/A	26.8	N/A	24.9	N/A	20.4
EV/EBITDA	na	N/A	22.6	N/A	15.6	N/A	12.1
Price/book (x)	33.3	N/A	4.5	N/A	3.8	N/A	3.2
Dividend yield (%)	na	N/A	na	N/A	na	N/A	na
ROE (%)	-46.4	25.0	25.0	17.3	17.3	17.7	17.7
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.*
Rating: *See report end for details of Nomura's rating system.*

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

There is minimal consensus data available.

Research analysts

Australia Health Care & Pharmaceuticals

Dr David Stanton - NAL

Zara Lyons - NAL

Key data on Mesoblast

Income statement (AUDmn)

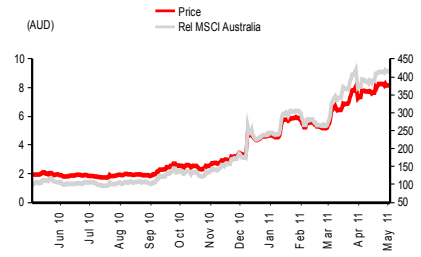
Year-end 30 Jun	FY09	FY10	FY11F	FY12F	FY13F
Revenue	**0**	**0**	**116**	**154**	**183**
Cost of goods sold	0	0	0	-1	-1
Gross profit	**0**	**0**	**116**	**153**	**182**
SG&A -10		-11	-25	-33	-37
Employee share expense					
Operating profit	**-10**	**-11**	**91**	**120**	**145**
EBITDA	**-10**	**-11**	**92**	**128**	**154**
Depreciation 0		0	-2	-8	-9
Amortisation 0		0	0	0	0
EBIT -10		-11	91	120	145
Net interest expense 1		1	7	15	20
Associates & JCEs					
Other income	-3	-4	-2	0	0
Earnings before tax	**-12**	**-15**	**96**	**135**	**165**
Income tax	0	0	-29	-40	-50
Net profit after tax	**-12**	**-15**	**67**	**94**	**116**
Minority interests	0	0	0	0	0
Other items					
Preferred dividends					
Normalised NPAT	**-12**	**-15**	**67**	**94**	**116**
Extraordinary items	0	0	0	0	0
Reported NPAT	**-12**	**-15**	**67**	**94**	**116**
Dividends 0		0	0	0	0
Transfer to reserves	**-12**	**-15**	**67**	**94**	**116**
Valuation and ratio analysis					
FD normalised P/E (x) na		na	26.8	24.9	20.4
FD normalised P/E at price target (x) na		na	34.4	31.9	26.1
Reported P/E (x) na		na	26.3	24.1	19.7
Dividend yield (%) na		na	na	na	na
Price/cashflow (x) na		na	16.2	22.6	18.5
Price/book (x) 43.0		33.3	4.5	3.8	3.2
EV/EBITDA (x) na		na	22.6	15.6	12.1
EV/EBIT (x) na		na	23.0	16.6	12.9
Gross margin (%) 100.0		100.0	99.8	99.4	99.3
EBITDA margin (%) -5,375	.1	-199,515.4	79.6	82.9	84.1
EBIT margin (%) -5,439	.4	-202,302.4	78.1	77.9	79.1
Net margin (%) -6,594	.6	-268,743.5	58.0	61.3	63.0
Effective tax rate (%) na		na	30.0	30.0	30.0
Dividend payout (%) na		na	0.0	0.0	0.0
Capex to sales (%) 91.3		1,583.9	1.5	5.0	5.0
Capex to depreciation (x) 2.2		0.8	1.0	1.0	1.0
ROE (%) -47.2		-46.4	25.0	17.3	17.7
ROA (pretax %) -83.9		-124.2	34.5	23.2	28.0
Growth (%)					
Revenue na		-97.0	2,110,163.9	32.7	19.1
EBITDA na		na	na	38.3	20.8
EBIT na		na	na	32.4	20.9
Normalised EPS	na	na	na	9.1	22.4
Normalised FDEPS	na	na	na	7.8	22.4
Per share					
Reported EPS (AUD) -0.10		-0.11	0.31	0.34	0.41
Norm EPS (AUD) -0.10		-0.11	0.31	0.34	0.41
Fully diluted norm EPS (AUD) -0.10		-0.11	0.30	0.33	0.40
Book value per share (AUD) 0.19		0.24	1.79	2.13	2.55
DPS (AUD) 0.00		0.00	0.00	0.00	0.00

Source: Nomura estimates

Notes

Revenue generation has commenced in 1HFY11

Price and price relative chart (one year)



(%)	1M	3M	12M
Absolute (AUD)	10.9	47.6	321.2
Absolute (USD)	17.2	60.0	395.0
Relative to index	11.4	46.6	321.3
Market cap (USDmn)	2,576.4		
Estimated free float (%)	55.0		
52-week range (AUD)	8.45/1.71		
3-mth avg daily turnover (USDmn)	5.94		
Major shareholders (%)			
Silviu Itescu	25.0		
Cephalon Inc	20.0		

Cashflow (AUDmn)

Year-end 30 Jun	FY09	FY10	FY11F	FY12F	FY13F
EBITDA -10		-11	92	128	154
Change in working capital -1		-1	31	2	2
Other operating cashflow	2	3	-12	-26	-30
Cashflow from operations	**-9**	**-9**	**111**	**104**	**127**
Capital expenditure 0		0	-2	-8	-9
Free cashflow	**-9**	**-9**	**110**	**96**	**118**
Reduction in investments	3	4	5	0	0
Net acquisitions 0		0	0	0	0
Reduction in other LT assets	0	0	-11	0	0
Addition in other LT liabilities	0	0	250	0	0
Adjustments -3		-5	-244	0	0
Cashflow after investing acts	**-9**	**-10**	**110**	**96**	**118**
Cash dividends	0	0	0	0	0
Equity issue	11	26	124	0	0
Debt issue	0	0	0	0	0
Convertible debt issue					
Others 0		0	0	0	0
Cashflow from financial acts	**11**	**26**	**124**	**0**	**0**
Net cashflow	**2**	**16**	**234**	**96**	**118**
Beginning cash	14	17	32	266	362
Ending cash	17	32	266	362	480
Ending net debt	-17	-32	-266	-362	-480

Source: Nomura estimates

Notes

We forecast MSB to have cash of A$266mn in FY11

Balance sheet (AUDmn)

As at 30 Jun	FY09	FY10	FY11F	FY12F	FY13F
Cash & equivalents 17		32	266	362	480
Marketable securities	0	0	0	0	0
Accounts receivable	0	1	2	2	3
Inventories 0		0	0	0	0
Other current assets	0	0	0	0	0
Total current assets	**17**	**34**	**268**	**365**	**483**
LT investments	9	5	0	0	0
Fixed assets	0	0	0	0	0
Goodwill 0		0	116	116	116
Other intangible assets	0	0	388	388	388
Other LT assets	0	0	11	11	11
Total assets	**27**	**40**	**783**	**880**	**998**
Short-term debt	0	0	0	0	0
Accounts payable 1		2	11	13	16
Other current liabilities	0	0	22	22	22
Total current liabilities	**1**	**2**	**33**	**35**	**38**
Long-term debt	0	0	0	0	0
Convertible debt					
Other LT liabilities	0	0	250	250	250
Total liabilities	**1**	**2**	**283**	**285**	**288**
Minority interest	0	0	0	0	0
Preferred stock 0		0	0	0	0
Common stock 62		88	481	481	481
Retained earnings -41		-56	12	106	222
Proposed dividends					
Other equity and reserves	4	6	8	8	8
Total shareholders' equity	**26**	**38**	**500**	**595**	**710**
Total equity & liabilities	**27**	**40**	**783**	**880**	**998**
Liquidity (x)					
Current ratio	14.28	21.01	8.14	10.39	12.80
Interest cover na		na	na	na	na
Leverage					
Net debt/EBITDA (x)	na	na	net cash	net cash	net cash
Net debt/equity (%)	net cash	net cash	net cash	net cash	net cash
Activity (days)					
Days receivable	420.5	55,780.0	5.3	5.2	5.2
Days inventory na		na	0.0	0.0	0.0
Days payable na		na	8,745.7	5,053.8	4,032.0
Cash cycle na		na	-8,740.4	-5,048.6	-4,026.8

Source: Nomura estimates

Notes

We forecast MSB to hit its timelines under the deal it negotiated with CEPH

Updating for clinical trial progression

MSB should start a Phase III trial in 3QCY11 for bone marrow transplantation. As a result, we revise our view of the probability of success of MSB's clinical trial program. In our scenario analysis of the opportunities for MSB, we assume the company will ultimately achieve a 5% market share in the US market, and that this will remain constant. On this basis, and updating for a recent increase in the A$/US$ exchange rate, we calculate that the NPV of the potential opportunities developed by MSB is A$17.14.

We believe MSB are about to enter a Phase III trial in Bone Marrow Transplant. Once MSB begins a Phase III trial, then we believe the probability of MSB getting its product onto market increases from 21.4% to 61.2% (according to data from Tufts University, USA). Hence, our risk-weighted valuation increases to A$10.45 (=0.61xA$17.14). We set this as our target price.

In this note, we:

- Outline the potential Phase III clinical trial in bone marrow transplant for MSB;
- Highlight the interim Phase II Congestive Cardiac Failure trial data, the final results of which are due in 4QCY11;
- Summarise near-term timelines for MSB AU;
- Delineate the Teva-Cephalon deal and why it is important for MSB; and
- Describe what our changes mean for our MSB target price.

What are MPCs?

Mesenchymal precursor cells (MPCs, also known as mesenchymal stem cells) are adult stem cells that have the ability to become solid organs and tissues such as bone, heart muscle and cartilage. They do not have immunological markers and will therefore cause no immune reaction when injected into a foreign host. This means MPCs can be harvested as a generic product for any recipient from any donor.

The proprietary technology being commercialised by MSB enables the efficient extraction, isolation and scale-up of MPCs. This technology has allowed for the potential application of commercial, off-the-shelf MPCs harvested from relatively few, non-specific donors in a wide range of serious medical issues. MSB aims to capitalise on its patents that relate to the identification, extraction and culture of adult mesenchymal precursor cells.

1. Bone-marrow transplant by expanding cord blood

What is a bone marrow transplant?

A bone marrow transplant delivers healthy bone marrow stem cells into the patient. It replaces bone marrow that is either not working properly or has been destroyed (ablated) by chemotherapy or radiation. In a bone marrow transplant, a patient will receive healthy stem cells after their own bone marrow has been destroyed. There are three kinds of bone marrow transplants:

- **Autologous bone marrow transplant**: Stem cells are taken from the patient before the patient gets chemotherapy or radiation treatment. When chemotherapy or radiation is complete, the patient gets their stem cells back. This allows the patient to receive high doses of chemotherapy and radiation;
- **Allogeneic bone marrow transplant**: In this transplant, stem cells come from another person. Stem cells come from the donor's bone marrow or their blood. Most times, a donor must have the same genetic typing as the patient, so that their blood "matches" the patient's. Donors who are not related to the patient may be found through national bone marrow registries; and
- **Umbilical cord blood transplant**: Stem cells are taken from an umbilical cord right after delivery of an infant. The stem cells are tested, typed, counted, and frozen until they are needed for a transplant.

Cord Blood transplantation

The cells collected from the umbilicus and placenta are known as haematopoietic stem cells, and are part of a cord blood unit. This blood is tested, frozen and stored at a cord blood bank for future use. Doctors search the registry of adult marrow or peripheral blood cell donors and cord blood units to find a suitable match for their patients who needs a bone marrow transplant. If selected, the matching haematopoietic stem cells in cord blood units are transplanted into a patient. The transplant process is the same as for marrow and peripheral blood cell transplants.

Umbilical cord blood is collected from the umbilical cord and placenta

Reasons for cord blood transplants

These include:

- **More tolerant matching**: a close match between the patient and the donor or cord blood unit can improve a patient's outcome after transplant. Even though a closely matched cord blood unit is preferred, clinical studies suggest the match may not have to be as close as is needed for marrow or peripheral blood transplants. This is especially the case if the patient has an uncommon tissue type;
- **More quickly available**: Cord blood units are stored and ready to use. A cord blood unit can be selected and delivered to the transplant centre in less than two weeks, whereas it can take two months or more to find an unrelated marrow or peripheral blood donor; and
- **Less graft-versus-host disease**: GVHD is a common complication after an allogeneic transplant (which uses cells from a family member, unrelated donor or cord blood unit). GVHD can range from mild to life-threatening. Studies have found that after a cord blood transplant, fewer patients get GVHD than after marrow or peripheral blood transplants. Patients in the studies who did get GVHD after a cord blood transplant tended to get less severe cases;

What is the focus and previous outcomes of the MSB trials?

MSB's MPCs act to grow the number of cells in a cord blood transplant before giving it to the patient. MSB has previously announced positive Phase IIb results from its bone marrow transplant clinical trial. In 30 patients transplanted with MPC-expanded haematopoietic progenitors from cord blood, MSB demonstrated:

80% of patients successfully achieved the treatment endpoint at 100 days of survival (p<0.01)

- **Increased rate of survival**: 80% of patients successfully achieved the treatment endpoint at 100 days of survival. This is significantly higher than the 38% rate for this composite endpoint achieved after transplantation with non-expanded cord blood in the US registry (p<0.01). We believe this was the primary outcome measure;
- **Increased expansion of the haematopoietic stem cells**: the proprietary MPCs expanded haematopoietic stem cells in umbilical cord blood by approximately 40-fold, thus increasing the chances of engraftment;
- **Quicker engraftment**: In patients receiving MPC-expanded cord blood, the median time to neutrophil (white blood cell) recovery was 16 days and to platelet (clotting) recovery 38 days, compared with approximately 30 days and over 90 days, respectively, in published reports of patients transplanted with an unexpanded cord. This implies less opportunistic infections and bleeding for patients post transplant ; and
- **Less GVHD**: To date, only 16% receiving expanded cord blood have developed severe graft-versus-host disease, compared to 40% in published reports of patients transplanted with unexpanded cord blood.

The Phase III trial

MSB is planning a Phase III trial to start in 3QCY11. For this Phase III trial, MSB's MPCs will be used under a US FDA Orphan Drug Designation to expand unrelated donor haematopoietic stem and progenitor cell numbers for use in patients with haematologic malignancies (such as leukaemia).

As a result of a previous meeting with the US FDA about the Phase III trial, and to increase the likelihood of alignment on product approval requirements, MSB will seek to obtain from the FDA a binding Special Protocol Assessment (SPA) prior to commencing the Phase III trial. The SPA provides an agreement between the FDA and MSB regarding designs, including size and clinical endpoints, of the pivotal trial to support an efficacy claim in a subsequent Biologic License Application (BLA). This implies that if the

MSB is planning a Phase III trial to start in 3QCY11 in Bone marrow transplant

results from a SPA are sufficiently positive, then the US FDA is more likely to approve a BLA.

We continue to forecast the start of US revenues for MSB from bone marrow transplant in 1HFY14. This is seen in the following figure.

Fig. 1: MSB AU Bone marrow transplant – potential timeline

As at May 2011

Date (CY)	Date (FY)	Trial	Nomura comment
3QCY11	Start FY12	Beginning of Phase 3 trial in Bone Marrow Transplant	Mesoblast has sufficient cash reserves to fund this Phase 3 trial
End 1HCY12	1HFY13	Completion of Phase 3 Trial in Bone Marrow Transplant	New Drug application (NDA) filing to be determined upon final results
End 1HCY13	1HFY14	US regulatory approval - NDA marketing authorisation for Bone Marrow Transplant	Start US revenues for MSB

Source: Nomura estimates

Market size and potential

The market is relatively small for this product, with only 20,000 bone-marrow transplants per year in the US and 40,000 worldwide. Considering the small market, MSB has been given orphan-drug status, allowing for an accelerated review process by the FDA, seven-year market exclusivity upon authorisation, tax benefits and exemption from user fees.

Although few in number, bone-marrow transplants are very expensive procedures, with total price ranging from US$50,000 to US$100,000 for the autologous type and from US$150,000 to US$200,000 for the allogeneic type in the US. This equates to an annual expenditure of around US$2bn. Cord-blood transplants are still in their infancy stage, so far totalling just 8,000 worldwide, but they are finding greater appeal as experience grows. MSB's product will only help to increase this appeal, in our view.

Growth rates for this product depend heavily on its efficacy. If useful, it will likely see significant growth given around 75% of patients who need a bone-marrow or cord-blood transplant do not receive one because of associated issues. If this product results in no significant improvement, its growth is likely to remain steady.

2. The MSB Cardiac failure trial

In 2009, MSB began a Phase IIa Congestive Heart Failure (CHF) Clinical Trial, with the aim of determining whether a single intra-myocardial injection of allogeneic MPC was useful in the treatment of Congestive Heart Failure.

What is heart failure?

Congestive Heart Failure (CHF) is a chronic condition characterised by the heart's inability to pump blood effectively to the body, resulting in shortness of breath, tiredness, potential organ damage and, ultimately, death. It usually occurs as a result of damaged heart tissue lost in, and progressively after, a heart attack, due to the sharp and then progressively increasing lack of blood flow and overworking of the weakened heart. This can be quantified as a measure of the ejection fraction (the percentage of blood ejected from the heart) via echocardiogram. An ejection fraction (EF) of 40% or less defines moderate to severe CHF. A heart considered healthy gives an EF range of 55-65%. Almost 50% of heart attack victims go on to develop heart failure within six years. There are around 5m CHF sufferers in the US alone and a further 550,000 new cases each year stemming from 1.25m new heart attacks. Current drug treatment of CHF does not regenerate heart muscle or tissue, but rather seeks to alleviate symptoms and reduce heart stress to prolong what is otherwise inevitable heart-function deterioration. We believe there is US$3.1bn spent annually in the US on medical durables for CHF.

Ejection fraction is the fraction of blood pumped out of the ventricles with each heart beat. In a healthy 70-kg man, the stroke volume is approximately 70 ml and the left ventricular end diastolic volume is 120 ml, giving an ejection fraction of 70/120, or 0.58 (58%)

What were the results?

This was a single-blinded, dose-escalation, randomised, multicenter clinical trial. Its Primary Endpoint was to evaluate the feasibility and safety of transendocardial injection of MPCs. Patients had a Class II-IV CHF with EF < 40%.

Interim results were presented in January 2011. Patients were randomized in ratio of a 3 treatment to 1 control patients. The treatment arm received Mesenchymal Precursor

Cells (MSB's Revascor product) at 25mn, 75mn, or 150mn cell doses. The cells were injected via a Johnson & Johnson (JNJ US, unrated) NOGA Myostar catheter.

The interim clinical results from the trial demonstrated a sustained increase in Ejection fraction.

Fig. 2: Responders To MPC Treatment Have Sustained Increase In EF Relative To Controls (EF < 40%)

Timeline	Control Ejection fraction	Treated Ejection fraction	p value
Baseline	30.5	27.8	0.05
plus 3 months	27.4	36.5	
plus 6 months	25.7	33.4	

Source: NYC Cardiac Cell Therapy Conference 2011

The Phase II CHF trial data is shown in the following figure. The trial now has >1.5 Years of Follow-Up. Major and serious adverse cardiac events declined significantly compared to controls.

Fig. 3: MSB - Phase II CHF trial >1.5 Years Study Follow-Up

Event	MPC treatment (N=45) No. patients with event (%)	Controls (N=15) No. patients with event (%)	p value
Any Serious Adverse Cardiac Event (SAE)	20 (44.4%)	14 (93.3%)	0.001
Repeat SAEs	5 (11.1%)	5 (33.3%)	0.102
Any Hospitalization For Heart Failure	5 (11.1%)	3 (20.0%)	0.4
All Cause Deaths	2 (4.4%)	2 (13.3%)	0.26
Cardiac Deaths	0 (0.0%)	2 (13.3%)	0.059
Any Major Adverse Cardiac Event (MACE*)	3 (6.7%)	6 (40%)	0.005
MACE or Any Hospitalization for Heart Failure	6 (13.3%)	6 (40%)	0.056

Interim data analysis December 2010, after all patients have reached 6 months follow-up.
*MACE defined as composite of MI, revascularization, or cardiac death

Source: NYC Cardiac Cell Therapy Conference 2011

MSB's MPC treatment also lowers the rate of serious adverse cardiac events over time. The major cardiac event rate per month declined by 84% during the trial (p=0.01).

Fig. 4: MPC Treatment Lowers Rate Of Serious Adverse Cardiac Events Over Time

Parameter monitored	Percentage change	p value
Event rate - cardiac serious adverse event per month subject follow-up	54% reduction	p=0.03
MACE event rate per month subject follow-up	84% reduction	p=0.01
Cardiac Hospitalisation event rate per month subject follow-up	48% reduction in rate of all cardiac hospitalisations	p=0.07
Heart failure Hospitalisation event rate per month subject follow-up	61% reduction in rate of heart failure hospitalisations (p=0.13)	p=0.13

Interim data analysis December 2010, after all patients have reached 6 months follow-up.
*MACE defined as composite of MI, revascularization, or cardiac death
Source: NYC Cardiac Cell Therapy Conference 2011

We continue to believe that should this trial continue to demonstrate significant results, this would be a major positive for the stock. We expect the end of the clinical trial in June 2011. Should the final results be positive, then we expect that MSB and its partner will approach the US FDA regarding initiating a Phase III clinical trial in congestive cardiac failure. The hard end-points achieved to date will likely form the basis for the key primary end-points for FDA Phase 3 trial in heart failure patients. We continue to forecast the start of US revenues for MSB from Revascor in FY15.

3. Near-term timelines

We enclose our near-term timelines for MSB below. By the end of CY11, MSB should have started trials to test the efficacy of MSB's MPCs in Heart Attack, Intervertebral Disc Regeneration and Diabetes Mellitus.

Fig. 5: MSB AU – near term timelines

Date (CY)	Date (FY)	Trial	Nomura comment
End CY11	End 1HFY12	Beginning of Phase 2 trial in Cardiac Disease (AMI)	Phase I trials have been promising
End CY11	End 1HFY12	Beginning of Phase 2 trial in Intervertebral Disc Repair Trial	Progression to Phase 3 trial based on final results of this trial
End CY11	End 1HFY12	Beginning of Phase 2 trial in Diabetes Mellitus (DM)	Progression to Phase 3 trial based on final results of this trial

Source: Company data

Diabetes

Type-II diabetes is a major worldwide health issue affecting around 210m people in the western world and around 24m in the US alone

Type-II diabetes is a major worldwide health issue affecting around 210m people in the western world and around 24m in the US alone. The number of cases has been growing at around 6.5% per year, reflecting increasing obesity rates. Type-II diabetes occurs initially as a result of the body's ineffective use of insulin due to prolonged exposure to excess blood sugar levels. This deteriorates the cells' ability to properly store glucose and react with the insulin, leading to an increased insulin requirement and thus to excess stress on the insulin-producing pancreas. This stress eventually leads to progressive damage and a gradual decline in the pancreas' functional ability. If left to progress unabated, this degraded functional ability can cause numerous complications such as heart disease, kidney failure, blindness, nerve damage and, ultimately, death.

Type-II diabetes is mainly considered a lifestyle disease, with obesity and inactivity being the primary causes in most cases (genetics and age normally play a secondary role). Hence, most early cases can be treated through lifestyle changes. Later progression requires the use of drugs and, ultimately, insulin injections. These are ideally avoided, as the risks of rapid hypoglycaemia (very low blood sugar levels) can be high. As a result, there is a market for developing a product that can boost the pancreas' ability to create insulin and control glucose levels naturally as an aid to treatment through positive lifestyle changes.

MSB application

MSB, is developing a product that uses MPCs to naturally enhance the ability of the pancreatic beta cells to produce more insulin. The pre-clinical trials on mice show promising early results with no complications. Of 35 mice, those treated with MPC injections showed a two-fold increase in their pancreatic islet cells relative to the controls, resulting in a 29% higher insulin-producing to glucagon-producing cell ratio, a 34% increase in blood insulin levels and a 35% decrease in blood sugar levels. No subjects' reduction in blood sugar went below normal healthy levels, indicating a lower risk of hypoglycaemia compared to insulin-injection treatment.

Intervertebral-disc regeneration

By the end of CY11, MSB should have started trials to test the efficacy of MSB's MPCs in Heart Attack, Intervertebral Disc regeneration and Diabetes Mellitus

Degeneration of the intervertebral disc, also known as degenerative disc disease (DDD), is a common condition that occurs naturally with age. Intervertebral discs are the pillow-like cushions between the spinal vertebrae that allow their slight relative movement and aid in shock absorption. Natural daily wear and tear slowly degrade these discs over time, such that clinical signs of DDD coming with age are almost inevitable. Of the 50 year olds in the US, 85% show signs of DDD, but most are asymptomatic. Severe degeneration, suffered by around 1m Americans, can lead to spinal fusions (less than 20%) and severe chronic back pain. There is no treatment to rebuild these discs, with spinal fusion or disc replacement the only real treatment options for advanced cases.

MSB's application

MSB is developing a treatment option through the injection of its off-the-shelf stem cells to rebuild degenerated discs, alleviating the problems associated with DDD. Pre-clinical trials on 36 sheep using a mix of placebo controls and single low-dose intra-discal injections of MPCs showed highly efficacious results. In short, there was a dramatic reversal of the degenerative process, regrowth of disc cartilage and sustained normalisation of disc pathology, anatomy and function for sheep injected with MSB's cells. Six months after the single injection, discs that were originally severely damaged and degenerated were found to have become indistinguishable from healthy non-

degenerated discs. By comparison, the sheep injected with hyaluronic acid (used to treat DDD inflammation and reduce pain symptoms) or with nothing at all continued to show reduced disc height, reduced cartilage content and disrupted histopathology.

4. TEVA to acquire CEPH - deal de-risks the further development of MSB's pipeline

Teva (TEVA US, unrated) and Cephalon, Inc. (CEPH US, unrated) have announced a definitive agreement under which Teva will acquire all of the outstanding shares of Cephalon for c$81.50 per share in cash, or a total EV of cUS$6.8 billion. Commentary from Teva suggests that the MSB AU potential portfolio is attractive, in their view. We believe this deal de-risks the further development of MSB's specialty pharmaceutical product pipeline, and provides MSB with a large global partner who has been progressively moving from generic into speciality pharmaceuticals.

Background

In March 2011, Valeant Pharmaceuticals International Inc. (VRX CN, unrated), a Canadian pharmaceutical company focused on neurology and dermatology, launched a hostile bid to buy Cephalon Inc. (CEPH US, unrated) for $73 per share in cash. CEPH owns a 20% stake in Mesoblast and has committed a further A$1.7bn to commercialise MSB's neurological and cardiac portfolio.

We believe this deal de-risks the further development of MSB's specialty pharmaceutical product pipeline

On 2 May 2011, Teva and Cephalon announced that their Boards of Directors unanimously approved a definitive agreement under which Teva will acquire all of the outstanding shares of Cephalon for c$81.50 per share in cash, or a total enterprise value of cUS$6.8 billion. The transaction is not conditioned on financing and is expected to be completed in the third quarter of 2011.

As a result of the Teva-Cephalon deal, VRX CN congratulated TEVA US on their announcement. In response to the news, Valeant has withdrawn its consent solicitation, and has stated it will not make a further bid for CEPH.

Background of the MSB - CEPH deal

As part of a deal signed in December 2010, CEPH made an upfront payment to MSB totalling US$130mn and regulatory milestone payments of up to US$1.7bn, and became a 19.9% shareholder in MSB. CEPH is responsible for the conduct and expenses of all Phase IIb and III clinical trials and subsequent commercialisation of the products.

We believe that any new owners of CEPH are obligated to fund MSB's phase IIb and beyond clinical trials through to commercialisation

MSB is likely to retain a significant percentage of the transfer price of net sales from any commercialised products. Importantly, MSB has retained all manufacturing rights for MPCs. Hence, we believe CEPH will effectively perform back-end sales and marketing for MSB in select indications. According to MSB, there is a binding clause that covers change of control. We believe that any new owners of CEPH are obligated to fund MSB's phase IIb and beyond clinical trials through to commercialisation.

Who are TEVA?

Teva Pharmaceutical Industries Ltd. is a global pharmaceutical company specializing in the development, production and marketing of generic and proprietary branded pharmaceuticals and active pharmaceutical ingredients. Teva is among the top 15 pharmaceutical companies and among the largest generic pharmaceutical companies in the world. Teva operates internationally through a network of worldwide subsidiaries. Headquartered in Israel, greater than 80% of Teva's sales, which totaled US$16.1Bn in 2010, are in North America and Europe. Teva has over 40,000 employees worldwide and production facilities in Israel, North America, Europe and Latin America.

Will Teva be interested in MSB's portfolio?

We believe Teva will be interested in MSB's technology for four reasons:

We believe Teva the patent protection for Teva's major product, Copaxone (70% of Teva FY10A branded pharmaceutical revenues) ends in 2015

- **Potential loss of revenues from 2015**: the patent protection for Teva's major product, Copaxone (70% of Teva FY10A branded pharmaceutical revenues) ends in 2015. Hence, MSB's product portfolio opportunities, which are reasonably long-dated, are likely to be of interest to Teva;

- **Teva interested in stem cells**: We note that Teva has also been progressing its own stem cell opportunity for some time – mostly in the orthopaedic area;
- **Relationship between Teva and Lonza**: We note that MSB's manufacturing partner, Lonza (LONN VX, unrated) already has a relationship with Teva. In 2009, TEVA and LONN announced their agreement to establish a joint venture to develop, manufacture and market a portfolio of biosimilars. Teva and Lonza will cooperate to develop, manufacture and market a number of generic equivalents of a selected portfolio of biologic pharmaceuticals. Hence, this is another area of overlap between Teva and MSB; and
- **Teva is now a 19.9% shareholder in MSB**: Finally, should MSB's trials continue to be positive, we note that Teva will have over US$1bn in cash post the CEPH acquisition. Hence, it is possible that should Teva wish to increase its inherited 19.9% stake in MSB, this could be funded internally.

What does it mean for MSB?

Commentary from Teva suggests that the MSB AU potential portfolio is attractive, in their view. We believe this deal de-risks the further development of MSB's specialty pharmaceutical products, and provides MSB with a large global partner that has been progressively moving from generic into speciality pharmaceuticals. Teva have made specific reference to CEPH's pipeline in including CNS, oncology, and respiratory as a key of its decision to acquire CEPH. MSB are developing CNS and oncology products with CEPH.

We believe the commentary from Teva regarding MSB is further confirmation of MSB's platform technology. We continue to believe that the potential opportunities for MSB are large, and this development goes some way to confirming this view. We include edited highlights of the Teva conference call discussing the acquisition.

Management present:

- Shlomo Yanai, President and Chief Executive Officer
- Eyal Desheh, Chief Financial Officer
- William S. Marth, President and Chief Executive Officer of Teva Americas
- Kevin C. Mannix, Vice President, Investor Relations

Q and A session

"***Q****: Can you just maybe drill down into the pipeline a little bit more down, how much value you see there?*

We believe the commentary from Teva regarding MSB is further confirmation of MSB's platform technology

A: This is an interesting pipeline. I think when you look at it, when you look at it as the third party everyone kind of has their favourite product. Obatoclax I think is a very interesting opportunity. There has really been nothing new in small cell lung cancer for about 25 years and there are some very good data, survival data in the study that was conducted with that product.

I think Cinquil is a very interesting product. It fits very nicely into the franchise that Teva already has within respiratory disease for eosinophilic asthma and I like the Mesoblast product, I like the product for congestive heart failure. I certainly concede that there is probably a higher level of risk in that product but the upside for a new product in congestive heart failure where there really is nothing available to treat these patients, nothing available to improve their condition is just enormous. So I think, I always been a big believer in our pipeline obviously and I think under Teva's leadership I think it's really going to flourish."

END OF PRESENTATION

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5. What does it mean for MSB?

In updating our valuation of market opportunities for the forecast Phase III clinical trial, we assume MSB will get its product to market within the timeframes listed in the figures below. We also assume the company will ultimately achieve 5% market share in the US

market, and that this will remain constant. Our assumptions are shown in the following Figure.

Fig. 6: Scenario analysis assumptions

Health inflation	5%
market share for MSB	5%
US$/A$ exchange rate	1.0
MSB NPATmargin (%)	20%

Source: Nomura estimates

Once MSB begins a Phase III trial, then we believe the probability of MSB getting its product onto market increases from 21.4% to 61.2% (according to data from Tufts University, USA).

Fig. 7: Probability of drug at clinical trial stage ultimately getting to market (Tufts DiMasi data)

Phase	Probability of success of moving to next phase (%)	Probability of drug getting on market from particular phase (%)
Phase I	62.5	13.4
Phase II	35	21.4
Phase III	68	61.2
Filing	90	90.0

Source: PubMed

On this basis, we calculate that the NPV of the potential opportunities developed by MSB is A$17.14. Outputs from our analysis are shown below.

We calculate that the NPV of the potential opportunities developed by MSB is A$17.14

Fig. 8: Outputs from MSB scenario analysis

Market opportunity	Estimated year of market entry	NPV per share (A$)
Cardiac	2015	$2.33
Diabetes	2016	$7.70
OA of the knee	2016	$0.66
Bone marrow regen.	2014	$1.57
Macular degeneration	2016	$0.99
Spinal Fusion	2016	$0.61
Disc regeneration	2016	$0.20
Bone repair	2015	$3.06
	Total value	**$17.14**
61% risk weighting of portfolio (in line with trial stage)		**$10.45**

Source: Add Source Here

Hence, our risk-weighted valuation for MSB increases to A$10.45 (=0.61xA$17.14).

Other reasons why we like MSB

- **Opportunity in diabetes** – a recent clinical trial indicates that the insulin-producing cells in the pancreas may be successfully regenerated by MSB's cells. This represents a potential treatment for diabetes, one of the developed world's most prevalent diseases. We believe this represents longer-term upside for MSB;
- **MPCs are a paradigm shift in bone-graft substitute technology** – having analysed the literature, and after discussions with our industry contacts, we believe that the potential inclusion of MPCs in bone-graft substitutes is a step change in the technology of these substitutes. We think that this is likely to make a synthetic bone graft much more likely to ingrow into existing bone;
- **We predict strong growth rates in volume and pricing of bone-graft technology** – our analysis of bone-graft technology suggests pricing for these products will likely remain strong, driven by a lack of supply in a market with high barriers to entry. Indeed, discussions with industry contacts suggest that in a revision joint replacement, a bone-graft substitute is the most expensive piece of equipment used. The current price is A$11,000 for a 10cc vial, and up to two vials of bone-graft substitute may be used in a single revision joint replacement;

We believe MSB has strong levels of IP protection

- **Strong levels of IP protection** – we believe that MSB's principal US patent is 7,122,178. This was issued on 17 October 2006 after first being filed on 7 July 2000. Hence, we believe the patent will not expire in the US before 2020. The patent relates to MPCs and is a method of enriching the cells, including the step of enriching for cells based on at least two markers. Recent advances have led to the development of novel monoclonal antibodies (MAbs), which recognise antigens on MPCs. MSB has developed and patented an identifying antibody for MPCs; and
- **Other opportunities in cartilage regeneration** – we believe that MPC technology can be applied to other types of cells other than bone, pancreatic cells, cartilage, and cardiac muscle.

Valuation and risks

As outlined above, we have updated our assumptions for MSB. Using DCF analysis, we value MSB at A$10.45 per share (increased from A$6.51 per share), using a WACC of 16.05%. Our assumptions include:

Using DCF analysis, we value MSB at A$10.45 per share

- **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.

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Mentioned companies

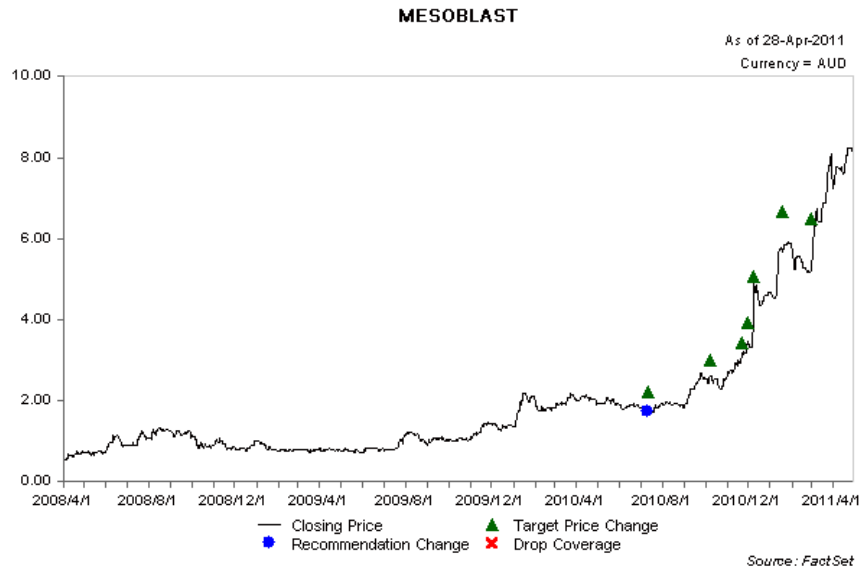
Issuer name	Ticker	Price	Price date	Stock rating	Sector rating	Disclosures
Mesoblast	MSB AU	8.15 AUD	02-May-2011	Buy	Not rated	

Previous Rating

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

Mesoblast (MSB AU) **8.15 (02-May-2011)** Buy (Sector rating: Not rated)

Rating and target price chart (three year history)



Date	Rating	Target price	Closing price
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 value MSB (with a TP of $10.45) using DCF analysis, with a WACC of 16.05%. 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 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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A '**Sell**' recommendation indicates that downside is more than 20%.

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