Southern Cross Equities

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Mesoblast (MSB)

The Canadians create a buying opportunity

Analyst
Stuart Roberts 612 8224 2871

Authorisation
Johan Hedstrom 612 8224 2859

Recommendation
Buy
Price
$7.25
Target (12 months)
$11.00

Mesoblast (MSB), an adult stem cell company, has enjoyed favourable clinical data and there is potential for multiple licensing opportunities beyond Cephalon. Time to market is fairly short and management is capable. We think the sell-off related to concerns over Valeant's hostile bid for Cephalon (Nasdaq: CEPH) has created a buying opportunity. Buy recommendation and $11.00 price target maintained.

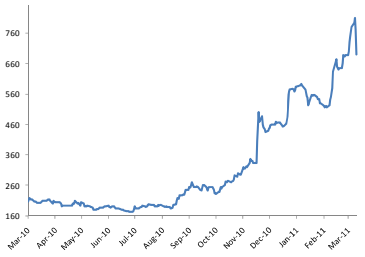
Expected Return

Capital growth	**52%**
Dividend yield	**0%**
Total expected return	**52%**

Company Data & Ratios

Enterprise value	**$1,745m**
Market cap	**$2,023m**
Issued capital	**279.1m**
Free float	**56%**
12 month price range	**$1.71-$8.30**
GICS sector	**Healthcare Equipment and Services**

Absolute Price



SOURCE: IRESS

NOTE: In May 2010 Southern Cross Equities managed a $37m capital raising for Mesoblast, while in December 2010 Southern Cross Equities placed, to institutional investors, 14.4 million of the MSB shares issued to acquire Angioblast. In each case Southern Cross earned fees.

Mesoblast has stem cell technology that works

Mesoblast is commercialising Mesenchymal Precursor Cell (MPC) technology that allows adult stem cells to be extracted from the bone marrow of donors, grown into therapeutic quantities and safely administered to non-related patients. The technology is non-controversial, and clinical data is emerging showing it to be effective compared to existing therapies. With the FDA only requiring one Phase II and one pivotal trial before approving a successful stem cell therapy, Mesoblast has potential to be yielding commercial revenues by 2012/13. Management led by Executive Director Professor Silviu Itescu has taken a commercial approach to creating shareholder value from Mesoblast's technology. This has helped attract the US specialty pharma company Cephalon as a 19.99% shareholder and partner in Mesoblast's heart failure, heart attack and bone marrow transplant programmes.

Valeant's Cephalon bid has created a buying opportunity

The Toronto-based Valeant Pharmaceuticals is making a hostile takeover offer for Cephalon, which has been investing heavily in its pipeline in recent days to offset the end of market exclusivity for its core blockbuster Provigil. Of around a dozen new products Cephalon hopes to launch between now and 2016, there are five potential blockbusters, and two of them are Mesoblast products (the heart failure and heart attack MPC applications). Given the tight nature of the Mesoblast/Cephalon partnering agreement we have no concerns about these programmes continuing even if Valeant succeeds in its bid. We therefore see any concerns about Valeant as a good buying opportunity for Mesoblast.

Target price $11.00 attainable with the help of clinical data

We value the MSB pipeline using a probability-weighted DCF approach with a base case $7.34 and optimistic case $14.56. Our $11.00 target price sits at the midpoint of our DCF range. There is potential for the market to rerate MSB stock as further clinical data on the therapeutic power of MPCs emerges during 2011 and the current Valeant concerns fade.

The Canadians create a buying opportunity

Mesoblast stock is down due to concerns over Valeant's bid for Cephalon. Mesoblast stock has fallen 10% over the last two days, from an $8.10 closing all-time high on 29 March. This has been due to concerns over a hostile takeover offer for the American specialty pharma company Cephalon[1], which owns 19.99% of Mesoblast and is Mesoblast's partner for its heart failure, heart attack and bone marrow transplantation programmes. Valeant Pharmaceuticals[2], a Canadian specialty pharma company with a key focus on dermatology and neurology products[3], is offering US$73 a share to buy Cephalon. The offer is a 24% premium to the pre-bid share price and values Cephalon at around US$5.7bn. It is a hostile takeover likely to be resisted by Cephalon management. Valeant has moved to take advantage of a stock only trading on a P/E of 8 due to concerns over loss of patent protection. Mesoblast is being sold off on the fear that Valeant would not progress the programmes that have been partnered to Cephalon should they obtain control of Cephalon.

Mesoblast programmes are the jewel in the Cephalon treasure chest. Cephalon has recently been investing heavily in its pipeline to offset the end of market exclusivity for its core blockbuster[4] Provigil, a narcolepsy drug. Of around a dozen new products Cephalon hopes to launch between now and 2016, there are five potential blockbusters, and two of them are Mesoblast products, the heart failure and heart attack applications of Mesenchmal Precursor Cells. The Mesoblast products that were partnered with Cephalon are, we understand, on track and have experienced no delays since the partnership was announced.

Valeant tends to be 'anti-R&D', but the Mesoblast/Cephalon agreements are strong. While Valeant does have a pipeline of mostly early-stage products[5],that company's corporate culture seems to be somewhat opposite to Cephalon's in that it generally favours acquiring approved products rather than development of new products[6]. This has led to concerns expressed in the marketplace that Valeant may choose not to fully support the Mesoblast programmes should they be successful in acquiring Cephalon. We think these concerns are unfounded, since:

- the Mesoblast/Cephalon partnering agreement, having been signed off by both parties, is 'assignable', meaning that whoever owns Cephalon is legally obliged to progress the heart failure, heart attack and BMT products within the time frame laid down in the partnering agreement; and
- there is potential for Valeant to find another partner for the Mesoblast assets given the favourable clinical data to date, particularly in heart failure – we understand that Valeant sold most of the R&D programs acquired with its Biovail[7] acquisition to other 'natural' partners.

[1] Frazer, Pa, Nasdaq: CEPH, www.cephalon.com.

[2] Mississauga, On, NYSE: VRX, www.valeant.com.

[3] It markets, for example, Efudex, a topical fluorouracil product for the treatment of actinic keratosis.

[4] ie, products with the potential to enjoy more than US$1bn in sales.

[5] See www.valeant.com/products/pipeline/index.jsp.

[6] In last night's conference call Valeant management referred to Cephalon's recent deals with Gemin X and Chemgenex as 'risky investments'. Interestingly, there was no mention of Mesoblast in a call that lasted over one hour.

[7] This Toronto-based company was built on a number of drug-delivery technologies such as controlled release, enhanced absorption, taste masking and oral disintegration. From 2008 the company moved away from drug delivery and towards the development of proprietary CNS drugs. Biovail's 2009 revenue was US$789m. Valeant and Biovail got together last year. Effectively Biovail bought Valeant in a deal worth US$3.3 billion and took its name.

Consequently in our view any concerns over Valeant's potential hindering of Mesoblast's clinical development can be regarded as a buying opportunity for Mesoblast stock.

Mesoblast can fund its own programmes, if it has to. In a theoretical scenario that would see the programmes returned to Mesoblast by Valeant, the Australian company's US$281m in cash[8] would be more than ample to fund the clinical development of all three products that were partnered with Cephalon. With Mesoblast now hiring key people to develop its various programmes we think the company could move forward with the former Cephalon programmes fairly quickly were it obliged to do so, particularly since Mesoblast, as a relatively young company, would lack the bureaucracy of more established operations. This is another reason to regard the Valeant issue as a buying opportunity for Mesoblast.

Cephalon's defense is likely to highlight Mesoblast assets, which may attract new investors to Mesoblast. We think that Cephalon's defence, with the help of the Wall Street law firm Skadden Arps[9], will highlight the value of its pipeline, which hasn't been factored into the Cephalon share price of late while US analysts stress over Provigil. This will turn the spotlight on Mesoblast and profile the value of MPCs to US investors who only heard of Mesoblast for the first time last December when Cephalon completed its partnering deal. We think this can be a net positive for Mesoblast.

This bid process may be over quickly, with Cephalon the victor. Valeant has asserted that it is seeking a quick deal process (30-45 days) or it will walk away. Also, it needs the Cephalon board to remove current Shareholders' Rights Plan (aka 'poison pill')[10] for any merger deal to proceed.

There is potential for Mesoblast to do other partnering deals with unpartnered programmes. We see the potential for further partnering deals with Big and Specialty pharma given that most of Mesoblast's programmes are still unpartnered. We expect that such deals would follow the model established by the Cephalon deal and yield attractive upfront and milestones payments as well as a generous transfer price on the manufacture of stem cells. The deals would undoubtedly boost sentiment towards the stock. Mesoblast noted in this afternoon's announcement to the market that it *'continue[s] to maintain advanced discussions with global Pharma and device companies'*.

[8] Gained mainly from the Cephalon upfront and placement – this money has been paid to Mesoblast by Cephalon with no obligation to repay.

[9] Famed for running the defence of RJR Nabisco in 1988 – see *Barbarians at the Gate* by Bryan Burrough and John Helyar (New York: Harper & Row, 1989).

[10] A Shareholders' Rights Plan is the most common form of takeover defence in North America. Under such plans, shareholders can purchase additional shares at a discount, making it far more difficult for an unwanted bidder to take control.

Fifteen reasons to own MSB

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, mainly in orthopaedic and cardiovascular applications, and is getting ready for its first pivotal trial, in bone marrow transplantation. Three Phase II trials are 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 39%-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 fifteen reasons why investors should own MSB at current prices:

1. **MSB is part of a wave of the future that is capitalised at under US$4bn globally.** Stem cells, which are cells with the ability to develop into many different cell types, 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 just over US$3.3bn, reflecting the early stages of what we think 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 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.

Cephalon has bought 19.99% of MSB

4. **A major partnering deal with Cephalon has derisked 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 (Nasdaq: CEPH) that saw Cephalon 1) take a 19.99% stake in the company 2) partner with MSB on the heart failure, heart attack and bone marrow transplant applications of the MPC technology and 3) agree to help fund new programmes in 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 derisks the company by providing adequate funding for all programmes, an established distribution platform for products as they gain regulatory approval, and strong financial upside. Cephalon's due diligence prior to the deal will also serve as a comfort factor for investors.
5. **MSB now has A$281m in cash.** The upfront payment and equity placement associated with the Cepahlon deal has left MSB amply funded for further clinical development and negated the possibility of further capital raisings.

6. **Multiple trials are now underway with a pivotal coming soon**. As we noted above, MSB is currently conducting or working towards Phase II trials in nine 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$636m[11], 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	SCE estimate of completion - optimistic case	SCE estimate of completion - base case	Patients
Posterior interbudy lumbar fusion	II	Mar-11	Aug-11	24
Cervical spinal fusion	II	Mar-11	Aug-11	24
Intervertebral disc repair	II pending			48
Heart failure	II	Jul-11	Aug-11	60
Heart failure with LVADS	II	Nov-11	May-12	80
Acute myocardial infarction	II pending			25
Knee osteoarthritis	II	Mar-11	Jul-11	24
AMD / diabetic retinopathy	II pending			25
Bone marrow transplant	III[12]	Jul-12	Oct-12	100

SOURCE: MSB, SOUTHERN CROSS EQUITIES. NOTE - ACUTE MYOCARDIAL INFARCTION AND AMD / DIABETIC RETINOPATHY PATIENT NUMBERS ARE SOUTHERN CROSS EQUITIES ASSUMPTIONS

7. **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 Special Protocol Assessment to be sought from the FDA. We think the market is now in a good position to start rating MSB as a Phase III opportunity. 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 Cochlear, which has a market capitalisation of A$4.5bn. Also, we see the success of the Phase II trial as pointing towards a significant derisking of the technology.

MSB's heart failure trial has generated solid interim data

8. **MSB's heart failure trial is on track for successful completion mid-2011.** With a 60-patient Phase II trial in Class II and III heart failure patients having generated solid interim Phase II data in January 2011, we expect a favourable outcome from this trial in mid-2011, opening up multi-billion dollar opportunities in heart failure.
9. **MSB has started to build a valuable spinal 'franchise'.** With the MPC technology being successfully applied across a spectrum of spine-related procedures in a Phase II setting, we see substantial value accruing to MSB for this franchise, since it allows a potential acquirer to comprehensively access a large and growing segment of the orthopaedics market.
10. **Other applications are growing in importance**. We like MSB's potential in applications such as knee osteoarthritis, long bone repair, AMD/diabetic retinopathy and Type I and II diabetes, where the animal data looks good.

[11] 30 March close on Nasdaq. It was $577m on 2 March, indicating that stem cells may be coming into favour on Wall Street this year.

[12] Initiating early 2011.

The FDA only requires two clinical trials per MSB application

11. **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.
12. **The management is commercial.** We have a high regard for MSB's leadership team led by Executive Director Professor Silviu Itescu, who owns 24.5% 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.
13. **We expect substantial news flow in 2011.** The next 6-9 months will feature some strong news flow from MSB, with potential announcements including:

- Initiation of clinical work on diabetes and AMD/diabetic retinopathy;
- Potential completion of the spinal fusion trials;
- Completion of the heart failure trial;
- Potential completion of the knee osteoarthritis trial;
- Formal completion of the Phase II BMT trial, and clearing of the pivotal trial and Special Protocol Assessment by the FDA;
- IND filings for intervertebral disc repair and acute myocardial infarction (the latter a refined version of an earlier IND); and
- Animal data on new MPC indications including Alzheimer's and Parkinson's.

14. **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 2026;
- *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 think Mesoblast can yield a similar advantage today in stem cells.

15. **The stock is trading significantly below our target price.** We assume the MSB pipeline has value for the both the older as well as newer programmes. Our $11.00 target price for MSB is at the midpoint of our base case $7.34 / optimistic case $14.56 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 2012/13. Mesoblast now has A$281m in cash on hand and therefore no further need to raise capital from the equity markets.

INVESTMENT STRATEGY

We see a major partnering deal with Cephalon (MSB's 19.99% shareholder) 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.

VALUATION

We assume the MSB pipeline has value across a range of clinical development programmes. Our $11.00 target price for MSB is at the lower level of our base case $7.34 / optimistic case $14.56 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

Research Team

Steve Goldberg
Head of Research
T 612 8224 2809
E sgoldberg@sceq.com.au

Daniel Blair
Industrial Analyst
Telco/Media
T 612 8224 2886
E dblair@sceq.com.au

Peter Chapman
Resources Analyst
Gold/Uranium
T 612 8224 2847
E pchapman@sceq.com.au

David George
Resources Analyst
Diversifieds
T 613 9235 1972
E dgeorge@sceq.com.au

Fleur Grose
Resources Analyst
Iron Ore/Coal/Diversifieds
T 613 9235 1678
E fgrose@sceq.com.au

Johan Hedstrom
Resources Analyst
Energy
T 612 8224 2859
E jhedstrom@sceq.com.au

Justin Hilford
Industrial Analyst
Emerging Growth
T 613 9235 1966
E jhilford@sceq.com.au

Judith Kan
Associate Analyst
Energy
T 612 8224 2844
E jkan@sceq.com.au

TS Lim
Financials Analyst
Banks/Regionals
T 612 8224 2810
E tslim@sceq.com.au

Toby Molineaux
Associate Analyst
Industrial
T 612 8224 2813
E tmolineaux@sceq.com.au

Paresh Patel
Industrial Analyst
Retail/Beverages
T 612 8224 2894
E ppatel@sceq.com.au

Hamish Perks
Industrial Analyst
Emerging Growth
T 612 8224 2804
E hperks@sceq.com.au

Stuart Roberts
Industrial Analyst
Healthcare/Biotech
T 612 8224 2871
E sroberts@sceq.com.au

Emma Sellen
Executive Assistant
T 612 8224 2853
E esellen@sceq.com.au

Jonathan Snape
Industrial Analyst
Emerging Growth
T 613 9235 1601
E jsnape@sceq.com.au

Mathan Somasundaram
Quantitative Analyst
Head of Quant & Data Services
T 612 8224 2825
E mathan@sceq.com.au

Lafitani Sotiriou
Analyst
Financials/Industrials
T 613 9235 1668
E lsotiriou@sceq.com.au

Janice Tai
Quantitative & System Analyst
T 612 8224 2833
E jtai@sceq.com.au

Joel Weiss
Associate Analyst
Industrial
T 612 8224 2895
E jweiss@sceq.com.au

Chris Whitehead
Associate Analyst
Resources
T 612 8224 2838
E cwhitehead@sceq.com.au

Southern Cross Equities Ltd and its associates hold 623,984 shares in MSB as at the date of this report. This position is subject to change without notice.

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Limited Incorporated ACN 071 935 441
Level 32, Aurora Place
88 Phillip Street, Sydney 2000
Telephone +61 2 8224 2811
Facsimile +61 2 9231 0588
Email general@sceq.com.au
www.sceq.com.au