



**BUY \$0.79**

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# Mesoblast (MSB)

*Building a sustainable business...*

## Company Data

ASX Code	MSB
Price	\$0.79
12 month price target	\$1.65
Implied return	109%

Shares on issue	120.9m
Market capitalisation	\$95.5m
12 Month price range	\$0.51 - \$1.35
Monthly turnover (volume)	2.3m

Yr to 30 June	2008A	2009F	2010F	2011F
Receipts	0.1	0.1	13.0	19.5
Interest	0.8	0.8	-	-
Oper. Cash Inflow	0.9	0.9	13.0	19.5
Oper. Cash Out	(6.3)	(12.0)	(43.7)	(47.9)
<b>Net Oper Cash</b>	<b>(5.4)</b>	<b>(11.1)</b>	<b>(30.7)</b>	<b>(28.4)</b>
Net Inv. Cashflow	(6.2)	-	-	-
Net Fin. Cashflow	13.5	-	-	-
<b>Inc/(Dec) Cash</b>	<b>(2.0)</b>	<b>(11.1)</b>	<b>(30.7)</b>	<b>(28.4)</b>
Opening Cash	12.1	14.1	2.9	(27.8)
<b>Closing Cash</b>	<b>14.1</b>	<b>2.9</b>	<b>(27.8)</b>	<b>(56.2)</b>

## Board of Directors

Brian Jamieson	Chairman (Non-Exec)
Silviu Itescu	MD & CEO
Michael Spooner	Non-Exec. Dir.
Donal O'Dwyer	Non-Exec. Dir.
Byron McAllister	Non-Exec. Dir.

## Major Shareholders

Silviu Itescu	30.7%
AMP	5.6%

## Share Price Chart



Source: Iress Market Technology

## Business overview

Mesoblast Limited is an ASX-listed biotechnology company developing therapies to treat patients with bone and joint diseases through the deployment of a proprietary adult stem cell technology.

Through its 38.4% interest in the US-based company Angioblast Systems, Inc., Mesoblast is also developing treatments using adult stem cells for cardiac and vascular diseases, as well as for other degenerative conditions.

## Technology

The Mesoblast technology is based on the use of a specific type of adult stem cells called mesenchymal precursor cells (MPC). These cells are found at various sites throughout the body, and are able to transform into bone, cartilage, fat, and other tissues.

Importantly, the technology allows stem cells to be taken from one person to be injected into another, unrelated person. This in turn means that cells can be collected from a donor pool under quality-controlled conditions and stored for later use, making the product more like a classic pharmaceutical than other cell-based therapies (a vitally important consideration when it comes to protecting IP and generating superior margins).

## Valuation & Recommendation

The key to understanding the value of Mesoblast is its carefully structured commercialisation strategy. The company understands the need to minimise development lead times through tight management of clinical programs and generation of early supporting data. Equally, the company remains tightly focussed on developing and maintaining relationships with industry market leaders – from these relationships will come strategic corporate alliances, from which Mesoblast expects to earn potentially significant short and mid-term milestone payments (and, in the longer term, significant royalty revenue).

The commercial strategy is underpinned by the technology strategy, which is based on fast-tracked development programs across multiple indications – allowing the opportunity of multiple strategic partnerships.

Mesoblast has succeeded in demonstrating in human clinical trials that it is able to take cells from one individual and safely transplant them into an unrelated donor – this “proof of concept” is an important validation of the use of *allogeneic* cells that is the basis of the Mesoblast commercialisation strategy.

We assess Mesoblast as a **BUY**, with a spot valuation of **\$1.29** and a 12-month price target of **\$1.65**. The past year has seen a significant de-risking of the portfolio, and we expect this trend to continue over the next 12 months.

## Valuation

### Price target

The current share price represents a discount of 39% to our spot valuation of **\$1.29**. However, we have taken a conservative view given current market conditions and believe the company has the potential to support a significantly higher price based on achieving several key milestones over the next 12-month period. Our 12 month price target is **\$1.65**.

### DCF based valuation

We have approached the valuation using a traditional probability adjusted discounted cash flow model based on our estimates of the costs of clinical trials and future milestones and royalty streams for each of the core development programs together with an estimated value of the 38.4% stake in Angioblast (determined on a similar basis). Based on the encouraging results to date, we have assumed an overall 60% probability that the products will reach market – although it may appear to be quite low this covers execution risk in addition to technical and commercial risks. Despite our view that Mesoblast will have few difficulties in securing the human and financial resources to execute on its strategy, we necessarily believe it is prudent in the current climate to take a conservative view of execution risk.

The model is based on the assumption that Mesoblast will fund each indication through Phase 2 clinical trials and then out-license the remaining development to third parties in exchange for upfronts, milestone payments and royalties. Although higher royalty rates may be achieved based on demonstrated safety and efficacy at the end of Phase 2, the device sector operates at lower rates and we have assumed a conservative royalty rate on end-user sales of 15% at that stage. In addition to probability adjustments to factor in the technical risk, we have used a discount rate of 20% to reflect the market risk.

The key market assumptions in our model are shown below. We have estimated the target markets based on the pricing points given on the assumption that Mesoblast will initially pursue a premium pricing strategy – as the technology gains acceptance the potential markets are likely to increase significantly. We believe that these assumptions are realistic, however given the progress being made by Mesoblast in advancing its clinical program, it is possible that market entry may be achieved earlier for some indications.

**Table 1: Market assumptions for MPC-based therapies**

Indication	Est. Market Entry	Est Price (USD)	Est. Peak Market Share	Initial Target US Market (No. Treatments pa.)
Spinal fusion	FY13	\$5,000	15%	500,000
Long bone repair	FY14	\$3,000	10%	300,000
Knee osteoarthritis	FY13	\$7,500	5%	560,000
Intervertebral cartilage	FY15	\$8,000	8%	280,000
Congestive heart failure	FY14	\$15,000	10%	750,000
Acute myocardial infarct	FY14	\$7,500	5%	1,000,000
Bone marrow	FY12	\$15,000	5%	30,000

SOURCE: *Lodge Estimates*

### Directly comparable company

The nearest directly comparable global company is US-based Osiris Therapeutics, Inc. (NASDAQ:OSIR). Osiris currently has two product candidates (Prochymal and Chondrogen) based on mesenchymal stem cells in clinical trials, in indications including three Phase 3 and two Phase 2 trials. Osiris has recently formed a strategic alliance with Genzyme Corporation to develop and commercialise its products – we see this deal as a major validation of Mesoblast's business approach.

### MSB relative to Osiris

Overall, Osiris is at a later stage of development than Mesoblast and has a significant partnering deal in place – however we consider that the Mesoblast products have significant commercial advantages, particularly in being able to produce differentiated products to serve different market segments with different pricing points. Osiris is currently valued at USD573m (AUD890m), which is an order of magnitude higher than Mesoblast's current market capitalisation of AUD95m – it does however indicate the very significant potential for substantial value appreciation as Mesoblast's products move into Phase 3 trials and partnering deals are done. It is interesting to note that the capitalisation of Osiris jumped by

over USD90m in the 10 trading days after the announcement of the Genzyme deal, again putting into perspective the value of such alliances.

**Potential upside to price target** Thus, while we consider that MSB is trading at a significant discount (39%) to its fair value today, we anticipate that further clinical trial results over the next 12 months could support a significant re-rating of the stock to beyond our current valuation.

## The commercial opportunity

**Commercial strategy** Mesoblast has a well-articulated commercial strategy, based on producing a range of differentiated products to address clinical needs across a range of indications, including orthopaedic and cardiovascular areas. The commercial strategy is well-integrated into the clinical/regulatory strategy and the technology strategy.

**Attempting to enhance shareholder value** The company seeks to deliver commercial relationships that will build shareholder value and enhance market-oriented execution capability. It plans to achieve this through timely completion of targeted Phase 2 trials and rapid progression of clinical programs towards Phase 3 registration trials. The company is acutely aware of the need to accelerate clinical studies, and its strategies reflect this understanding.

Mesoblast itself is focussing its development program on orthopaedic applications for its adult stem cell products, while its sister company Angioblast is looking to cardiovascular indications.

**Paths to market** Companies such as Mesoblast have several approaches to commercialisation open to them, each with a different risk/reward trade-off.

**Go it alone** Many companies aspire (sometimes naively) to take their products through to approval and to manufacture, market and distribute them themselves. This approach potentially provides the greatest shareholder return but carries with it much higher funding requirements and a significantly increased execution risk. Often the well established companies effectively control distribution channels, making this strategy unattractive – similarly a geographically dispersed customer base would make the cost of setting up a new physical distribution network expensive. One product that might suit this strategy would be the bone marrow transplant indication.

**Multiple partners** Another approach is to partner each application separately – “slicing the salami”. This has the potential to increase returns by targeting specific partners with products that are a strategic fit (hence valuable) for their portfolio, as well as potentially increasing price tension. By having multiple products/partners, execution risk is reduced. However, to implement this strategy requires that the individual products are clearly differentiated so that crossover use is avoided. Most of Mesoblast’s products have been designed with this approach in mind.

**Single partner** Finally, a company can throw in their lot with one partner – this is the approach taken by Osiris (presumably driven by the lack of product differentiation in their portfolio, compared to Mesoblast). This strategy is attractive in the sense that very significant partner resources can be brought to bear on product development, but the salami approach may provide greater returns and more focussed development programs. This strategy, although not preferred, is open to Mesoblast – there is a reasonable probability that a large Pharma company may want to acquire all of the MPC technology to apply it to their broader disease portfolio.

Mesoblast has carefully thought through its paths to market, and tailored its technology strategy to ensure maximum flexibility in terms of partnering options. It has also been active in establishing relationships with delivery companies for the development of cell-therapy applications – for example, Angioblast’s clinical trials use catheters from Johnson & Johnson. While no formal commercial relationship has been established with these partners, the market potential of the combined product provide opportunities to establish a more formal commercial relationship in the future.

**The spinal franchise** The core markets being addressed by Mesoblast are in the spinal area, covering spinal fusion (both lumbar – the lower back – and cervical – the neck) and intervertebral discs (repairing or rebuilding the cartilage between the bones in the spine). Approximately 500,000 procedures are currently undertaken each year in US for the fusion of vertebrae after irreparable damage

has occurred to the cartilage disc that separates them.

The warning by the US FDA on the use of a recombinant protein, rhBMP, in cervical fusions due to potentially severe complications opens up a significant opportunity for Mesoblast in the cervical fusion market. The size of the rhBMP market is estimated at \$800m pa, and the need for an effective alternative treatment means that Mesoblast must be looking very attractive to established players in the market such as Medtronic.

**Clinical trials in the spinal area**

Mesoblast is currently planning or conducting several clinical trials in the spinal area:

- cervical – Phase 2a trial (interbody fusion) planned to commence shortly, following encouraging preclinical data
- lumbar – Phase 2a trial (posterolateral fusion) on track, safety confirmed and efficacy data expected shortly
- pivotal trial for intervertebral fusion (interbody) planned in 2009, based on results from above trials
- IND submission for planned Phase 2a trial in intervertebral disc repair

So far, safety data in humans for the allogeneic cells looks good, and there is strong evidence for efficacy in the preclinical studies.

**Knee osteoarthritis**

Mesoblast is also developing a formulation of stem cells for use in knee osteoarthritis, one of the leading causes of disability among elderly men and women. Arthritis develops as the cartilage in the joint begins to deteriorate, and normal activity becomes painful and difficult. In the United States more than 15 million people suffer from osteoarthritis of the knee. While current therapies seek to reduce pain they are unable to preserve or restore the cartilage, and thus joint replacement is often necessary.

Mesoblast's preclinical trials demonstrated that MPC's can both prevent further deterioration early in the disease and regenerate cartilage tissue joint in later stage disease.

A local Phase 2a trial for the prevention of knee osteoarthritis after surgery to repair the anterior cruciate ligament will commence in the next month, following ethics approval. The recently announced strategic collaboration with ParkwayHealth in Singapore will facilitate a clinical study of Mesoblast's allogeneic stem cells to prevent or treat knee osteoarthritis – the first stage of a broad based collaborative clinical program for MPC's.

**Long bone repair**

A further program in orthopaedics is directed at long bone repair in patients where current methods to achieve fusion have failed. The initial clinical data from 10 patients demonstrated spectacular results, with 9 of the 11 fractures demonstrating complete union and no adverse events reported.

**Angioblast portfolio**

While Mesoblast is focused on orthopaedic applications, its sister company Angioblast Systems, Inc (in which Mesoblast holds a 38.4% interest) is concentrating its efforts in the cardiovascular area. The Angioblast portfolio comprises three core programs.

**Congestive heart failure**

Congestive heart failure (CHF) is a condition in which the heart can't pump enough blood to the body's other organs. This can result from a variety of causes, including coronary artery disease, previous heart attack, high blood pressure and cardiomyopathy. If the heart becomes severely damaged, a heart transplant may be necessary. There are currently five million people in the United States with congestive heart failure, with over 550,000 new cases annually.

The FDA has cleared a 60 patient Phase 2a clinical trial, with 20 patients on the lowest dose of allogeneic cells having already been enrolled, and recruitment commenced for the next dose level. So far, there have been no adverse events reported.

**Angioblast collaboration with Abbott**

Angioblast has entered into a collaboration with Abbott, a major broad-based global healthcare company, to develop the heart failure indication. Under the terms of the agreement, Abbott will provide funding for a collaborative product development program and has also made a USD5m equity investment in Angioblast.

**Acute myocardial infarct (AMI)**

Acute myocardial infarct (AMI) is what we commonly know as a heart attack. It occurs when the blood supply to part of the heart is interrupted, usually by blockage of a coronary artery.

Globally, heart attacks are the leading cause of death for both men and women.

Angioblast is developing an allogeneic MPC product to prevent this complication of heart failure after a heart attack. In the Phase 2 trial, patients recruited to date have demonstrated no cell-related safety issues – cardiac function will be evaluated at 6 and 12 months.

#### Bone marrow transplants

Based on preclinical studies, MPC's may be used as "feeder cells" to enhance the growth of haematopoietic stem cells used in bone marrow transplants. The FDA has granted an orphan drug designation for this indication, allowing for an accelerated review and a 7-year period of market exclusivity. Angioblast is running an FDA-cleared trial at Texas' MD Anderson Cancer Center, evaluating MPC-expanded haematopoietic stem cells for repair of bone marrow in up to 30 cancer patients.

#### Other diseases

Angioblast has also commenced preclinical studies on the use of MPC's in treating eye diseases such as age-related macular degeneration and diabetic retinopathy. These are potentially large markets, and clinical trials are planned to commence during 2009.

## The technology

#### Mesenchymal precursor cells (MPC's)

Mesoblast's patented technology is based on multipotent stem cells which can be isolated from various adult tissues (including bone marrow, fat and skin). These cells are called Mesenchymal Precursor Cells (MPC's) and have the potential to differentiate into various types of connective tissue such as bone, cartilage, muscle, fat and tendon.

Being derived from adult tissues, MPC's are not subject to the ethical concerns that surround embryonic stem cells (ES cells) which are derived from human embryos (also, some specific characteristics of ES cells have raised safety concerns).

Mesoblast has developed a technique for separating out a specific, pure, homogenous and clinically effective population of MPC's, generating a highly purified population with approximately 1000x greater number of stem cells than competing technologies.

Importantly, the Mesoblast MPC's do not express the cell surface antigens responsible for triggering an immune response in the body – thus MPC's from an unrelated individual can be used without activating the recipient's immune system which would normally reject the infused cells. Thus the Mesoblast cells are referred to as *allogeneic* – as distinct from *autologous* cells which are harvested from the same patient that they will be used to treat.

This means that cells can be harvested from a quality-controlled donor population and grown up (expanded) in a manufacturing facility to produce a large batch of cells which can then be dispensed out into a large number of treatment doses – and the whole process subjected to standard Good Manufacturing Practice and quality control protocols. In other words, it has all of the characteristics of a normal pharmaceutical drug – and fits the processes of a pharma company more closely than a classic cell-based therapy (hence more likely to be acceptable to them). It also results in a lower cost of goods, because the fixed manufacturing costs are amortised across a large batch.

Also, from a commercial perspective, it means that the company's intellectual property can be enforced – classic cell-based therapies are very difficult to protect because they rely on a method or technique which can be readily duplicated. The Mesoblast approach results in a defined and validated "traditional" product which can be protected.

A further advantage of allogeneic cells is that they can be stockpiled (in large, quality controlled batches) and be available for immediate use – by contrast the time involved in preparing and expanding autologous cells means that their clinical utility is limited (it may be too late by the time they are ready for infusion).

The core patent family is a composition-of-matter patent covering the unique adult stem cells, which were first identified at the Hanson Institute in Adelaide, Australia. The granted US patent (7,122,178, expiry 2019) includes claims to both the cells and to compositions comprising the cells.

This is supported by a second family including the granted US patent 7,399,632 (expiry 2019) covering the method for preparing mesenchymal precursor cells including the step of enriching for cells based on at least two markers. This patent is important in that its granted

claims provide broad protection, even where the method results in a preparation where only 1.5% of the cells are the targeted MPC's.

Taken together, the two patents provide strong protection for Mesoblast's cells. The company has also filed several application-specific patents.

## Competitors

### Differentiation from competitors

While there are a number of companies developing stem cell technologies, many of these are using embryonic stem cells or are also focused on different applications. Many of the adult stem cell companies are developing products based on haematopoietic stem cells for cancer, blood disorders and post-radiation bone marrow rejuvenation.

### Osiris

Osiris (NASDAQ: OSIR) has a current market capitalisation of USD573m. Of all the competitors, Osiris is probably the closest to Mesoblast. It had one product on the market called Osteocel for spinal and other orthopaedic surgical procedures (recently sold to NuVasive, Inc. in a transaction worth up to USD85m in upfront and milestone payments).

Osiris has two other products in development, Prochymal for graft-versus-host disease, Crohn's disease and cardiac applications, and Chondrogen for cartilage applications. These are based on enriched and expanded mesenchymal stems cells (MSC's) from bone marrow aspirate.

Prochymal has completed a 53 patient Phase 1 trial in acute myocardial infarction (AMI) which demonstrated safety and showed evidence of efficacy. This study recently reported two-year data, and Osiris will proceed to a Phase 2 study on this basis.

Prochymal is also currently in Phase 3 trials for steroid refractory graft-vs-host disease, newly diagnosed acute graft-vs-host disease, and Crohn's disease with both Orphan Drug and Fast-track status (neither MSB nor Angioblast are currently developing products for these applications). Osiris has also completed enrolment for a Phase 2 trial evaluating Prochymal in patients with chronic obstructive pulmonary disease (COPD).

Chondrogen is currently being evaluated in clinical trials for the treatment of osteoarthritis in the knee. While the Phase 1/2 trial met its primary endpoint (product safety), no meaningful evaluation of meniscus regeneration could be made. At this stage, Osiris have not stated their intentions for taking this program forward providing a clear opportunity for Mesoblast.

Osiris was recently awarded a US Department of Defense contract valued at USD224.7 million to develop and stockpile Prochymal for acute radiation syndrome (ARS).

The results obtained by Osiris, and its ability to do significant deals with pharmaceutical companies, provides important validation for the Mesoblast model. On balance, we feel that the Mesoblast market segmentation approach offers greater potential value.

### Aastrom

Aastrom (NASDAQ:ASTM) has a current market capitalisation of USD48m. It is developing autologous stem cell products for use in regenerative medicine, currently in clinical trials for cardiac, vascular and bone tissue regeneration applications, with plans to expand into the neural therapeutic area. Aastrom is using bone marrow aspirates as a source of adult stem cells for bone, vascular, cardiac and neural regeneration, and unlike Mesoblast and Osiris does not attempt to enrich for MPC's.

The company is in a pivotal Phase 3 clinical trial for osteonecrosis and in Phase 2 trials for cardiomyopathy and limb ischaemia.

Mesoblast's allogeneic cells have significant advantages over the Aastrom autologous offering.

### Athersys

Athersys (NASDAQ:ATHX) has a current market capitalisation of USD11m. It is developing the MultiStem technology based on allogeneic Multipotent Adult Progenitor Cells (MPACs) from the University of Minnesota. The company is at a very early stage of development with a professed focus on myocardial infarction, stroke and other indications, and for conditions involving the immune system, such as autoimmune disease. It recently received approval for

a Phase 1 trial in stroke – a very challenging application.

**Cytori**

Cytori Therapeutics (NASDAQ:CYTX) has a current market capitalisation of USD81m. It is isolating autologous adult stem cells from adipose tissue for use in reconstructive surgery (mainly breast reconstruction) and cardiovascular disease. All of Cytori's clinical studies are being conducted in Europe, with trials in the US not planned for several years. Given its early stage, its autologous product and absent any US trials, Cytori poses no threat to Mesoblast.

## **Management and Board**

The Mesoblast board has a balanced blend of technical and commercial expertise, including global industry experience. The Board is backed by a strong management team with a clear strategic focus as well as "hands on" operational experience within the industry.

Both Mesoblast and Angioblast were founded by Professor Silviu Itescu who is the Chief Scientist and a Director of both companies. Prof Itescu was an advisor on cell therapy for cardiovascular diseases to both the United States President's Council on Bioethics and the US FDA Biological Response Modifiers Advisory Committee (BRMAC). He has consulted for pharmaceutical companies and has been an advisor to biotechnology and health care investor groups. Prof Itescu has also served on the boards of two Australian biotechnology companies (Zenyth Therapeutics Limited and Ambri Limited).

The Chairman is Brian Jamieson, a former Chief Executive of Minter Ellison lawyers. He is currently a non-executive director of Sigma Pharmaceuticals Limited, Oxiana Limited and HBOS Australia Pty Ltd.

The Deputy Chairman is Donal O'Dwyer, who has broad experience as a senior executive in the global cardiovascular and medical devices industries – including as worldwide president of Johnson & Johnson's Cordis Cardiology. He is a non-executive director of Cochlear Limited and Sunshine Heart.

MSB also has two other non-executive directors on the Board, Michael Spooner (the past Chairman) and Byron McAllister. Mr Spooner has experience in the international commercialisation of high growth companies including within the medical technology sector. Most recently, Mr Spooner was Managing Director of ASX-listed Ventracor Limited – he is currently a non-executive director of Peplin Limited. Mr McAllister has experience in product development and regulatory experience, particularly in the area of biologics. He has worked for a number of international life science companies including Amersham, Abbott Laboratories and Coulter Electronics.

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Recommendations are assessments of each Lodge Partners Analyst's view of potential total returns over a 1 year period.

Expected total Return is measured as (capital gain (or loss) + dividend)/purchase price

We have divided our recommendations into three main categories:

**Buy:** Expected Total Return in excess of 15% over a 1 year period.

**Hold:** Expected Total Return between 0% and 15% over a 1 year period.

**Sell:** Expected Total Return less than 0% over a 1 year period.

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I verify that I Graeme Kaufman, have prepared this research report accurately and that any financial forecasts and recommendations that are expressed are solely my own personal opinions. In addition, I certify that no part of my compensation is or will be directly or indirectly tied to the specific recommendation or financial forecasts expressed in this report.

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