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In this edition...
We provide an in depth update and analysis of Mesoblast, which is seeking to commercialise an adult stem cell technology. The company now has one Phase II trial underway in orthopaedic applications and its investee company, Angioblast, has two Phase II trials underway in the US in cardiac applications to rebuild the heart muscle. The next 12 months will be an important period for the company.

Across the sector many companies are making strong progress, including Bionomics and Cogstate. Bionomics recently signed a licensing deal with Merck Serono, the second MS deal this year by Australian biotechs.

The editors
Companies covered: BNO, CGS, MSB, OIL

	Bioshares Portfolio
Year 1 (May '01 - May '02)	21.2%
Year 2 (May '02 - May '03)	-9.4%
Year 3 (May '03 - May '04)	70.0%
Year 4 (May '04 - May '05)	-16.3%
Year 5 (May '05 - May '06)	77.8%
Year 6 (May '06 - May '07)	17.3%
Year 7 (May '07 - May '08)	-36%
Year 8 (May '08 - current)	-7.3%
Cumulative Gain	**93%**
Av Annual Gain (7 yrs)	**17.8%**

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Delivering independent investment research to investors on Australian biotech, pharma and healthcare companies.

Mesoblast – Strong Progress Continues

For an emerging technology such as stem cell therapy, one of the most important considerations is the business model that will be used to commercialise a new type of treatment. Mesoblast is developing a number of adult stem cell therapies based on the one core technology in the area of orthopedics. It also owns 39% of a private company that is applying the same technology for the treatment of heart disease.

Since listing in 2004, the company has made strong progress moving its programs towards commercialization. The company has three leading orthopedic applications of its adult stem cell technology. These are spinal fusion, bone fracture repair and cartilage repair and preservation in the knee.

Move from Autologous to Allogeneic Stem cells

Initial trials with the Mesoblast technology involved the use of autologous adult stem cells (i.e. patient's own stem cells) where initial proof of efficacy was established in preclinical then human trials. The company has since established proof-of-concept of the use of allogeneic adult stem cells (off the shelf stem cells from unrelated donors) in preclinical trials. Commercial applications will all involve allogeneic cells, with phase II trials underway with the allogeneic cells, which brings with it obvious and less obvious benefits (see business models below).

Results to date from orthopaedic trials

Bone Fractures – Autologous

In December 2005, the company started a 10 person trial to treat non-healing, long bone fractures. The trial used autologous (patients' own) stem cells. In February 2008, final results from this trial were released after six months follow-up. The trial was successful.

Details: The 10 patients had not shown any new bone formation for between 5-41 months prior to the trial. In seven of the 10 patients, the bone defect healed in a median time of 4.9 months, with the remaining three patients showing bone growth. There was also a dose dependency effect noticed.

This trial was conducted at The Royal Melbourne Hospital under Mr Richard Farrugia, the Clinical Research Co-ordinator for the Department of Orthopaedics who said 'the trial demonstrated an exciting new development for the orthopedic field.

Allogeneic Preclinical Trials

The company has shown in preclinical models that its allogeneic adult stem cells were

effective in bone regeneration (February 2006), in spinal fusion (April 2006), in cardiovascular applications (May 2006) and in the prevention of knee cartilage degeneration (August 2007). In July 2007, the company started a preclinical trial in intervertebral disc repair, which is the cartilage between the vertebrae that acts as shock absorbers. Degeneration of this cartilage leads to a more invasive spinal fusion procedure. The aim in this trial is to regenerate the cartilage between the vertebrae.

Spinal Fusion -– Allogeneic

In December 2006, Mesoblast received an IND approval to start a Phase II spinal fusion trial with its allogeneic adult stem cells. The trial started in July 2007 at the Hospital for Special Surgery in New York under Joseph Lane, who is the Chief of the Metabolic Bone Disease Service and Attending Orthopedic Surgeon. Lane is a world leader in bone repair and regeneration and sits on the Zimmer Scientific Advisory Board. **Zimmer** is a world leading orthopaedics group.

In April this year the company reported that this trial was progressing well with no adverse safety effects. It plans to accelerate clinical development with a Phase III trial in spinal fusion expected to begin in mid 2009. No efficacy results from the current Phase II spinal fusion trial are available. Our understanding is that the Principal Investigator is planning to present an abstract on the study. These points would suggest the trial results have been positive.

Business Model Progression

Mesoblast has given careful consideration to its business model for its novel emerging stem cell therapy which is crucial to the success of this platform technology.

Allogeneic Over Autologous

Mesoblast has elected to commercialise off-the-shelf allogeneic stem cells, which are harvested and grown from unrelated donors. The stem cells do not appear to attract the attention of a patient's immune system, lending itself to such an allogeneic system. Results to date have shown that the allogeneic cells have been effective in preclinical studies.

The use of off-the-shelf cells obviously makes production and delivery easier with resulting higher margins potentially for the product. However a less obvious benefit from using the same population of cells relates to regulatory clearance. With autologous (patient's own) cells, there is more room for error in delivering an incorrect cell source to the patient. From a regulatory aspect, it is easier to control the production of one batch of cells that may treat 20,000 patients rather than ensuring correct processing of 20,000 autologous samples.

Adult Stem Cells Over Embryonic Stem Cells

Once again from a regulatory (safety) point of view, the use of adult stem cells carries with it less risk of triggering an uncontrolled (cancerous) cell growth, which is the main risk at this stage of using embryonic stem cells. There are also fewer contentious issues surrounding the use of adult-derived stem cells.

With mesenchymal stem cells, it has been shown that it takes 60 cell divisions before chromosomal errors occur in the cells potentially leading to development of cancerous cells. Mesoblast will divide its cells up to 20 times in its production system, well below the theoretical 60 division peak limit. This will allow sufficient quantities of cells to be produced for between 500-1000 patient treatments per batch.

Clinical requirements

According to the company, the FDA views these adult stem cell products as hybrid drug/device product. It's expected that the regulatory approval route will be shorter, with only Phase IIb trials required (in about 100 people) and a pivotal Phase III trial (involving about 200 people), cutting down the development time by two years over a new drug.

Differentiated Product Lines

Mesoblast will tailor its cells produced for each particular application through manipulation of reagents and processing technique. The variation of the end product will not be major, however it will allow the company potentially to slice and dice the market for its different applications with different global partners and generate more competitive tension. This is a clever approach to maximizing the deal flow for this particular platform technology.

Lead-in Product

In the orthopedic industry, which is extremely competitive, a product such as that being developed by Mesoblast has the potential to become a 'lead-in' product for orthopedic hardware majors to win over major hospital sites and clinics. An example of this is the success that Medtronic has enjoyed since it launched its INFUSE Bone Graft product for spinal fusion product that stimulates bone growth using a recombinant human bone morphogenetic protein (rhBMP-2).

Orthopaedic Licensing Precedent

The licensing deal between **Genetics Institute** (Wyeth) and Medtronic for rhBMP-2 lays a precedent for orthopedic deals for stem cell type products. Wyeth manufactures and sells rhBMP-2 to Medtronic at 50% of the final sale price, which is a very lucrative deal for Wyeth

Competing Product

Mesoblast would be looking for its product to be similar if not superior to INFUSE and is initially targeting indications for which INFUSE is not approved. However, there appear to synergistic benefits from combining MPCs with the rhBMP-2.

Mesoblast's Potential Partners in the Spinal Fusion Market

A question for investors is which company might Mesoblast partner with in the orthopaedics reconstruction area and in particular the spinal fusion market, should its clinical trial results yield convincing data. The spinal fusion market is an attractive opportunity, with the market estimated at US$6.1 billion in 2007 with year on year growth of 16%, and strong growth anticipated to continue.

Cont'd over

Mesoblast's likely partnering opportunities for its mesenchymal precursor stem cell (MPC) products in the spinal fusion market could include companies currently offering biological products or bone matrix products or are conducting there own stem cell product research. As such partnering opportunities may more likely eventuate with **Medtronic Sofamor Danek** (**Medtronic**), **Stryker** and **De Puy** (**Johnson & Johnson**),

However, companies such as **Zimmer**, **Synthes** and **Smith and Nephew** may also be as interested in acquiring new stem cell technologies because they are lagging in R&D and have yet to develop products in the area.

Medtronic

Medtronic is a diversified medical devices business, with divisions that encompass cardiac rhythm disease management, spinal, cardiovascular, neuromodulation, diabetes, and ear, nose and throat ENT. In the year ended April 2007, Medtronic recorded revenues of US$13.5 billion, up 10% from the previous year, with its spine unit **Medtronic Sofamor Danek** posting sales of US$3 billion, a 23% increase for the year. The spinal products business is Medtronics' second biggest division after the cardiac rhythm disease management group, which registered US$5 billion in sales for 2007 with growth flat at 2%. Unlike other orthopaedic device companies, Medtronic is exclusively focused on spinal products and would appear to be the dominant force in the sub-sector.

In addition to selling plates, screws and fusion devices, Medtronic Sofamor Danek also sells bone matrix, allograft material, synthetic bone graft substitutes and the novel biologic product, a recombinant version of BMP-2, a bone growth protein. This product (INFUSE Bone Graft /LT Cage Lumbar Tapered Fusion Device) garnered $772 million in sales in 2007, an increase of 14% from 2007. The Infuse product is indicated for patients with degenerative disc disease.

Based on some animal studies that have been conducted, what may be appealing to Medtronic about an MPC product designed by Mesoblast is that the joint application of MPCs with INFUSE (rhBMP-2) may mean that lower doses of rhBMP-2 would be required, although the study also noted an even better outcome if another protein (bFGF) was also used.

Sales in Medtronics' core spinal business look to be under some pressure, recording 9% growth for 2007. Medtronic acquired a business, **Kyphon**, in July 2007 for US$3.9 billion to add minimally invasive technologies to its suite of products. It is not out the question that Medtronic will actively look for technologies and products to support its dominant position in the spinal sector.

Stryker

Stryker is a diversified medical devices and products business which include a range of orthopaedic implant systems. The company posted sales of US$6 billion in 2007, of which US$3.6 billion was generated from sales of orthopaedic implants. Unit sales of spinal products were not disclosed but the year on year increase of 18% for 2007 was reported.

Stryker was the first company to enter a recombinant protein product for use in bone repair into clinical trials. As of December 31, 2007, more 600 patients have received Stryker's OP-1 Implant, a product that is composed of recombinant human OP-1 (also known as BMP-7) and a resorbable collagen matrix, under Humanitarian Device Exemption (HDE) provisions.

A second product, OP-1 Putty, has been used and evaluated in more than 700 patients under HDE provisions. In 2006, Stryker filed a submission for the administration of OP-1 Putty in patients with posterolateral spinal fusion, based on results from a two year follow-up to a trial now before the FDA with a decision pending.

OP-1 (BMP-7) is a competitor product to MPC products that may be developed by Mesoblast. However, the development and approval process has been slow, with the FDA's reluctance to act on the product a poor sign. It is possible that high rates of antibody formation, as much as 38%, have impacted on this device's progress.

De Puy (Johnson & Johnson)

De Puy is a unit of **Johnson & Johnson**. The unit posted sales of US$4.6 billion in 2007, an increase of 11.7% from the previous year. However, specific figures for De Puy Spinal are not disclosed. De Puy Spinal ranks itself as the number two spinal business in the world, most probably after Medtronic. De Puy Spinal does concede that its growth in 2007 of 7% was under the industry average. According to recent company presentations, De Puy is not looking to grow its business with biologic or cell products. This may mean it would be less interested in partnering with Mesoblast, despite its slowing rate of sales growth.

Zimmer

Zimmer is predominantly an orthopaedic implants company which generated sales of US$3.9 billion in 2007. Sales of spinal products totalled US$197 million. Zimmer calculates that its holds the sixth position by sales amongst the spinal product companies. Although its position in the spinal market is modest, the company operates an Orthobiologics Institute in Austin Texas. Through this unit, Zimmer is collaborating with ISTO Technologies on the development of chondral and osteochondral grafts for cartilage repair. Although the company does not appear to manage any cell therapy programs, Zimmer may be a lesser ranked candidate for partnering with Mesoblast, because of its small market share in the spinal market.

Synthes

Synthes is a Swiss listed but US head-quartered company that sells products across a range of orthopaedic and surgical tool areas. Sales of US$2.8 billion were reported for 2007, an increase of 15.4% from the previous year. Synthes claims strong positions in spinal products in Europe and the US. However, an absence of next-generation technologies could make Synthes a potential licensing candidate for one of Mesoblast's MPC products.

Cont'd over

Smith and Nephew

One other company with an interest in orthopaedic implants is UK company Smith and Nephew. Smith and Nephew recorded sales in the orthopaedic reconstruction market of US$1.25 billion in 2007. However, the company does not operate in the spinal repair and reconstruction market but has eye on new orthopaedic technologies. In October 2007, Smith and Nephew entered a collaboration with the **Regenerative Medicine Institute** at the **National University of Ireland Galway** to use adult bone marrow cells for the repair of damaged joints and to re-grow healthy cartilage with a view to developing treatments for osteo-arthritis. An engagement of this types provides a degree of validation for Mesoblast's MPC program in bone repair and spinal fusion and its probable that the research program would be seeking to harvest MPCs from bone marrow. However, this program would appear to lag the Mesoblast MPC program by many years.

Smith & Nephew has established expertise over the years using biologics in the area of wound repair. The company may have an advantage over other orthopaedic reconstruction companies in taking on board a cell therapy technology because of that accumulated expertise.

Protein Drugs Help Pave the Way For Cell Therapies

Although the global orthopaedic re-construction and repair sector is significant in terms of product sales, as is the spinal implant and repair sub-sector, it is subject to very strong competition. With recombinant protein drugs such as BMP-2 on the market, the conditions are being set for cell therapies to also enter the market and provide new competitive advantages that may deliver revenues and profits.

Angioblast

Mesoblast currently owns 39% of Angioblast, a private US company that is applying the same mesenchymal precursor stem cell technology for cardiac applications. Mesoblast is currently conducting a 25 person Phase II trial in the US under an IND to repair damaged hearts of people who have experienced a hear attack.

Earlier this month the company received approval from the FDA (also through an IND) to start a Phase II study in 60 patients who have congestive heart failure. Both of these trials are using allogeneic cells.

In an early pilot study in six patients with heart disease using autologous cells, all patients experienced heart muscle recovery and four of the patients were reclassified into a reduced class of congestive heart failure.

Less than ideal corporate structure remains

The corporate structure between Mesoblast and its sister company Angioblast is not ideal. The relationship lacks transparency, with part of the funds raised by Mesoblast being invested into Angioblast. Being a private company, the operations of Angioblast are not open to scrutiny by Mesoblast investors. A more appealing arrangement would be to merge the two businesses. The founder of Mesoblast, Silviu Itescu, has substantial ownership in both companies.

Summary

Mesoblast has made exceptionally good progress with its adult stem cell therapy in several applications. It has delivered positive proof of concept using its autologous cells in non-union bone fractures and in congestive heart failure through its interest in Angioblast. The company has a well constructed business plan that is positioning the company to deliver on multiple licensing opportunities. The major risk is technical, that it achieves its clinical outcomes. Mesoblast is capitalised at $125 million with $16 million in cash at the end of March.

Bioshares recommendation: **Speculative Buy Class B**

Bionomics Licenses MS Program to Merck Serono

Bionomics (BNO: 38 cents) has signed a licensing and development deal with **Merck Serono** for its preclinical stage multiple sclerosis (MS) program. The deal comes with a US$2 million up front payment, milestone payments of up to US$47 million, and royalties from sales of any products that may come out of the program. The project will now also be fully funded by Merck Serono.

The early outlicensing of this program had been flagged by Bionomics and confirms the commercial discipline it is employing throughout the company. It is expected this program will move into the clinic in 2010, with the anti-anxiety BNC210 program expected to move into Phase I trials in 2009. Earlier this year the company started its first clinical trial with its lead program, BNC105, a vascular disrupting agent for the destruction of solid tumours. Bionomics made two acquisitions in 2005 to build its drug discovery and development engine room which is now clearly bearing fruit.

Both the Phase I BNC105 drug candidate and the MS program came through the acquisition of chemistry group **Iliad Chemicals** in Melbourne and its collaboration with the **Walter and Eliza Hall Institute**. Iliad, now fully integrated into Bionomics, developed a 'Multicore' chemistry platform which comprised at the time of a library of 60 molecular ring cores that could be interchanged whilst leaving the functional groups that bind to the target the same. Bionomics has been collaborating with WEHI for the last three years.

The MS program involved the construction of synthetic analogues of natural existing compounds that bind to the Kv1.3 ion channel. It is believed that blocking this ion channel can inhibit the function of overactive memory T-cells that destroy the insulating myelin sheath in the central nervous system that leads to multiple sclerosis.

This is the second MS deal this year for Australian biotech companies, with Antisense Therapeutics having signed a deal earlier this year with Teva Pharmaceutical Industries (for ATL1102, which has just completed Phase IIa studies and results expected in the

Cont'd over

next month). The quality of both deals is highlighted by the important franchises that each partner has in the MS space; Teva sells Copaxone, which last year generated sales of US$1.7 billion, and Merck Serono sells Rebif, which notched up sales in excess of 300 million Euros in the first quarter of this year.

Bionomics is progressing well on all fronts, with enrolment in the Phase I BNC105 trial on schedule. The payments from Merck Serono although small initially, will be helpful to Bionomics in the current market, with a lower burn as well under the R&D funding from this deal. Bionomics is capitalised at $89 million and had $7.6 million cash at the end of March this year.

Bioshares recommendation: **Speculative Buy Class A**

Bioshares

Solid Growth Continues at Cogstate

For the third successive year, Cogstate (CGS: 11 cents) should deliver on consistent revenue growth, this financial year expected to be 50%, to approximately $3.5 million. There is a degree of certainty building into this business, which provides cognitive testing services to biotech and pharmaceutical companies, in trials of drug candidates primarily for the treatment of central nervous system disorders. With strong growth expected to continue, the challenge for the company, which now employs 27 people, will be to manage that growth and the increasing size of its clinical trial contracts.

Although it is still a small company, capitalised at only $5.7 million, it has been a very successful 12 months for the Cogstate. In this financial year the company doubled the number of its customers, to 14, has signed $4.8 million of contracts this year (compared to $1.95 million for the previous year), has signed 12 contracts for Phase II clinical trials (none in the previous year) and one Phase IV study (similar to the previous year).

Another measure of the interest in the company's service is the level of quotes the company provided this year, over $7 million, with a conversion rate of around 80%. The company has reached a stage where it has become well known and well respected by its clients, with regular customers including the majors **Pfizer**, **Merck**, **GlaxoSmithKline** and **AstraZeneca**. Last year Cogstate was winning contracts mainly for Phase I studies, this year there has been a large emphasis on Phase II studies, and in the next year we expect the company to be bidding for several large Phase III studies.

This year has seen the company move into new indications such as pain and obesity drug trials. The acceptance by the FDA of the Elan/Wyeth protocol for a new testing battery (NTB) for a Phase III Alzheimer's disease trial, the same as that being used by Prana Biotechnology, over the industry standard ADOSCOG test, may also have significance for Cogstate. This change has the potential also for Cogstate's testing regime to be considered as a primary measure for future clinical Alzheimer's disease trials.

This half should see the company reach at least a cashflow neutral position. We forecast sales to exceed $5 million in FY009, which should see the company deliver a maiden profit next year. With $4.8 million of contracts signed this year, strong revenue can be expected from existing contracts. At the end of March, the company had $870,000 in cash, which should be sufficient for the company although does not leave much room for error.

Much of the hard work in developing a brand name and reputation in the industry has been achieved. The company is now position to accelerate its level of work into major Phase III contracts. The risk for the company is to manage that growth and its cost base moving forward. With a capitalisation of only $5.7 million, the stock is appealing and should offer good prospects over the next three years.

Bioshares recommendation: **Speculative Buy Class A**

Bioshares

Optiscan Imaging Signals More Aggressive Approach

There are signs at Optiscan Imaging (OIL: 24.5 cents) that the company is taking the bull by horns in a more aggressive growth strategy by the company. In the last two weeks the company has announced a $3 million capital raising, with three of the company's directors participating in the funding round; it has made a decision to form a global sales and distribution network for one of its products, the FIVE 1 (used for research purposes); and it has added some heavy hitters to its Board in Dr Jim Fox (former CEO of **Vision Systems**) and Paul Wright (a former CEO of **Vision Biosystems**).

While Optiscan has limited influence in the rollout of its lead product, the flexible endomicroscpe, which is sold by the company's partner **Hoya** (Pentax), the company looks to want to be more in control of its own destiny with subsequent products. The guidance from the Vision Systems team on the board will be very instructive to effect this more aggressive commercialisation approach from the company.

Bioshares recommendation: **Speculative Buy Class A**

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Bioshares Model Portfolio (20 June 2008)

Company	Price (current)	Price added to portfolio	Date added
Cellestis	$2.70	$2.27	April 2008
IDT	$2.04	$1.90	March 2008
Circadian Technologies	$0.86	$1.03	February 2008
Patrys	$0.27	$0.50	December 2007
NeuroDiscovery	$0.11	$0.16	December 2007
Bionomics	$0.38	$0.42	December 2007
Cogstate	$0.11	$0.13	November 2007
Sirtex Medical	$3.05	$3.90	October 2007
Clinuvel Pharmaceuticals	$0.34	$0.66	September 2007
Starpharma Holdings	$0.29	$0.37	August 2007
Pharmaxis	$1.62	$3.15	August 2007
Universal Biosensors	$0.86	$1.23	June 2007
Biota Holdings	$0.85	$1.55	March 2007
Probiotec	$1.30	$1.12	February 2007
Peplin Inc	$0.40	$0.83	January 2007
Arana Therapeutics	$1.15	$1.31	October 2006
Chemgenex Pharma.	$1.11	$0.38	June 2006
Cytopia	$0.23	$0.46	June 2005
Optiscan Imaging	$0.25	$0.35	March 2005
Acrux	$1.01	$0.83	November 2004
Alchemia	$0.34	$0.67	May 2004

Portfolio Changes – 20 June 2008

IN:
No changes.

OUT:
No changes.

How Bioshares Rates Stocks

For the purpose of valuation, *Bioshares* divides biotech stocks into two categories. The first group are stocks with existing positive cash flows or close to producing positive cash flows. The second group are stocks without near term positive cash flows, history of losses, or at early stages of commercialisation. In this second group, which are essentially speculative propositions, *Bioshares* grades them according to relative risk within that group, to better reflect the very large spread of risk within those stocks.

Group A

Stocks with existing positive cash flows or close to producing positive cash flows.

Buy	CMP is 20% < Fair Value
Accumulate	CMP is 10% < Fair Value
Hold	Value = CMP
Lighten	CMP is 10% > Fair Value
Sell	CMP is 20% > Fair Value

(CMP–Current Market Price)

Group B

Stocks without near term positive cash flows, history of losses, or at early stages commercialisation.

Speculative Buy – Class A
These stocks will have more than one technology, product or investment in development, with perhaps those same technologies offering multiple opportunities. These features, coupled to the presence of alliances, partnerships and scientific advisory boards, indicate the stock is relative less risky than other biotech stocks.

Speculative Buy – Class B
These stocks may have more than one product or opportunity, and may even be close to market. However, they are likely to be lacking in several key areas. For example, their cash position is weak, or management or board may need strengthening.

Speculative Buy – Class C
These stocks generally have one product in development and lack many external validation features.

Speculative Hold – Class A or B or C

Sell

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