meso blast

investor update

ISSUE NINE

Near-term commercialisation of three bone and cartilage products

Mesoblast's record of accomplishment since its ASX listing in December 2004 has been first rate. Within only 3.5 years, the Company has established itself as a world leader in the development of innovative biological products in the emerging and potentially highly lucrative regenerative medicine field.

Our adult stem cell platform has shown real and substantial commercial applicability for the global orthopaedic industry. We are targeting a wide range of bone, cartilage and musculoskeletal conditions, and aim to bring at least three products to market in the near-term for these diseases.

We have added substantial value by taking a 39% equity holding in US-based sister company Angioblast Systems Inc, which is simultaneously advancing the platform stem cell technology towards commercialisation of new cardiovascular treatments.

Clinical and commercial strategy

Mesoblast is firmly focused on a clinical and commercial strategy to bring three bone and cartilage repair products to market concurrently and as quickly as possible.

The Company is sufficiently funded to bring its lead product to Phase 3 and two follow-on products through Phase 2 trials.

For each of the three products, Mesoblast will seek to execute strategic alliances prior to commencing Phase 3 trials. These will focus on one or more commercial partners having both distribution strength and product depth in the global spinal, trauma and/or osteoarthritis markets.

Three orthopaedic products to market within short timeframe

Mesoblast's lead bone repair product, NeoFuse, targets the lucrative spinal fusion market. The strategy for market launch of this product involves expansion of the Phase 2 clinical program to include multiple US sites, and progression to Phase 3 during 2009.

Mesoblast's second bone repair product is targeting the very large trauma market for fracture repair. Following on from the successful Phase 1b trial for repair of non-union long bone fractures, the Company is now finalising plans for a large multi-centre trial that will set the path to product registration.

Mesoblast's third product, its first for cartilage regeneration, targets the massive knee osteoarthritis market. The Company's strategy is to commercialise a product that is injected into damaged knee joints of patients who have developed osteoarthritis either as a result of prior meniscal surgery or due to age-related degeneration. The Company expects to commence a Phase 2 trial for knee osteoarthritis in Q3 of 2008.

Key milestones achieved on time and on budget since 2005

- Received United States Patent Office grant of its base stem cell patent, effectively granting broad ownership to a unique stem cell population; further international patents pending
- Successful scale-up of patented stem cell manufacturing process
- Demonstrated effectiveness of allogeneic ("off-the-shelf") stem cells in an extensive range of preclinical trials, including for spinal fusion, fracture repair and knee osteoarthritis
- Shown that its bone repair product is effective in a Phase 1b clinical trial for treatment of patients with non-union fractures
- Received clearance from US FDA in less than 30 days to begin Phase 2 trial of its allogeneic product NeoFuse in patients needing spinal fusion
- Shown that NeoFuse is safe for up to five months of follow-up in initial patients implanted
- Expansion of number of US clinical sites recruiting patients in order to complete Phase 2 Spinal Fusion trial in shorter timeframe
- Stated goal to accelerate FDA submission process to commence Phase 3 pivotal/registration trial for NeoFuse by second half 2009.

Spinal Fusion

Proven market for biologicals and associated hardware

The number of spinal fusion procedures in the United States alone is expected to exceed 500,000 annually by 2010. Today, the bone regenerative biologic drug component of a single spinal fusion procedure receives reimbursement of approximately USD $5,000. An even greater amount is reimbursed for the hardware (rods, screws, cages etc.) used for each procedure.

Mesoblast is targeting the existing biologic drug market by seeking to obtain US FDA approval for a stem cell product that will be implanted by a minimally invasive technique together with existing hardware to achieve intervertebral body spinal fusion.

Accelerated clinical trial program and Phase 3 pivotal trial

The Company recently provided an update on its single-centre Phase 2 trial for its proprietary product NeoFuse in spinal fusion. In this trial, safety outcomes are compared between patients randomised to receive either implantation into the spine of autograft alone (patients' own bone transplanted from the pelvis) or Mesoblast's allogeneic stem cells. No cell-related adverse events have been reported in up to five months of follow-up.

Based on the encouraging initial safety results, Mesoblast will now expand its Phase 2 spinal fusion clinical trial activities to include up to 10 new major clinical trial sites in the United States. This will serve to accelerate the company's FDA submission process for a Phase 3/pivotal trial in spinal fusion in 2009.

Choice of strategic partner based on strength in market

Prior experience with biologicals in the spinal fusion field indicates that it is highly likely that sales of Mesoblast's NeoFuse product will also serve to "pull-through" sales of hardware that are associated with the cell implant and spinal surgical procedures. This has significant implication for the choice of strategic partner Mesoblast must make for this particular clinical indication.

To ensure rapid uptake and significant sales of NeoFuse, the Company will need to choose a partner with significant distribution strength with the spinal surgeons who will use the product, and with an existing suite of spinal hardware products.

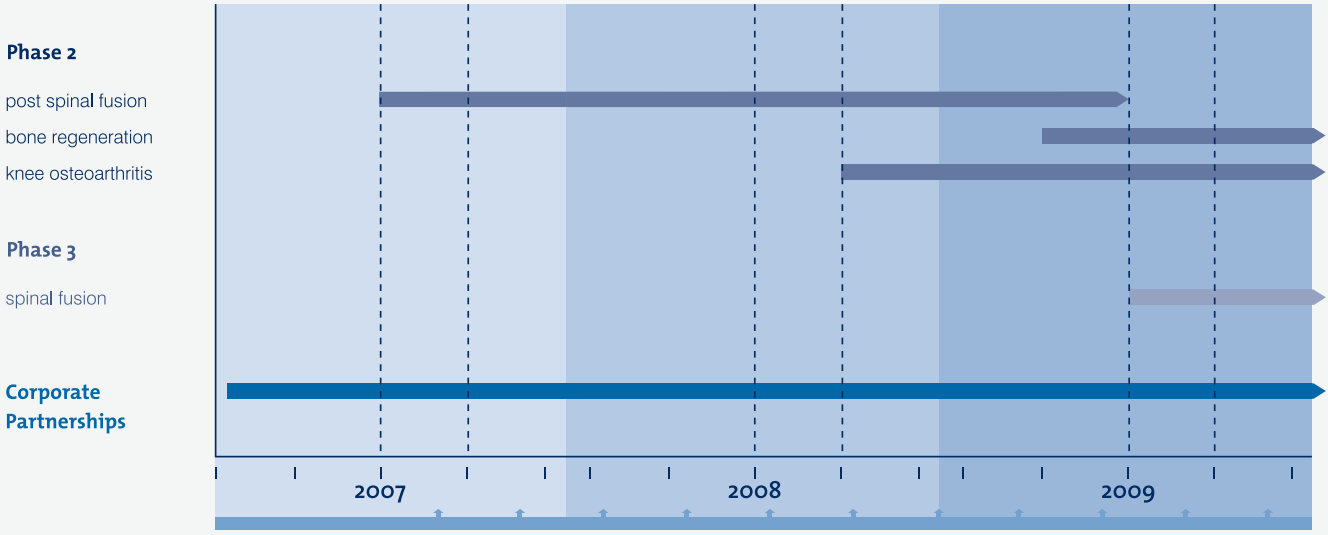
Bone Fracture Repair

Trauma market

From Mesoblast's earliest inception it was clear that our technology was ideally suited to the fracture repair markets. These markets are massive, encompass fresh closed and open fractures, as well as the complications of delayed fracture healing and fracture non-union.

As a proof-of-principle, Mesoblast decided to target the most difficult subset first, namely those patients with non-union fractures of the legs, the rationale being that success here would have broad applicability for the whole trauma market.

Tracking Clinical Value Drivers



Successful results in Phase 1b trial of non-union long bone fractures

Indeed, we recently announced highly successful results from the clinical trial at The Royal Melbourne Hospital of our proprietary stem cells in 10 patients suffering from non-healing, long bone fractures of the legs.

After six months of follow-up, all patients showed new bone growth, whereas none of the 10 had shown any evidence of new bone formation for 5-41 months prior to stem cell implantation. Seven of the ten showed 100% union of their long bone defects within a median time period of 4.9 months. There were no cell-related adverse events.

All patients with successful long bone union have been able to fully weight bear and resume a normal quality of life. Mesoblast's technology eliminated the need in these patients for a second operation to harvest bone from the pelvis.

Next steps in bringing trauma product to market

Many strategic decisions need to be made in order to successfully bring a trauma product to market. These include which injured bone to target in pivotal trials, the type of bone fracture (closed versus open), prevention versus treatment of fracture complications such as non-union, mode of delivery of the cells, and reimbursement issues.

Mesoblast is currently reviewing all options in this field with a view to embarking on a Phase 3 clinical trial strategy that will ensure both the shortest time to market and product approval for use in the broadest unmet need in the trauma field. The Company anticipates that a number of these strategic decisions will be taken in conjunction with a commercial partner with extensive strength and presence in the trauma market.

Osteoarthritis of the knee

Major new market opportunity

Osteoarthritis of the knee affects more than 15 million people in the US alone, and up to 15% of those aged over 65. It is a degenerative disease, which is characterised by the loss of cartilage and joint pain and disability. Current therapies attempt to alleviate painful symptoms but are unable to preserve the cartilage lining the joint. Moreover, many of the currently used pharmaceutical therapies are associated with severe side effects and can even cause death. Joint replacement is often the only option for restoring function.

The causes of knee osteoarthritis and cartilage breakdown include age-related degeneration of knee cartilage and surgery-related changes in anatomy of the knee joint following knee procedures.

Meniscectomy (partial or total removal of meniscal tissue) is one of the most common knee surgical procedures, with more than 450,000 performed in the US alone each year. Of significance, this procedure is subsequently followed by development of knee osteoarthritis in up to 50% of patients.

Mesoblast's allogeneic cells provide sustained cartilage protection …progression to Phase 2 trials

Mesoblast recently announced very promising 12-month preclinical results that showed that a single injection of its proprietary allogeneic, or "off-the-shelf", adult stem cells into knees developing osteoarthritis after surgical meniscectomy provided sustained protection against cartilage destruction and degeneration for up to nine months.

Based on these results, Mesoblast intends to submit an IND submission to the FDA during Q3 2008 to commence a blinded, randomised Phase 2 clinical trial of its stem cell treatment to protect knee cartilage against osteoarthritis in patients with recent knee meniscectomy.

While the primary end-point of the trial will be to determine the safety of the cells injected into the knee joint, secondary endpoints will be pain score reduction, improvement in joint function, and MRI assessment of cartilage thickness at six and 12 months after the cells are directly injected into the knee.

The commercial opportunity for Mesoblast in this area is enormous, and if the clinical results continue to parallel the preclinical results we have obtained to date, the Company will have a unique product for long-term cartilage protection and regeneration in osteoarthritis of the knee.

Conclusion

Our proprietary adult stem cells can deliver market leadership in regenerative medicine.

Mesoblast is aiming to have three lead products – for spinal fusion, fracture repair and osteoarthritis of the knee – approved for clinical use in the near term with a Phase 3 spinal fusion clinical trial underway next year.

Mesoblast's business model and margins are akin to pharmaceuticals.

Mesoblast's technology is an ideal opportunity for enhancing "pull-through" of already existing device-based revenues. This makes it a supreme technology to gain market leadership in global regenerative medicine with many opportunities for value-creating strategic partnerships.

High margin business model - allogeneic or "off-the-shelf" products

Mesoblast's business model is to develop clinical products using allogeneic or 'off the shelf' adult stem cells. The two key properties that make Mesoblast's cells uniquely suited for allogeneic use are their ability to be greatly expanded from a very small starting number of cells, and the fact that they do not activate the immune system of an unrelated person.

Consequently, Mesoblast's cells obtained from a single donor can be used to treat thousands of unrelated patients. This results in an efficient, highly reproducible product, with low manufacturing costs that can generate high margins akin to pharmaceutical sales. Equally as important, such "off-the-shelf" products will be available at hospitals for immediate use by orthopedic surgeons when the acute trauma or other injury needs rapid treatment.

Knee Osteoarthritis *Fast Facts*

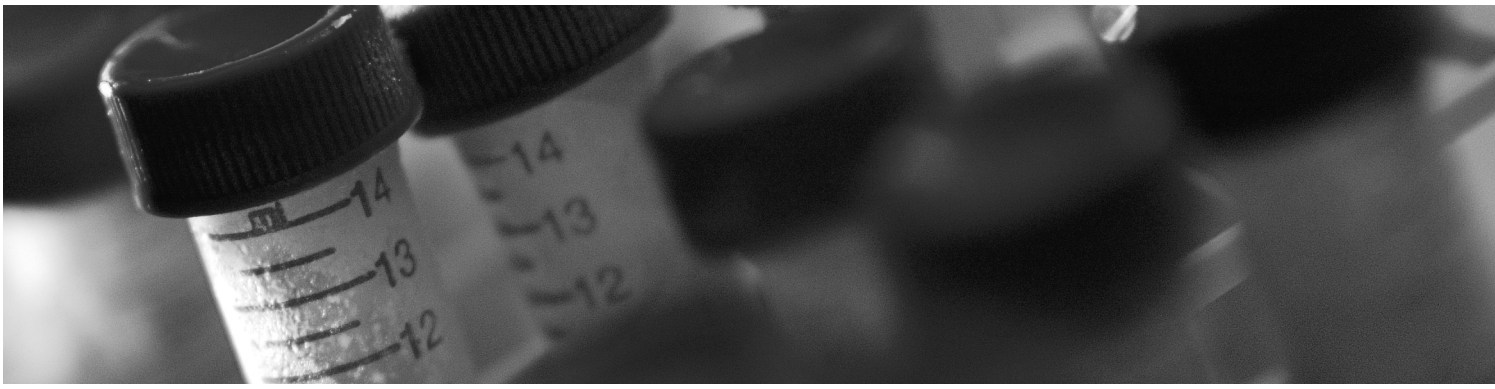
1. Arthroscopic partial meniscectomy is the most common surgical intervention performed by orthopedic surgeons, with more than 450,000 procedures in the USA annually
2. Meniscectomy, whether total or partial, is recognised as a strong risk factor for the development of knee osteoarthritis
3. OA is the most common cause of musculoskeletal disability in developed countries
4. OA is listed among the top 10 of global disease burdens according to the WHO
5. The disorder is more than 10-times as common as rheumatoid arthritis

– Future Medicine

What they say...

In an era of great medical breakthroughs, it is easy to underestimate the work of our research teams. A Melbourne company, Mesoblast, is trying out an injection using adult stem cells that could revolutionise the treatment of chronic knee injuries. The world-first treatment could be a multi-million-dollar earner and dramatically enhance the lives of professional athletes and thousands of others who suffer debilitating osteoarthritis and joint injuries.
– Sunday Herald Sun editorial

Leading sports physician Dr Peter Larkins said stem cell therapy had the potential to prolong athletes' careers. "In terms of medical breakthroughs, it's a sensational prospect, if it works," he said. **– Sunday Herald Sun**



Newsletters

This Mesoblast newsletter is available online on Mesoblast's website – www.mesoblast.com

Announcements to the Australian Stock Exchange and other public announcements are posted on a timely basis on the Mesoblast website.

If you would like to be informed of Mesoblast's progress by e-mail, please register by sending your contact details to: info@mesoblast.com

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