

mesoblast asx announcement

Mesoblast achieves major milestones: positive results accelerate product commercialisation

Major Achievements During the Quarter

- Pilot clinical trials demonstrate safety of the company's manufacturing process and cell delivery
- Eight patients enrolled to date in orthopaedic and cardiovascular trials with Australian clinical investigators continuing active and ongoing patient recruitment
- Use of company's proprietary stem cells obtained from one donor for treatment of unrelated recipients shown to be safe and effective in multiple preclinical trials
- Positive results in preclinical trials for spinal fusion and long bone repair
- Positive initial results in preclinical trials for prevention of heart failure progression after a heart attack
- These results have validated the company's business model to develop an "off-the-shelf" cell-based therapy for multiple organ systems
- The preclinical trial results will form an essential component of the Phase II Investigational New Drug (IND) clinical trial submissions for orthopaedic and cardiovascular applications by Mesoblast and its US-based sister company, Angioblast Systems Inc; respectively, to the US Food & Drug Administration (FDA).
- The strength of the preclinical data will enable these IND submissions to be filed with the FDA over 6 months ahead of schedule.

"Mesoblast has accomplished three very significant milestones: commercial scalability of our stem cell manufacturing process, safety of our stem cells in patients, and effectiveness of our allogeneic (or "off-the-shelf") stem cells in unrelated recipients. Together, these achievements will facilitate commencement of Phase II clinical trials in patients with orthopaedic and cardiac conditions, two major areas of unmet clinical needs and very large global markets." – Founder & Chief Scientific Adviser, Professor Silviu Itescu

Significant progress in clinical trials

The overriding goal of Mesoblast's Pilot Clinical Trials in Australia is to validate the company's Standard Operating Procedures (SOPs) in a clinical setting. To date, the medical investigators participating in the two trials have enrolled 8 patients. From the clinical experience so far, the company is confident that its adult stem cell manufacturing SOPs and cell products are safe. Importantly, these observations on product safety in humans have been independently confirmed in six separate preclinical orthopaedic and cardiovascular trials where the company's adult stem cells, manufactured in accordance with similar SOPs, have been implanted safely in studies involving over 120 sheep.

The ability to manufacture a safe adult stem cell product under stringent regulatory conditions in a centralised manufacturing facility is a critical component of Mesoblast's business strategy. To this end, the parallel clinical and preclinical safety data generated to date underscore the company's successful accomplishment of a key operational milestone that will increase the likelihood of product commercialisation for massive global markets.

In line with Mesoblast's stated communications protocols, clinical Trial updates will continue to report on the entirety of the trials and will not focus on individual outcomes.

Orthopaedic clinical trial underway at The Royal Melbourne Hospital

The first orthopaedic patient was safely implanted with the company's specialist adult stem cells by a medical team led by the Director of Orthopaedics at The Royal Melbourne Hospital, Mr Richard de Steiger.

The patient sustained a major fracture of his femur following a motorcycle accident, which failed to heal after nine months. Usually, for this type of non-healing defect, a bone graft (or autograft), using a large amount of bone taken from the patient's own hip would be considered. However, this requires a second surgical procedure, which often results in long-term complications including pain at the graft donor site and possible infection.

The Pilot Trial at the Royal Melbourne Hospital is an independent assessment of the safety of Mesoblast's specialist adult stem cell technology and involves up to 10 patients suffering from long bone fractures that have failed to heal, termed non-union. These fractures are usually a result of accidents and affect many thousands of people each year in Australia and as many as two million people in developed countries around the world.

"The use of Mesoblast's adult stem cells could result in the healing of the defect without the complications of a bone graft taken from a separate incision. This procedure may significantly reduce or eliminate long-term patient complications, whilst decreasing hospital time and costs associated with the treatment of long bone fractures."
– Mr Richard de Steiger, Director of Orthopaedics, The Royal Melbourne Hospital

Mesoblast taps into a new massive orthopaedic market - spinal fusion

During the past quarter, Mesoblast announced that results from pre-clinical trials being undertaken at the Colorado State University in the US clearly indicated that the company's stem cells obtained from a

single adult donor and produced using its proprietary technology were highly successful in generating intervertebral spinal fusion in multiple, unrelated (or allogeneic) recipients. On the strength of the trial results, the company will proceed with an FDA Phase II clinical trial submission for spinal fusion.

Spinal fusion is used to treat patients with degenerative intervertebral disc disease. Over 300,000 spinal fusion procedures are currently performed annually in the United States alone. This number is expected to grow to over 500,000 per year by 2009. As with non-union long bone fractures, the current gold standard therapy for spinal fusion is autograft bone harvested from a patient's own hip. This requires a second surgical procedure that frequently results in long-term complications such as chronic pain and infection.

Mesoblast's stem cells generated significantly superior spinal fusion to controls and fusion that was at least as effective as hip bone autograft. Accordingly, Mesoblast's therapy may eliminate the need for a second surgical procedure and its potential costs and complications.

"Most importantly, the fusion resulting from the stem cells was equally or more robust, continuous, and mechanically strong when compared with the current standard surgical treatment, hip bone autograft." -- Professor Silviu Itescu

Positive results from preclinical trial for heart failure

Additional results obtained during the quarter from preclinical trials indicated positive initial outcomes of our "off-the-shelf" adult stem cells in heart disease. The initial results indicated that our proprietary stem cells obtained from a single donor and injected into unrelated recipients were effective for the prevention of heart failure progression, confirming heart failure as a major market opportunity.

Over 500,000 new patients with heart failure are treated annually in the United States alone. Current therapies offer only modest symptomatic benefit, do not result in rebuilding of heart muscle, and do not prevent progression of heart failure and long-term deterioration. In contrast, in multiple preclinical models the company's proprietary adult stem cells have been shown to result in significant improvement of heart function and to prevent heart failure progression.

In line with the study's protocols, final data from the preclinical trial will be produced at the conclusion of the study, scheduled for early third quarter 2006.

No clinical barriers to high margin business model for multi-billion dollar markets, multiple opportunities

There are no clinical barriers to market entry.

Mesoblast's business model supports a very high profit margin business, equivalent to a pharmaceutical. Cell delivery is highly complementary to current treatment regimes and importantly aims to significantly enhance beneficial outcomes to patients.

We know that our adult stem cells can be frozen and made immediately available for the treatment of trauma accident, sports injury, and heart attack victims. These cultured cells will be instantly available to orthopaedic surgeons and interventional cardiologists at the time and place of need. The Mesoblast cells will be used in combination with existing bone defect fillers, polymers, catheters and so on.

Mesoblast cells are isolated from one adult donor in less than an hour; cultured over a four to six-week period to safely manufacture hundreds, if not thousands, of doses for use in many unrelated recipients.

The markets for our unique adult stem cell technology are very significant. The major proportion of the population will suffer from orthopaedic and cardiovascular diseases at some point during their

lives and for which there are no satisfactory alternatives.

The diseases being targeted by our stem cell therapy are multi-billion dollar markets that today represent unmet clinical opportunities. These markets share an unusual characteristic in that many of the major players -- the large international pharmaceutical companies and medical device companies - see stem cell technology as an adjunct to existing product offerings, with the potential to result in blockbuster partnerships in terms of creating significant market share. Mesoblast's proof that it can generate an "off-the-shelf" stem cell product serves to significantly enhance the likelihood of commercial partnerships being realised in the shorter term.

"The results achieved to date further serve to emphasise our business model - we will produce a low cost and high margin therapy for major orthopaedic and cardiovascular markets." -- Executive Chairman, Mr Michael Spooner

The biologic advantage...translates to significant savings in time and costs to commercialisation

Mesoblast continues to work collaboratively with the FDA in our approach to regulatory approvals. Our cells are a well-characterised biologic, something that occurs in nature and is not a new chemical compound.

Since biological responses among different types of large mammals is quite similar, the results we have obtained with the stem cells in preclinical studies are more likely to be reproducible when tested in patients compared with studies from conventional drugs. Moreover, the lack of any side-effects seen with the stem cells in the preclinical trials strongly predicts their likely safety in humans, again something that cannot necessarily be said for standard drugs.

For these reasons, we believe the regulatory path to FDA product approval and sales may be significantly shorter than for conventional drugs, with early Phase II trials and rapid progression to pivotal trials. This should translate to significant savings of many years and millions of dollars for each application of the stem cell technology.

New and complementary technologies for cardiovascular markets

Mesoblast's American sister company, Angioblast Systems Inc, has obtained an exclusive, worldwide license to commercialise a variety of new technologies for multi-billion dollar markets in the frontline treatment of coronary and peripheral artery disease.

The technologies were developed at the internationally acclaimed Columbia University in New York and show tremendous promise for use in preventing restenosis or re-blockage of arteries, particularly in the treatment of diabetics.

This technology will form a unique and highly effective combination regime with the adult stem cell products in the treatment of patients with heart attacks or peripheral artery disease. The product pipeline is highly synergistic with the company's stem cells whilst commercialisation timelines fit neatly within the existing adult stem cell regulatory programs.

Under the terms of the license agreement, Columbia University will become a minor equity holder in Angioblast. The transaction will not dilute Mesoblast's 33.3% equity holding in Angioblast.

Importantly, the company anticipates that its relationship with Columbia University may over time provide a number of additional opportunities to access breakthrough technologies with very large market potential.

Finance

Mesoblast held cash reserves of \$9.2 million at 31 March 2006, which included an initial receipt of \$431,000 from an Australian Government

Commercial Ready grant. Importantly, Mesoblast's American sister company, Angioblast Systems Inc., in which Mesoblast owns a 33.3 per cent equity stake, has cash reserves of \$1.66 million bringing the funds available for jointly developing and progressing the platform technology to \$10.86 million, with an additional \$2.3 million from a Government grant to be received.

The company is adequately funded to reach its primary goal of filing an IND submission to the FDA. The financial results are in line with our forecasts and reflect the rapid pace of commercialisation including undertaking two human clinical trials plus extensive pre-clinical trial work required for the FDA submission.

What the analysts say...

"We believe MSB represents a higher chance of success proposition with several tremendous potential applications."

"If success continues, lucrative co-development, distribution or royalty agreements would then beckon by which stage the market cap would potentially be multiples of the current \$168m."

"Management experience is borne out by strong IP protection, the streamlining of the regulatory process and MSB resisting the temptation to sell the technology at a relatively early stage of trialing."

Ord Minneft Limited Equity Research

"Mesoblast is making good progress in developing its adult stem cell technology and accordingly has received appropriate support from investors".

"Although the field of adult stem cell therapy has become a popular area of research and development, Mesoblast's core technology has an important point of difference that underpins its commercialisation prospects."

Bioshares

"Mesoblast is a very promising company in terms of its potential products. The technology works, the business model will be profitable and the path to commercialisation has been identified.

"In summary, Mesoblast is a company that can execute well, has promising products geared for the billion-dollar markets in regenerative medicine, and can manage its risks. Its is therefore a recommended stock."

Lodge Partners Research



"I think the benefits outweigh the old procedure; being able to not have big chunks of bone taken out of my hip." – Mesoblast's first orthopaedic patient



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