

# mesoblast asx announcement

## Mesoblast Well Ahead of Schedule Adult Stem Cells...Today's Reality

### Major Achievements During the Quarter

- Well ahead of schedule for FDA submissions
- Proprietary adult stem cells safely implanted into first two patients
- Stem cell heart trial a world first for J&J's latest catheter system
- 'Universal' donor business model confirmed in pre-clinical trials
- \$2.7M Australian Government award for arthritis and other cartilage diseases
- Key patent granted

### Well Ahead of Schedule for FDA Submissions

In December 2004 Mesoblast outlined an ambitious schedule of activities as part of the company's Initial Public Offering. Our primary objective has been to rapidly commercialise our adult stem cell technology and in particular to successfully submit an Investigational New Drug (IND) Application to the United States Food and Drug Administration (FDA). Our goal was to complete these activities by 2007.

Based upon an extremely rapid series of events and the hard work of our staff and partner organisations, it is clear that we will now accomplish this major goal during the second half of 2006 and will be significantly ahead of our original schedule.

The ensuing update is designed to provide a synopsis of activities undertaken by the company over the past quarter and points toward just some of the exciting projects the company is currently engaged in. We will, however, remain focused on our primary objectives.

### Clinical Trials Commence...First Patients Safely Implanted

Mesoblast's Pilot Clinical Trials to test the safety of its unique adult stem cells in humans are underway.

The purpose of these trials is to validate Mesoblast's Standard Operating Procedures in a clinical environment as a significant step toward the commercialisation of our technology. Data collected during these Pilot Trials will provide important information in support of our FDA submissions.

Adult stem cells developed using Mesoblast's proprietary technology were safely implanted in the first two patients taking part in a world-first cardiovascular clinical trial, bringing new hope to patients in Class III Congestive Heart Failure with severe coronary artery disease.

The implant procedure, performed under local anaesthetic, went well for both patients and we are looking forward to monitoring the progress of patients and to rapidly completing the Trial of up to 10 patients as quickly as possible.

Many millions of people worldwide are affected by congestive heart failure and coronary artery disease. There are very few options available to treat these conditions including pharmaceuticals, surgery, cardiac replacement and mechanical assistance – but these do not result in cardiac regeneration, are generally extremely expensive and may be highly invasive.

Recruitment for the second Pilot Clinical Trial, for repair of long-bone fractures that have previously failed to properly heal, is underway at The Royal Melbourne Hospital. Failure to properly heal broken bones impacts thousands of Australians and millions of people in developed countries worldwide annually. Affected persons suffer from reduced quality of life and have few options available to them.

### Partnership With Johnson and Johnson's Cordis Corporation Sees World First Use Of Latest Catheter Technology In Stem Cell Trial

Our stem cell heart trial was also the setting for the world first use in man of the latest generation cardiac catheter technology made by Johnson & Johnson's Cordis Corporation.

The NOGA XP cardiac catheter system, provided by Cordis through a partnership with Mesoblast's American affiliated company Angioblast Systems Inc, is a generational improvement on existing technologies and proved to be an ideal vehicle for the accurate and safe delivery of our specialist adult stem cells.

The partnership with Cordis reflects the strategy of Mesoblast and Angioblast to enhance the commercial value of our proprietary stem cell technology by working closely with global dominant players in significant potential markets.

### Pre-Clinical Trials Confirm Business Model

In September 2005 the company announced the commencement of two pre-clinical trials as part of our regulatory requirements for the FDA. Positive initial results from these trials for bone regeneration have been received, marking major milestones for the company.

The Pre-Clinical Trials at the Colorado State University clearly demonstrated that adult stem cells produced using Mesoblast's unique technology may be collected from one donor and commercially expanded to produce therapeutic doses for the treatment of potentially hundreds of completely unrelated recipients.

The Trials validated Mesoblast's unique business model to produce an 'off-the-shelf' adult stem cell product for multiple unrelated recipients, similar to a pharmaceutical with high profit margins.

Importantly, the preliminary results showed that the extent of bone regeneration was in proportion to stem cell dose escalation.

## \$2.7 Million Award To Develop New Treatments For Arthritis And Other Cartilage Disorders

Mesoblast was awarded a \$2.7million Commercial Ready Grant from the Australian Government to develop new cartilage treatments using its proprietary stem cells. This will enable the company to expand its initial indications beyond bone regeneration and cardiovascular applications. New clinical indications targeted by Mesoblast using its specialist stem cell technology will include osteoarthritis of large joints, such as knees, and degenerative intervertebral disc disease. These are exciting opportunities with massive potential markets.

### So what does all this mean?

Mesoblast is commercialising a technology that has a highly viable business model to safely and effectively treat patients with many common, but debilitating, diseases. These diseases represent some of the largest global markets in the health care industry, and include disorders of bone, cartilage, and cardiovascular systems.

Mesoblast's technology enables the repeatable, rapid and safe isolation of highly specialised adult stem cells from a donation of bone marrow in much the same way as blood is donated. Cells are isolated in 1 to 2 hours using monoclonal antibodies and are expanded over a 4 to 6 week period in a fully Good Manufacturing Practice (GMP) compliant facility.

The expansion, or cell division process, enables the production of sufficient numbers of new adult stem cells from one donor to produce potentially hundreds of doses for the treatment of a variety of degenerative diseases in an extremely safe and proven environment. The new cells may be frozen indefinitely and made available immediately to many unrelated patients at the time and place of need.

### What Differentiates Mesoblast's Technology?

Mesoblast's technology ensures that its starting population of adult stem cells is up to 1000-fold purer.

Mesoblast's adult stem cells have been shown in pre-clinical studies to both create new blood vessels and stimulate cells at the site of damage to repair themselves, as well as providing functional cells to the region of tissue in need of repair.

Because Mesoblast's cells do not cause an immune reaction, Mesoblast's cultured cells obtained from a single universal donor can be used to treat many unrelated individuals, making the treatment cost effective, accessible to many patients, and a high-margin enterprise for the company.

### What Ensures Mesoblast's World-Leading Position...Our Intellectual Property

The basis to Mesoblast's technology is a patented ability to accurately characterise, select and greatly expand or multiply a population of adult stem cells known as Mesenchymal Precursor Cells or MPCs.

These cells are known to exist in all people and appear to be a mature and stable progenitor for the repair of damaged and diseased cells. The MPCs can differentiate into a variety of cell types including bone, cartilage, fat, and heart tissue, and to propagate significant blood supply.

### What Ensures Mesoblast's World-Leading Key Patent Granted

The company has a broad international strategy to protect and build upon its technology platform, which has been developed over a 10-year period.

IP Australia has now granted a patent that covers the composition of matter relating to MPCs as well as methods associated with purifying and enriching these cells.

The granted patent is fundamental to Mesoblast's commercial model of creating a world leading, adult stem cell platform technology.

Using this patented technology, Mesoblast aims to produce large numbers of stem cells that may be frozen and held in storage for later use as an "off the shelf" product to generate a host of new tissues for the repair and treatment of many diseases. These treatments cover major markets associated with bone repair, arthritis, spine disease, and heart or vascular diseases.

This newly granted patent further strengthens Mesoblast's overall leadership position in tissue regeneration, and expands the company's commercial opportunities.

### Funding

Mesoblast is adequately funded to meet its IPO goals, remains on budget and is well ahead of schedule.

At 31 December 2005, Mesoblast had cash reserves of over \$12.0 million whilst our American sister company, Angioblast Systems Inc., had cash reserves of approximately \$1.3 million. Since Mesoblast and Angioblast are using their funds to jointly develop and commercialise the platform adult stem cell technology, the total of funds available at the end of the 2005 calendar year for product development was \$13.3 million.

The \$2.7 million Commercial Ready Award will enable Mesoblast to commence its additional cartilage programs without affecting its planned budgetary allocations for its ongoing programs as outlined in its annual report.

### ADR Program

Under approval by the US Securities and Exchange Commission, American investors are now purchasing Mesoblast American Depositary Receipts on the US Over-the-Counter market. Mesoblast ADRs are trading under the code of MBLTY.

The Bank of New York had been appointed as the depositary bank to manage the ADR program on behalf of Mesoblast. Further information can be obtained from the Bank of New York's ADR website - [www.adrbny.com](http://www.adrbny.com)

### Conclusion

2006 is an exciting year for the company. Major milestones will include rapid progress of at least two pilot clinical trials in Australia - for the treatment of multi-vessel coronary artery disease and for the treatment of non-union large bone fractures.

Our principal objective for 2006 is to seek FDA approval and to commence Phase II clinical trials in the United States.

Importantly, the company will look to regularly communicate with its shareholders and the investment community on outcomes associated with its pre-clinical and clinical trials.

**Melbourne, Australia; 28 February 2006**



Level 39, 55 Collins Street Melbourne  
Victoria 3000 AUSTRALIA

t +61 3 9639 6036

f +61 3 9639 6030

ACN 109 431 870

[www.mesoblast.com](http://www.mesoblast.com)