mesoblast

investor update

ISSUE SEVEN

FDA Clearance Positions Mesoblast To Commercialise Stem Cell Products In World's Largest Health Care Market

Mesoblast has achieved a tremendous amount in a very short timeframe, and has now reached a significant new stage of maturity characterised by upcoming commencement of human Phase 2 clinical trials in the United States, the world's largest health care market.

The company is focused upon bringing to market a safe, high profit margin, allogeneic (unrelated or 'off the shelf') adult stem cell product for the effective treatment of a broad range of orthopaedic conditions.

Highlights during the final quarter of 2006 included:

- United States Food and Drug Administration (FDA) clearance of Mesoblast's spinal fusion Investigational New Drug (IND) submission
- Further positive results from clinical and pre-clinical trials;
- Granting of a key patent in the US; and
- Shareholder approval for additional investment in Mesoblast's US-based sister company, Angioblast Systems, Inc.

What does FDA clearance mean to the Company?

In order to commercialise our products in the world's largest health care market, the United States, we must receive FDA clearances for clinical trials and ultimately approval of safety and efficacy endpoints for product sales.

Our FDA submission in November 2006 contained detailed results of our product manufacturing and scale-up processes, our large animal studies, and our pilot clinical trials. Its rapid clearance enables us to map out our clinical timelines to product registration, and consequently product commercialisation.

FDA clears Mesoblast's Phase 2 clinical trial submission

The major highlight of the past quarter occurred on 18 December 2006 when Mesoblast received clearance of its IND submission from the FDA to commence a Phase 2 Clinical Trial for spinal fusion in the United States.

FDA clearance was received within 30 days of the Company's filing its IND application, demonstrating the strength and robustness of the data package submitted by the Company. Importantly, the IND submission and clearance were key milestone targets outlined in the company's IPO Prospectus in December 2004, and were accomplished over 6 months ahead of schedule.

Results of the Phase 2 trial will be used to support a pivotal Phase 3 clinical trial of Mesoblast's patented technology for spinal fusion, aiming to eliminate the need for autograft (or patient's own hip bone graft), reduce complications associated with existing treatment regimens, and improve fusion outcomes.

Equally as important is the progress made by Angioblast which is focused on commercialising the same platform stem cell technology for the treatment of cardiovascular diseases.

Angioblast has completed final pre-IND meetings with the FDA and, based on these as well as ongoing discussions with potential strategic partners, is in final preparations to complete its IND submission for a first cardiovascular clinical indication by the end of this quarter. In this case, Angioblast will seek to be the first company to receive FDA clearance to test catheter-based delivery of allogeneic cells in patients with heart attacks.

The road to US product registration

Clinical trials

CY Q1 2007	FDA IND submission for Phase 2 trial in first cardiac application
CY Q2 2007	Phase 2 spinal fusion allogeneic trial begins in US
CY Q2 2007	Pilot Trial long bone fractures enrolment complete
CY Q2 2007	Pilot Trial severe coronary artery disease enrolment complete
CY Q3 2007	Phase 2 allogeneic trial for heart attacks begins in US
CY 2008	Additional Phase 2 orthopaedic and cardiac trials commence
CY 2008	Allogeneic Phase 2 spinal fusion and first cardiac trials complete
>2008	Pivotal/Phase 3 registration trials commence in lead orthopaedic and cardiac indications

How does FDA clearance affect potential commercial partnerships and opportunities?

Both Mesoblast and Angioblast have established successful collaborative relationships with major device and pharmaceutical organisations in the execution of preclinical and clinical trials.

To date, these relationships have focused on ways to optimise delivery of our cells in the treatment of orthopaedic and cardiovascular diseases using carriers and devices that are today commonly used by physicians.

Completion of Phase 2 clinical trials will be followed by progression to pivotal Phase 3 registration trials. Commercial sales and distribution arrangements for our stem cell products may very well need to be in place prior to completion of these trials, and therefore with FDA clearance to move into each additional Phase 2 clinical trial, and with positive Phase 2 results, the partnering opportunities for each company will greatly expand and accelerate.

What clinical and preclinical results were reviewed by the FDA?

FDA clearance to begin Phase 2 clinical trials entailed a comprehensive review of all data that had been accumulated by the company over the past two years in respect of our manufacturing processes, the safety endpoints following cell implantation in patients and animals, and the effectiveness of the therapy to support progressing to larger human trials.

Specifically:

- We have successfully accomplished large scale manufacture of a well characterised, uniform, and safe 'off the shelf' stem cell product. This product is generated using our proprietary process through large scale expansion of stem cells obtained from one donor for the treatment of as many as thousands of unrelated (allogeneic) patients with various orthopaedic conditions.
- We have successfully completed a number of large animal preclinical trials, demonstrating that our allogeneic stem cells are very effective for inducing bone growth in various indications such as spinal fusion and long bone defects.
- Our two clinical trials in Australia evaluating the safety and feasibility of the Company's Standard Operating Procedures and cell implantation in patients with orthopaedic and cardiovascular conditions are progressing well. During the last quarter of 2006, Mesoblast reported periodically on some extremely exciting progress made to date in these trials. While formal conclusion of both pilot trials is at the sole discretion of the principal investigators, the company believes that its objectives in establishing the safety of implanting our proprietary stem cells have already been accomplished.

Since product sales and commercialisation ultimately requires FDA approval, FDA clearance of our IND submission underpins our product commercialisation strategy to produce a unique high margin, allogeneic adult stem cell product. This product is obtained from a single donor, commercially expanded and frozen, and subsequently used in potentially thousands of unrelated, or allogeneic, recipients at the time and place of need. Mesoblast's patented technology produces a well characterised product with defined purity and demonstrated potent biological activity.

How do we protect our commercial accomplishments?

On 18 October 2006, Mesoblast announced that the United States Patent and Trade Mark Office (USPTO) had granted a key patent covering composition-of-matter over a unique population of adult stem cells which we refer to as Mesenchymal Precursor Cells or MPCs. These cells enable regeneration and repair of a host of tissues including bone, cartilage, fat, blood vessels and heart muscle. The patent confers rights through at least the year 2019 and will underpin our exclusive rights to commercialise MPC products in the world's largest health sector market.

"Patents are the lifeblood of the Company, and granting of patents in various jurisdictions protect our commercial rights and ensure we have freedom to operate commercially. The company is absolutely committed to the ongoing expansion, broadening, and development of our intellectual property portfolio" – Mesoblast Founder and Chief Scientific Adviser, Professor Silviu Itescu.

Strong cash position and further investment in Angioblast Systems Inc

At 31 December 2006, Mesoblast had cash reserves of more than $15.7 million.

The financial results for the six months to 31 December 2006 showed a net loss of $3,969,751 whilst the comparative figure for the six months to 31 December 2005 was $2,883,547. The increased net loss directly related to the increase in activity and operations of the company in achieving its core milestones. Revenue for the period was $1,101,776 as compared to $883,586. In line with Mesoblast's accounting practices, all development expenditure associated with bringing the technology to market is expensed.

The company's financial results are in line with our forecasts and reflect the ongoing and significant activity associated with the rapid commercialisation of Mesoblast's specialist adult stem cell technology. Importantly, the Board of Directors believes that there are sufficient funds on hand to meet the Company's immediate objectives.

An Extraordinary General Meeting on 23 November 2006 approved an additional $8.5 million investment in Angioblast to complete a Phase 2 clinical trial using the proprietary adult stem cell technology for an agreed cardiovascular indication. These funds will be paid by Mesoblast in tranches to achieve critical Phase II clinical trial milestones. Combined with the proposed investment is a 15 month option for Mesoblast to acquire a further $5 million in Angioblast preferred stock on substantially similar terms and pricing.

"The further investment by Mesoblast in Angioblast will enable both companies to continue their focus on delivering clinical trial results and shareholder value, whilst enabling a further strengthening of our relationships. Importantly, the investment will enable both Mesoblast and Angioblast to focus on delivering significant shareholder value through completion of Phase II clinical trials." – Mesoblast Executive Chairman, Mr Michael Spooner.

Equally, the investment is intended to provide both companies with a position of strength in any potential discussions with large, third party, medical device and pharmaceutical companies.

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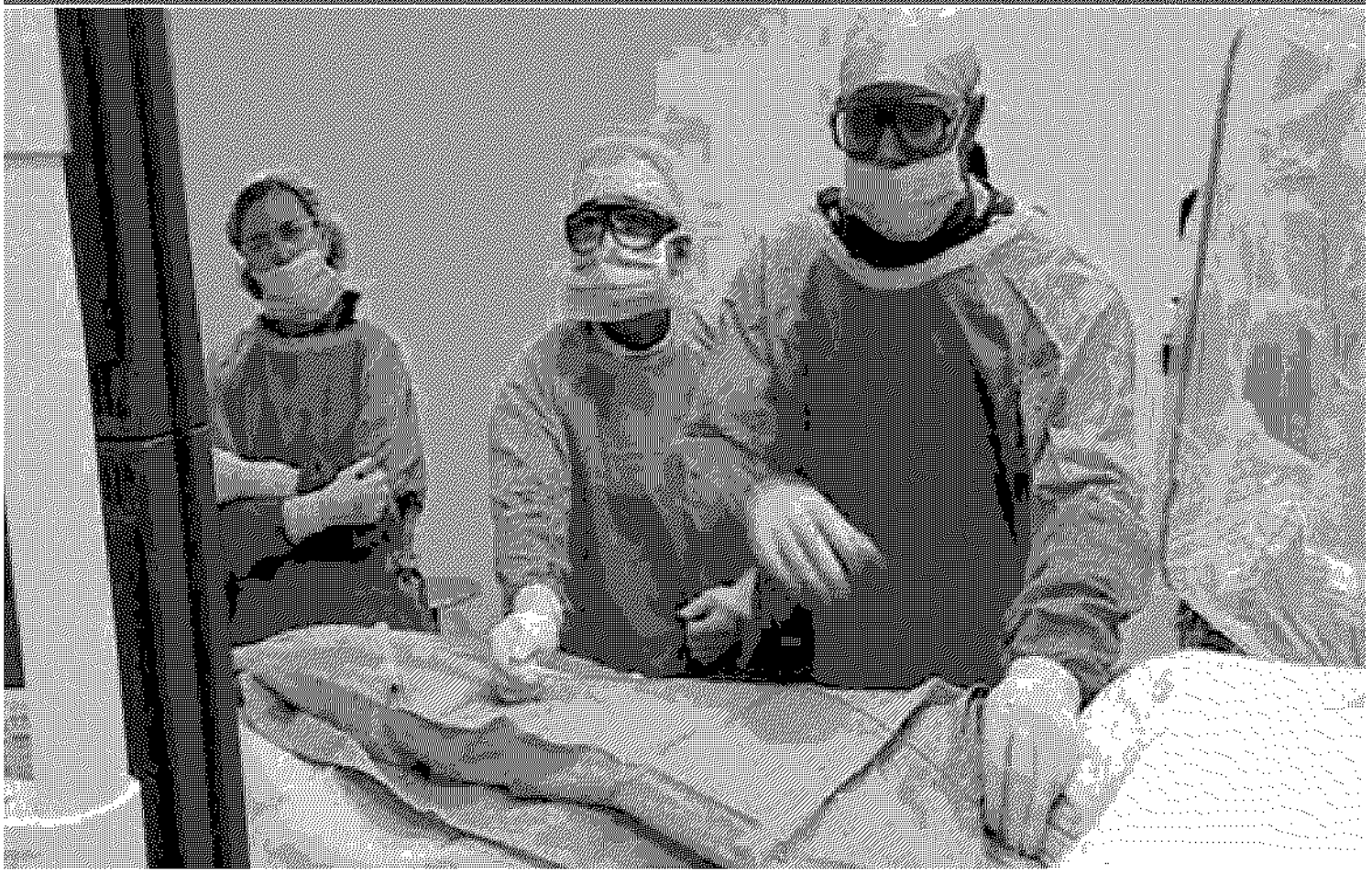
Stem cell catheter delivery procedure

A catheter based procedure to deliver our patented adult stem cells into the heart of a patient with multi-vessel coronary artery disease and heart failure was televised live to an international gathering of leading cardiologists attending the Asia Pacific Interventional Advances Conference (APIA) in Sydney last December.

The highlighted procedure was performed under a local anaesthetic at the John Hunter Hospital in New South Wales by interventional cardiologist and Hunter Medical Research Institute researcher, Dr Ilyas Thambar.

television coverage of the live procedure showed Dr Thambar using the latest generation NOGA catheter mapping system for stem cell delivery from Johnson & Johnson's Cordis Corporation to deliver our proprietary stem cells to the damaged heart.

The procedure was part of our clinical trial over a 12-month period of 10 patients suffering from severe coronary artery disease. Millions of people worldwide suffer from severe coronary artery disease. Our adult stem cell technology aims to improve cardiac function by creating new blood supply and regenerating heart muscle.



A news item on Channel 9 highlighted a live stem cell procedure using Mesoblast technology and the latest generation mapping system for stem cell delivery from Johnson & Johnson's Cordis Corporation

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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