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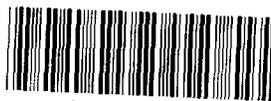
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OFFICE OF INTERNATIONAL  
CORPORATE FINANCE



22 May 2006

US Securities and Exchange Commission  
Office of International Corporate Finance  
100 F Street, N.E.  
WASHINGTON DC 20549  
USA  
Mailstop: Room 3628



06013834

**SUPPL**

Dear Sirs

**Re: Submission by Mesoblast Limited under Rule 12g3-2(b) - SEC File Number 82-34929**

We enclose copies of all documents lodged with the Australian Securities Commission on behalf of Mesoblast Limited for filing with the US Securities & Exchange Commission.

These lodgements date from 14 April 2006 to the present date 22 May 2006.

Yours sincerely

Kevin Hollingsworth  
Company Secretary

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MAY 31 2006

STHOMSON  
FINANCIAL

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

ABN 68 109 431 870  
ACN 109 431 870

## asx announcement

### **Next Generation Drug Eluting Stent Technology For Coronary And Peripheral Artery Disease**

**Melbourne, Australia; 22 March 2006:** Mesoblast Limited (ASX:MSB) today announced that its American sister company, Angioblast Systems Inc, has obtained an exclusive, worldwide license to commercialise next generation drug-eluting stent technology for the multi-billion dollar markets in the frontline treatment of coronary and peripheral artery disease.

This technology was developed at the internationally acclaimed Columbia University in New York.

Diseases of the coronary or peripheral arteries affect a great proportion of the population and are major causes of mortality and morbidity, resulting in severe pain, heart failure, and limb amputation. Almost two million patients with these conditions are treated with stents annually in the United States alone.

"The Columbia University technology is at an advanced stage of development," the company's Chief Scientific Advisor, Professor Silviu Itescu, said today.

"It shows tremendous promise for 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 our adult stem cell products in the treatment of patients with heart attacks or peripheral artery disease.

"Our immediate goal is to obtain early regulatory approval for the stents as medical devices.

"The timelines for this will fit neatly within our existing adult stem cell regulatory programs," Professor Itescu said.

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 massive market potential.

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## asx announcement

### **About Mesoblast Limited:**

Mesoblast Limited (ACN 109 431 870) is an Australian biotechnology company committed to the development of novel treatments for orthopaedic conditions, including the rapid commercialisation of a unique adult stem cell technology aimed at the regeneration and repair of bone and cartilage. Our focus is to progress through clinical trials and international regulatory processes necessary to commercialise the technology in as short a timeframe as possible. Mesoblast Limited, which listed on the Australian Stock Exchange in December 2004, has the worldwide exclusive rights for a series of patents and technologies that have been developed over more than 10 years and which relate to the identification, extraction and culture of adult Mesenchymal Precursor Cells (MPCs). The technology has achieved outstanding results in pre-clinical in vivo studies in the regeneration and repair of large bone fractures.

The company has also acquired a 33.3% interest in Angioblast Systems Inc, an American company developing the platform MPC technology for the treatment of cardiovascular diseases, including repair and regeneration of blood vessels and heart muscle. Mesoblast and Angioblast are jointly funding and progressing the core technology. Mesoblast's strategy is to maximise shareholder value through both corporate partnerships and the rapid and successful completion of pre-clinical and clinical milestones.

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## asx announcement

### **FIRST PATIENT RECEIVES ADULT STEM CELLS FOR REPAIR OF LONG BONE FRACTURE**

**Melbourne, Australia; 3 April 2006:** Australia's adult stem cell company, Mesoblast Limited (ASX:MSB), today announced that a first orthopaedic patient had been safely implanted with the company's specialist adult stem cells developed using its unique and proprietary technology.

The Director of Orthopaedics at The Royal Melbourne Hospital, Mr Richard de Steiger, said today that the patient was in a stable condition after the procedure and was expected to be released from hospital shortly.

"The patient had sustained a major fracture of his femur some nine months ago, which had not healed and resulted in a 5 cm defect," he said. "For this type of non-healing defect, we would typically consider a bone graft using a large amount of bone taken from the patient's own hip. However, this often results in long-term complications including pain and possible infection. The use of adult stem cells could result in the healing of the defect without the complications of a bone graft taken from a separate incision.

"If successful, 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 de Steiger said.

The Pilot Trial at the Royal Melbourne Hospital is an independent assessment of the safety of Mesoblast's specialist adult stem cell technology.

This Pilot Trial will involve up to 10 patients suffering from non-union, long bone fractures. 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.

Mesoblast's focus is firmly on the successful completion of this Pilot Trial and to ensure that the public and market is kept informed of the company's ongoing progress.

Periodic market updates to the Australian Stock Exchange will focus on outcomes of the entire trial rather than the details of an individual patient.

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## asx announcement

### **About Mesoblast**

Mesoblast Limited (ASX:MSB) is an Australian biotechnology company committed to the development of novel treatments for orthopaedic conditions, including the commercialisation of a unique adult stem cell technology aimed at the regeneration and repair of bone and cartilage.

Mesoblast has the worldwide exclusive rights for a series of patents and technologies that have been developed over more than 10 years and which relate to the identification, extraction and culture of adult Mesenchymal Precursor Cells (MPCs). The technology has achieved outstanding results in pre-clinical in vivo studies in the regeneration and repair of large bone fractures.

Mesoblast is focused on delivering a safe and effective cell therapy product for a number of substantial, unmet, orthopaedic markets where current treatment regimes may be significantly improved upon. The company's goal is to deliver a product which reduces the overall cost of medical treatment whilst dramatically improving patient outcomes and long term quality of life.

### **About The Royal Melbourne Hospital**

The Royal Melbourne Hospital is one of Victoria's leading public teaching hospitals and a level one trauma centre, providing acute tertiary referral service at its City site and aged care, rehabilitation, ambulatory care and residential and community services at its Royal Park Campus.

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Rod Jackson-Smith  
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The Royal Melbourne Hospital  
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## asx announcement

### MESOBLAST NATIONAL TELEVISION COVERAGE

**Melbourne, Australia; 6 April 2006:** Australian adult stem cell company, Mesoblast Limited (ASX:MSB), today confirmed that national television news items broadcast on Channel 9, ABC-TV and Channel 7 last night focused on its adult stem cell orthopaedic trial at The Royal Melbourne Hospital.

Executive Chairman, Mr Michael Spooner, said the coverage included interviews with the first patient involved in the orthopaedic trial using Mesoblast's specialist mesenchymal precursor cells and the hospital's Director of Orthopaedics, Mr Richard de Steiger.

In line with clinical trial protocols and The Privacy Act, Mesoblast will not publish the patient's name.

In the interests of fair and full disclosure, transcripts of the ABC-TV, Channel 9 and Channel 7 news items follow.

#### ABC-TV News - 5 April 2006

**Newsreader:** Australian scientists have started using stem cells to repair fractures in patients whose bones won't heal. The new therapy promises to spare the many painful and often expensive operations.

**Reporter:** The 21-year-old (patient) fell off his motorbike nine months ago, fracturing his thigh bone. It didn't heal, leaving a five-centimetre gap. The usual treatment would be to graft a new bone from his hip. Instead, he was chosen as the first Australian patient to get an injection of specially treated stem cells.

**Patient:** I think the benefits outweigh, sort of, the old procedure. Being able to not have big chunks of bone taken out of my hip.

**Dr Richard de Steiger, Royal Melbourne Hospital:** What's radical is it's the first procedure in the world to use a patient's own stem cells and make them turn into bone forming cells.

**Reporter:** Stem cells were taken from (the patient's) bone marrow, then treated and purified. Surgeons at the Royal Melbourne Hospital placed a tiny scaffold made of calcium into the bone and injected the cells inside. So far the signs are that the procedure went well.

**Mr de Steiger:** We won't know the true success of the operation until we find out if his bone has healed. And that will be maybe 12 to 16 weeks away.

**Reporter:** Nine other patients with bone fractures will have the procedure. A similar technique used stem cells to treat patients with heart failure.

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### Channel 9 News – 5 April 2006

**Newsreader:** A 21-year-old man is the first in the world to undergo radical new surgery using stem cells to mend his broken leg. Surgeons involved in the clinical trial claim the procedure is a promising alternative for patients with problem fractures.

**Reporter:** Still sore and swollen, (the patient) is showing positive signs of recovery after having surgery to fix his leg, fractured in a motorbike accident last year. He's the first person to ever undergo this type of stem cell procedure.

**Patient:** Pretty happy to be the first one to do it. I wouldn't say I understand it, but it's all pretty, you know, sort of new, so ...

**Dr Richard de Steiger, Royal Melbourne Hospital:** What's radical it's the first procedure in the world to use a patient's own stem cells and make them turn into bone forming cells.

**Reporter:** A titanium rod used to mend his thighbone didn't work and, as a result, a large cavity remained, so surgeons turned to cutting edge science. (The patient's) own stem cells taken from his bone marrow were grown in the lab.

**Mr de Steiger:** We have to actually take the injection from the pelvis, grow the cells which takes six weeks or so to multiply into millions and millions of cells, before we can go back in and inject them.

**Reporter:** The specialised cells coat two scaffolding pads made of calcium phosphate to form part of the implant. (The patient) preferred the technique to a hip bone graft.

**Patient:** I've been able to not have big chunks of bone taken out of my hip.

**Reporter:** (The patient) is the first of 10 patients to be recruited for the year long trial. The results of his operation won't be known for at least three months. But he's already looking to the future.

**Patient:** Being able to get fit again.

## asx announcement

### Channel 7 News – 5 April 2006

**Newsreader:** Melbourne doctors have become the first in the world to use stem cells to treat broken bones. The breakthrough could mean the end of painful bone grafts for patients whose fractures refuse to heal.

**Reporter:** At 21, (patient's name) doesn't know much about stem cells.

**Patient:** I wouldn't say I understand it.

**Reporter:** But he does know they could be the remedy for a fractured leg which has refused to heal for nine months. He's undergone a breakthrough stem cell implant at the Royal Melbourne Hospital.

**Dr Richard de Steiger, Royal Melbourne Hospital:** It's radical and it's the first procedure in the world to use a patient's own stem cells and make them turn into bone forming cells.

**Reporter:** Surgeons took bone marrow from (the patient's) hip and in the lab grew thirty million stem cells, which were turned into a paste. They were attached to a calcium scaffold and packed into the large hole in his femur.

**Mr de Steiger:** With time this should then become his own bone.

**Reporter:** Were it not for this procedure, (the patient) would have undergone a painful graft using bone from his hip. While the 10-person trial has just begun, doctors are excited.

**Mr de Steiger:** There are many applications hopefully to growing new bone. People have had bone that's died for some reason; we can stimulate new bone growth.

**Reporter:** The question now is whether the procedure has worked. Doctors will know in three to four months but say early signs are promising. The patient hopes will be his cure.

**Patient:** Getting back to work, just getting back to have my own life.

**End of segments**

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### **About Mesoblast Limited:**

Mesoblast Limited (ACN 109 431 870) is an Australian biotechnology company committed to the development of novel treatments for orthopaedic conditions, including the rapid commercialisation of a unique adult stem cell technology aimed at the regeneration and repair of bone and cartilage. Our focus is to progress through clinical trials and international regulatory processes necessary to commercialise the technology in as short a timeframe as possible. Mesoblast Limited, which listed on the Australian Stock Exchange in December 2004, has the worldwide exclusive rights for a series of patents and technologies that have been developed over more than 10 years and which relate to the identification, extraction and culture of adult Mesenchymal Precursor Cells (MPCs). The technology has achieved outstanding results in pre-clinical in vivo studies in the regeneration and repair of large bone fractures. The company has also acquired a 33.3% interest in Angioblast Systems Inc, an American company developing the platform MPC technology for the treatment of cardiovascular diseases, including repair and regeneration of blood vessels and heart muscle. Mesoblast and Angioblast will jointly fund and progress the core technology. Mesoblast's strategy is to maximise shareholder value through both corporate partnerships and the rapid and successful completion of pre-clinical and clinical milestones.

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## POSITIVE RESULTS CONFIRM SPINAL FUSION AS MAJOR MARKET FOR MESOBLAST

### Key points:

- Mesoblast's adult stem cells highly effective for induction of spinal fusion, with efficacy proportional to stem cell dose
- Results are equal to or better than current gold standard treatment for degenerative intervertebral disc disease (autograft), indicating that Mesoblast's therapy can eliminate need for second operation to harvest bone
- Spinal fusion is a major and growing market
- Mesoblast to proceed with FDA Phase II clinical trial submission for spinal fusion
- Further validation of Mesoblast's unique business model to produce an "off-the-shelf" adult stem cell product for multiple unrelated recipients.

**Melbourne, Australia; 27 April 2006:** Mesoblast Limited (ASX:MSB) today announced positive results from a pre-clinical trial of its proprietary adult stem cells for spinal fusion.

Mesoblast Founder and Chief Scientific Adviser, Professor Silviu Itescu, said the results 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. The extent of bony fusion seen was in proportion to stem cell dose escalation.

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. Current fusion therapies use bone harvested from a patient's own hip (termed autograft), and require a second surgical procedure that frequently results in long-term complications such as chronic pain and infection.

"The results showed that bony spinal fusion in the stem cell-treated recipients was significantly superior to controls. 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 Itescu said.

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"This indicates that Mesoblast's therapy may eliminate the need for a second surgical procedure and its potential complications. Moreover, this is a major step forward in proving the company's primary business model to develop an off-the-shelf cell therapy product for bone regeneration", he added.

The study was one of several pre-clinical trials being conducted at Colorado State University in the United States to evaluate the safety and efficacy of Mesoblast's proprietary adult stem cell technology for the regeneration of bone, including long bone fractures and spinal fusion. In this study, 34 sheep underwent a standard surgical model for spinal fusion. The company's adult stem cell technology was used in increasing dosages to treat 20 animals, there were 10 controls, and 4 received autograft. At four months, the results were analysed by independent blinded investigators.

The data collected from the pre-clinical trials are essential to the company's Investigational New Drug (IND) submissions to the United States Food and Drug Administration (FDA). In line with the study's protocols, final safety data will be produced at the conclusion of the study, scheduled for early third quarter 2006.

In view of the strength of the data generated, the company intends to file a Phase II IND clinical trial submission for spinal fusion to the FDA. The submission is expected by 4<sup>th</sup> quarter 2006 and over 6 months ahead of Mesoblast's original schedule.

### **About Mesoblast Limited**

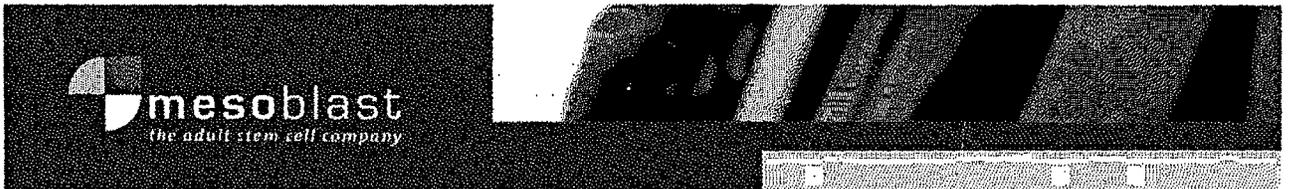
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## asx announcement

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## asx announcement

### MESOBLAST ANNOUNCES STRONG CASH POSITION FOR ADULT STEM COMMERCIALISATION

**Melbourne, Australia; 28 April 2006:** Australia's adult stem company, Mesoblast Limited (ASX:MSB), today announced cash reserves of \$9.2 million at 31 March 2006.

Executive Chairman, Mr Michael Spooner, said that the company was adequately funded to reach its primary goal of filing an Investigational New Drug (IND) submission to the United States Food & Drug Administration (FDA) for a lead orthopaedic application by the fourth quarter of 2006.

Mr Spooner said the cash reserves included an initial payment of \$431,000 through 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.

"This brings the total of funds available for jointly developing and progressing the platform technology to \$10.86 million.

"The financial results are in line with our forecasts and reflect the rapid pace of commercialisation including undertaking two human clinical trials for an orthopaedic and a cardiovascular indication plus extensive pre-clinical trial work required for the FDA submission.

"In line with Mesoblast's accounting practices, all development expenditure associated with bringing the technology to market is being fully expensed," Mr Spooner added.

#### About Mesoblast

Mesoblast Limited (ACN 109 431 870) is an Australian biotechnology company committed to the development of novel treatments for orthopaedic conditions, including the rapid commercialisation of a unique adult stem cell technology aimed at the regeneration and repair of bone and cartilage. Our focus is to progress through clinical trials and international regulatory processes necessary to commercialise the technology in as short a timeframe as possible. Mesoblast Limited, which listed on the Australian Stock Exchange in December 2004, has the worldwide exclusive rights for a series of patents and technologies that have been developed over more than 10 years and which relate to the identification, extraction and culture of adult Mesenchymal Precursor Cells (MPCs). The technology has achieved outstanding results in pre-clinical in vivo studies in the regeneration and repair of large bone fractures.

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DEPARTMENT OF COMMUNICATIONS



## asx announcement

Mesoblast has also acquired a 33.3% interest in Angioblast Systems Inc, an American company developing the platform MPC technology for the treatment of cardiovascular diseases, including repair and regeneration of blood vessels and heart muscle. Mesoblast and Angioblast are jointly funding and progressing the core technology. Mesoblast's strategy is to maximise shareholder value through both corporate partnerships and the rapid and successful completion of pre-clinical and clinical milestones.

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## Appendix 4C

### Quarterly report for entities admitted on the basis of commitments

Introduced 31/3/2000. Amended 30/9/2001

Name of entity

Mesoblast Limited

ABN

68 109 431 870

Quarter ended ("current quarter")

31 March 2006

#### Consolidated statement of cash flows

Cash flows related to operating activities	Current quarter \$A'000	Year to date \$A'000
1.1 Receipts from customers		
Government grant received	431	431
1.2 Payments for		
(a) staff costs		
(b) advertising and marketing		
(c) research and development		
(d) leased assets		
(e) other working capital		
1.3 Dividends received		
1.4 Interest and other items of a similar nature received	126	453
1.5 Interest and other costs of finance paid		
1.6 Income taxes paid		
1.7 Other (provide details if material)		
Commercialisation costs	(1,068)	(2,486)
General Administration	(285)	(1,176)
<b>Net operating cash flows</b>	<b>( 796)</b>	<b>(2,778)</b>

+ See chapter 19 for defined terms.

**Appendix 4C**  
**Quarterly report for entities**  
**admitted on the basis of commitments**

	Current quarter \$A'000	Year to date \$A'000
1.8 Net operating cash flows (carried forward)	(796)	(2,778)
<b>Cash flows related to investing activities</b>		
1.9 Payment for acquisition of: (a) businesses (item 5)		
(b) equity investments (see attached note 4)	(2,000)	(3,000)
(c) intellectual property	(29)	(90)
(d) physical non-current assets		
(e) other non-current assets		
1.10 Proceeds from disposal of: (a) businesses (item 5)		
(b) equity investments		
(c) intellectual property		
(d) physical non-current assets		
(e) other non-current assets		
1.11 Loans to other entities		
1.12 Loans repaid by other entities	61	(14)
1.13 Other (provide details if material)	-	4
<b>Net investing cash flows</b>	<b>(1,968)</b>	<b>(3,100)</b>
<b>1.14 Total operating and investing cash flows</b>	<b>(2,764)</b>	<b>(5,878)</b>
<b>Cash flows related to financing activities</b>		
1.15 Proceeds from issues of shares, options, etc.		
1.16 Proceeds from sale of forfeited shares		
1.17 Proceeds from borrowings		
1.18 Repayment of borrowings		
1.19 Dividends paid		
1.20 Other (Government grant receivable)		
<b>Net financing cash flows</b>	<b>-</b>	<b>-</b>
<b>Net increase (decrease) in cash held</b>	<b>(2,764)</b>	<b>(5,878)</b>
1.21 Cash at beginning of quarter/year to date	11,980	15,094
1.22 Exchange rate adjustments to item 1.20		
<b>1.23 Cash at end of quarter</b>	<b>9,216</b>	<b>9,216</b>

+ See chapter 19 for defined terms.

**Payments to directors of the entity and associates of the directors**

**Payments to related entities of the entity and associates of the related entities**

		Current quarter \$A'000
1.24	Aggregate amount of payments to the parties included in item 1.2	129
1.25	Aggregate amount of loans to the parties included in item 1.11	(61)

1.26 Explanation necessary for an understanding of the transactions

Silviu Itescu	41
Byron McAllister	10
Michael Spooner	69
Donal O'Dwyer	9

**Non-cash financing and investing activities**

- 2.1 Details of financing and investing transactions which have had a material effect on consolidated assets and liabilities but did not involve cash flows

N/A
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- 2.2 Details of outlays made by other entities to establish or increase their share in businesses in which the reporting entity has an interest

N/A
-----

**Financing facilities available**

N/A

*Add notes as necessary for an understanding of the position. (See AASB 1026 paragraph 12.2).*

		Amount available \$A'000	Amount used \$A'000
3.1	Loan facilities		
3.2	Credit standby arrangements		

+ See chapter 19 for defined terms.

**Appendix 4C**  
**Quarterly report for entities**  
**admitted on the basis of commitments**

**Reconciliation of cash**

Reconciliation of cash at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts is as follows.	Current quarter \$A'000	Previous quarter \$A'000
4.1 Cash on hand and at bank	136	399
4.2 Deposits at call	418	2,919
4.3 Bank overdraft		
4.4 Other – Term Deposits	8,662	8,662
<b>Total: cash at end of quarter (item 1.22)</b>	<b>9,216</b>	<b>11,980</b>

**Acquisitions and disposals of business entities**      **N/A**

	Acquisitions <i>(Item 1.9(a))</i>	Disposals <i>(Item 1.10(a))</i>
5.1 Name of entity		
5.2 Place of incorporation or registration		
5.3 Consideration for acquisition or disposal		
5.4 Total net assets		
5.5 Nature of business		

**Compliance statement**

- 1 This statement has been prepared under accounting policies which comply with accounting standards as defined in the Corporations Act (except to the extent that information is not required because of note 2) or other standards acceptable to ASX.
- 2 This statement does give a true and fair view of the matters disclosed.



Sign here: ..... Date: ....28 April 2006.....  
 (Company secretary)

Print name: Kevin Hollingsworth

+ See chapter 19 for defined terms.

## Notes

1. The quarterly report provides a basis for informing the market how the entity's activities have been financed for the past quarter and the effect on its cash position. An entity wanting to disclose additional information is encouraged to do so, in a note or notes attached to this report.
  
2. The definitions in, and provisions of, *AASB 1026: Statement of Cash Flows* apply to this report except for the paragraphs of the Standard set out below.
  - 6.2 - reconciliation of cash flows arising from operating activities to operating profit or loss
  - 9.2 - itemised disclosure relating to acquisitions
  - 9.4 - itemised disclosure relating to disposals
  - 12.1(a) - policy for classification of cash items
  - 12.3 - disclosure of restrictions on use of cash
  - 13.1 - comparative information
  
3. **Accounting Standards.** ASX will accept, for example, the use of International Accounting Standards for foreign entities. If the standards used do not address a topic, the Australian standard on that topic (if any) must be complied with.
  
4. Item 1.9 (6) – equity investment – A\$1 million

The equity investment relates to Section 1.4 (1) of the Supplementary Prospectus which reflects the agreement that on completion of the Mesoblast offer and its ASX listing, Mesoblast would pay A\$2 million to Angioblast Systems Inc. as the first instalment to acquire 33.3 percent of equity interest in Angioblast Systems Inc. Mesoblast would then continue to pay quarterly instalments of A\$1 million to Angioblast Systems Inc. up until quarter ending 31 December 2006.

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+ See chapter 19 for defined terms.

## Significant progress toward achieving clinical trial goals

### Key points:

- Eight patients enrolled in two clinical trials
- The company is confident that manufacturing Standard Operating Procedures and cell products are safe
- Achievement of these key operational milestones paramount to rapid global commercialisation

**Melbourne, Australia; 16 May 2006:** Mesoblast Limited (ASX:MSB) today provided an update to financial markets on the significant progress that has been made during the conduct of the two Pilot Clinical Trials currently being undertaken in Australia using the company's proprietary adult stem cell technology.

The overriding goal of these Pilot Clinical Trials is to validate the company's Standard Operating Procedures (SOPs) in a clinical setting. The specific objectives of the trials are to demonstrate the safety and the feasibility of the SOPs, and so provide complementary data for use by the company in its impending Phase II Investigational New Drug (IND) clinical trial submissions to the United States Food and Drug Administration (FDA). These submissions are of paramount importance to the company and its mission of rapid product commercialisation.

Mesoblast's adult stem cell technology and its SOPs are currently being trialled at the John Hunter Hospital in New South Wales in patients with severe coronary artery disease, and at the Royal Melbourne Hospital in Victoria in patients with long bone fractures that have failed to heal. The conduct of the trials is at the discretion of the medical investigators and the individual hospital ethics committees. To date, the medical investigators participating in the two trials have now 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.

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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 which will increase the likelihood of product commercialisation for massive global markets.

In line with Mesoblast's stated communications protocols for the conduct of the Pilot Clinical Trials, the company will at all times look to ensure the privacy and confidentiality of patients whilst focusing entirely on their well being. Clinical Trial updates will continue to report on the entirety of the trials and will not focus on individual outcomes.

### **About Mesoblast Limited**

Mesoblast Limited (ACN 109 431 870) is an Australian biotechnology company committed to commercialisation of novel treatments for orthopaedic conditions, including a unique adult stem cell technology aimed at the regeneration and repair of bone and cartilage. Mesoblast has worldwide exclusive rights to a series of patents and technologies that have been developed over more than 10 years relating to the identification, extraction and culture of adult Mesenchymal Precursor Cells (MPCs). The company has also acquired a 33.3% interest in Angioblast Systems Inc, an American company developing the platform MPC technology for the treatment of cardiovascular diseases, including repair and regeneration of blood vessels and heart muscle. Mesoblast's strategy is to maximise shareholder value through both corporate partnerships and rapid product commercialisation.

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## **POSITIVE RESULTS IN PRECLINICAL TRIAL FOR HEART FAILURE**

### **Key points:**

- \* Proprietary adult stem cells effective for prevention of heart failure progression

- \* Further validation of the company'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

- \* Heart failure confirmed as major market opportunity

- \* Ahead of schedule for cardiovascular FDA submission

**Melbourne, Australia; 22 May 2006:** Australia's adult stem cell company, Mesoblast Limited (ASX:MSB), today announced positive initial results in preclinical trials of its proprietary adult stem cells for prevention of heart failure progression following a heart attack.

Mesoblast's Founder and Chief Scientific Adviser, Professor Silviu Itescu, said that the initial positive results using adult stem cells from one universal donor to treat unrelated recipients clearly demonstrated the safety of the company's product and validated its plan to develop an "off-the-shelf" cell-based therapy for heart failure.

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. The complete data sets collected from the preclinical trials form an essential component of the Phase II Investigational New Drug (IND) submissions to the US Food and

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Drug Administration (FDA) for treatment of patients with heart failure. These submissions are expected to be filed during the fourth quarter 2006 by Mesoblast's US-based sister company Angioblast Systems, Inc, well ahead of schedule.

Executive Chairman Mr Michael Spooner said: "The positive results obtained with our universal adult stem cells in heart disease are complementary to the results we have previously announced in bone repair. We have now proven that our commercial strategy is viable for the treatment of multiple organ systems. We will obtain our unique adult stem cells from one donor and commercially expand them to produce therapeutic doses for the treatment of potentially hundreds of completely unrelated recipients.

"These results further serve to emphasise our business model - we will produce a low cost and high margin therapy for major orthopaedic and cardiovascular markets," Mr Spooner said.

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