



Biotech Daily

Thursday September 25, 2008

Daily news on ASX-listed biotechnology companies

- * **ASX DOWN, BIOTECHS UP: SUNSHINE HEART UP 10%, PSIVIDA DOWN 12%**
- * **COCHLEAR CEO DR CHRIS ROBERTS TAKES ON AMWU**
- * **SUNSHINE HEART WINS FDA REIMBURSEMENT FOR C-PULSE**
- * **XENOME BEGINS PHASE II TRIAL OF XEN2174 FOR ACUTE PAIN**
- * **STEM CELL GRANTS FOR VICTORIA-CALIFORNIA COLLABORATIONS**
- * **SIRTEX WITHDRAWS FROM UWA APPEAL**
- * **NEURODISCOVERY APPOINTS CHRIS MOYSES CEO**
- * **RESONANCE HEALTH DIRECTOR DR ANDREW WALKER TO RESIGN**
- * **BIO-MELBOURNE CHINA BIO-BREAKFAST**

MARKET REPORT

The Australian stock market fell 0.9 percent on Thursday September 25, 2008 with the All Ordinaries down 47.4 points to 4,960.8 points.

Thirteen of the Biotech Daily Top 40 stocks were up, 10 fell, eight traded unchanged and nine were untraded.

Sunshine Heart was best, up one cent or 10.0 percent to 11 cents on small volumes.

Antisense, Starpharma and Ventracor climbed five percent or more; Cellestis and Chemgenex were up more than four percent; Peplin was up 3.57 percent; Clinuvel, Genetic Technologies, Heartware and Stem Cell rose two percent or more; with Biota up 1.45 percent.

Psivida led the falls, down 35 cents or 11.67 percent to \$2.65 on very small volumes, followed by Alchemia down 9.8 percent to 23 cents.

Arana, Avexa, Bionomics, Living Cell and Prana fell two percent or more; with Cochlear, Phosphagenics, Universal Biosensors and Viralytics down more than one percent.

COCHLEAR

Cochlear's chief executive officer Dr Chris Roberts claims the Australian Manufacturing Workers Union has been running "smear campaigns" against his company.

"Since last year, the AMWU has targeted Cochlear in a series of smear campaigns to further the union's own political agenda," Dr Roberts said in a media release not sent to the ASX.

"The trigger for this was Cochlear moving its workers to individual common law contracts when a collective agreement expired," Dr Roberts said.

He said the union refused to represent Cochlear workers in negotiations for an employee collective agreement, demanding a union collective agreement instead.

AMWU representatives were not available for comment.

Dr Roberts said that "just last month the Australian Industrial Relations Commission confirmed the validity of these individual contracts and that they could remain in place".

He said "the AMWU continued its campaign against Cochlear by engineering for an employee, who happens to be a union delegate, to breach company policy".

"That the AMWU filed an application in the Federal Court for an injunction preventing Cochlear from dismissing the employee, before Cochlear had even investigated the matter, let alone mentioned dismissal, indicates the AMWU's ulterior motives," Dr Roberts said.

He said the employee has been suspended on full pay, pending an investigation.

Dr Roberts said the union made "a baseless and trumped up discrimination complaint against Cochlear for using English in the workplace ... [and] withdrew the case once the media interest in it subsided after the election".

"We are sick of being used in baseless and ill-informed smear campaigns on behalf of the AMWU," Dr Roberts said. "The fact of the matter is that we pay our manufacturing workers wages more than 40 percent above the award rate."

"We have introduced world-class manufacturing processes which the union has on multiple occasions attempted to block," Dr Roberts said.

"As a global leader in implantable hearing solutions and an Australian manufacturer we can ill afford to have our manufacturing processes dictated to us by the self-serving interests of the union," he said

"We will continue to work closely with our employees to serve our mission which is to help people hear now and always," Dr Roberts said.

Cochlear fell 65 cents or 1.09 percent to \$58.78.

SUNSHINE HEART

Sunshine Heart says the US Food and Drug Administration have approved reimbursement category B for its C-Pulse US clinical trial.

The company said the approval would provide reimbursement during the clinical trial, providing an initial revenue stream for the company and making the cost of the C-Pulse aorta pump system eligible for US Medicare reimbursement coverage.

Sunshine Heart together with its clinical sites and regional offices of the Center of Medicare and Medicaid Services will resolve reimbursement amounts.

Sunshine Heart said it had retained Quorum Consulting of San Francisco as its reimbursement consultant.

Sunshine Heart chief executive officer Donald Rohrbaugh said the FDA decision was "another key milestone for the company".

The company said it expected patient enrollment to begin by the end of 2008.

Sunshine Heart climbed one cent or 10 percent to 11 cents.

XENOME

Xenome says it has begun a phase II clinical trial of Xen2174 drug for moderate to severe pain.

The phase II study is the first trial of Xen2174 for the control of acute post-operative pain and will enroll 200 patients at multiple clinical sites in the US.

The study will evaluate the safety and efficacy of Xen2174 administered as a single intrathecal administration to patients undergoing unilateral bunionectomy, a standard and well-accepted model for the assessment of acute pain therapies.

Results from the study will be assessed against multiple safety and efficacy endpoints and will supplement the clinical data previously generated in a chronic pain setting, where Xen2174 was safe and well-tolerated across a broad range of doses and showed evidence for an analgesic effect.

Xenome's chief executive officer Dr Ian Nisbet said the study was "an important next step in the development of Xen2174".

"If successful, it will provide proof-of-concept in a well-accepted human model of post-surgical pain," Dr Nisbet said.

"Importantly, the study was initiated on schedule and we intend to complete it and announce the results in the second half of 2009," he said.

Xenome said Xen2174 controlled pain through "a completely different mechanism compared to opioid drugs".

The company said early studies had shown that Xen2174 had the potential to overcome some of the disadvantages of opioids and, as a result, could provide a new treatment option for people suffering from moderate to severe pain.

Xenome is a public unlisted company.

VICTORIAN GOVERNMENT

The Victorian Government says stem cell researchers working in collaboration with Californian scientists can compete for jointly funded grants.

A media release from Victoria's Innovation Minister Gavin Jennings said the funding would come from the California Institute for Regenerative Medicine and was the first milestone of the Victoria-California Stem Cell Alliance, created at BIO2008 in San Diego in June.

Mr Jennings said the California Institute for Regenerative Medicine (CIRM) had a \$US3 billion research budget.

"The fact that it has chosen Victoria as its first international collaborative link reflects the world-leading strengths of Victoria's stem cell research," Mr Jennings said.

Grants will support projects that can meet an unmet medical need or address a significant bottleneck in the translation of stem cell biology into new therapies for patients.

He said the Victorian Government had invested \$5 million from the Biotechnology Bridges program, part of its 2008 Innovation Statement to support the local research components of the collaborations.

"For successful joint applicants, Victoria will help fund the research undertaken inside the state and CIRM will fund the research undertaken in California by Californian researchers, Mr Jennings said.

"Already, more than 25 of our stem cell researchers and research teams have indicated they are interested in jointly participating in CIRM-funded research projects," he said.

The new CIRM 'Early Translational Research' grants program is designed to move promising basic research in stem cell science towards real clinical outcomes.

SIRTEX

Sirtex Medical has discontinued its application to intervene in the University of Western Australia and Dr Bruce Gray appeal proceedings.

On April 17, 2008 Federal Court Judge Justice Robert French dismissed the claims by the University of Western Australia against Sirtex and founder Dr Bruce Gray and found in Sirtex's favor on its cross claim against Dr Gray and ordered Dr Gray to pay damages to Sirtex (see Biotech Daily; April 18, 2008).

The University of Western Australia has appealed the judgment dismissing the claim against the University by Dr Gray, but the University and Dr Gray have not appealed the judgment in favor of Sirtex, the company said (see Biotech Daily Sept 16, 2008).

Sirtex said it was informed by the University of Western Australia that it "strongly opposes" Sirtex's application.

Sirtex was unchanged at \$2.24.

NEURODISCOVERY

Neurodiscovery says Dr Chris Moyses will become group chief executive officer on September 29, 2008 replacing Dr Iain Chessell.

Neurodiscovery said Dr Chessell would remain a director and become a non-executive director from the beginning of November.

The company said Dr Moyses joined the board earlier this month and has experience as a director of public healthcare companies.

Neurodiscovery said his "extensive commercial and clinical experience" would provide the company with the leadership to extract the maximum value from its clinical-stage assets.

Dr Moyses has degrees in physiology and medicine from Oxford and Cambridge Universities.

He has worked in the pharmaceutical industry, for Searle and ICI, before being appointed vice-president of clinical and regulatory affairs at Amylin Europe.

Dr Moyses was chief medical officer and development director of Oxford Glycosciences plc, before taking positions as non-executive director of Ketocytomyx, research and development director of Pharmagene plc and most recently chief medical officer of Argenta Discovery.

Dr Moyses is a non-executive director of Ardana plc and Senexis Limited.

Neurodiscovery has also appointed Morgan Barron as company secretary, replacing Narelle Warren.

Neurodiscovery was untraded at nine cents.

RESONANCE HEALTH

Resonance Health says Dr Andrew Walker has will resign as a director at the November annual general meeting.

The company said it would review the composition of the board and "seek a replacement that provides the company with complementary experience for its future development".

Resonance Health was untraded at 1.6 cents.

BIO-MELBOURNE NETWORK

China's biotechnology industry is the focus of the Bio-Melbourne Network Bio-Breakfast on October 7, 2008.

The Bio-Melbourne Network says there are "great opportunities for Australian biotech companies to consider the advantages of research and clinical collaborations with China". The Network said that with a gross domestic product (GDP) of \$US3,450 billion in 2007, China was the third largest economy in the world, behind the US and Japan. The industry organization said China was the world's ninth largest market for pharmaceuticals.

Glaxosmithkline, Astrazeneca, Bayer, Eli Lilly, and Hoffman-La Roche have all set up Chinese research and development or clinical trial centres.

Glaxosmithkline Australasia's head of research and development alliances Dr Ashley Bates will talk about biotechnology developments in China, explain his company's views on the global power shift in the pharmaceutical industry and comment on the opportunities for Australian biotech companies.

AT-Bio chief executive officer, Jim Murray, will present a case study of setting up a joint venture company in China.

AT-Bio is a joint venture between Melbourne's Atholl Pty Ltd and the Tianjin Institute for Pharmaceutical Research focused on drug development.

The Bio-Breakfast will be at the Supper Room, Melbourne Town Hall, Swanston St, Melbourne.

Registration is at 7.15am with presentations at 8am.

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