



Biotech Daily

Wednesday December 12, 2012

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH UP: LIVING CELL UP 11%, ANTISENSE DOWN 8%**
- * **TEVA BACKS MESOBLAST PHASE III CARDIAC TRIAL**
- * **HARDING LOEVNER TAKES 6% OF COCHLEAR**
- * **CORRECTION: AGENIX**
- * **BIODIEM INDIA PARTNER PREPARES FOR EXPORT**
- * **PRANA 24% AGM DISSENT AGAINST DIRECTOR OPTIONS**
- * **CONSEGNA TAKES CAPITAL RAISING HALT TO SUSPENSION**
- * **NOVOGEN APPOINTS ANDREW BURSILL COMPANY SECRETARY**

MARKET REPORT

The Australian stock market was up 0.17 percent on Wednesday December 12, 2012 with the S&P ASX 200 up 7.8 points to 4,583.8 points.

Nineteen of the Biotech Daily Top 40 stocks were up, eight fell, nine traded unchanged and four were untraded. All three Big Caps were up.

Living Cell was the best, up 0.5 cents or 11.4 percent to 4.9 cents with 67,000 shares traded.

Genetic Technologies climbed 9.3 percent; Pharmaxis, Phylogica and Starpharma were up more than four percent; Anteo, GI Dynamics, Mesoblast, Sunshine Heart and Tissue Therapies were up more than three percent; Acrux, Clinuvel, CSL and Reva rose more than two percent; Circadian, Cochlear, Impedimed, Nanosonics, QRX, Resmed and Viralytics were up more than one percent; with Sirtex up 0.4 percent.

Antisense led the falls, down 0.1 cents or 7.7 percent to 1.2 cents with 13.6 million shares traded.

Alchemia and Benitec lost six percent or more; Neuren, Patrys and Prana shed more than two percent; Optiscan was down 1.1 percent; with Psivida down 0.4 percent.

MESOBLAST

Israel's Teva Pharmaceutical Industries has confirmed that the phase III Teva Mesoblast Revascor stem cell congestive heart failure trial will proceed next year.

The US-based Teva vice-president of corporate communications (Americas) Denise Bradley, told Biotech Daily in writing that the company's president of global research and development and chief scientific officer Dr Michael Hayden made the statement in a question and answer session in Teva's teleconference this morning.

Dr Hayden told the teleconference: "We have reviewed the program and we are proceeding with a phase III clinical trial ...with an early interim analysis, starting in 2013." Dr Hayden said that Teva wanted "an early read out" and would do the interim analysis after a set number of patients had been treated in the trial.

The delay in confirmation of the trial has fueled speculation, primarily from Macquarie Equities analyst Dr Craig Collie, about the relationship between Mesoblast and Teva and that Teva might not support the phase III trial.

In a research note today, following the Teva teleconference, Macquarie Equities questioned the statement, saying it was "hesitant ... and more akin to a phase II" trial, claiming Teva's level of commitment was unclear.

Biotech Daily emailed Ms Bradley and Teva's vice president, head of corporate investor relations Kevin Mannix and asked the direct question: "Did Teva's head of R&D Dr Michael Hayden tell today's teleconference that the Teva-Mesoblast Revascor phase III cardiac trial would definitely be going ahead?"

In an email copied to Mr Mannix, Ms Bradley replied: "Yes, that is correct."

Biotech Daily called Dr Collie, but he said it was Macquarie's policy not to talk to the media.

Mesoblast chief executive Prof Silviu Itescu told Biotech Daily that he was pleased by the definitive comment.

"I'm pleased that the new Teva management has reconfirmed the Mesoblast heart failure program, which is proceeding to phase III," Prof Itescu said.

Biotech Daily editor David Langsam owns shares in Mesoblast.

Mesoblast was up 20 cents or 3.4 percent to \$6.03 with 470,067 shares traded.

COCHLEAR

The Bridgewater, New Jersey-based Harding Loevner LP has increased its substantial shareholder in Cochlear from 2,861,083 shares (5.03%) to 3,434,019 shares (6.02%).

The substantial shareholder notice said the New Jersey based investment management firm acquired 551,527 Australian shares and 42,819 American depository receipts equivalent to 21,409.5 Australian shares between June 4 and December 10, 2012.

Cochlear was up \$1.35 or 1.8 percent to \$76.81 with 241,631 shares traded.

AGENIX

Last night's edition reported Agenix executive chairman Nick Weston saying he expected to begin clinical trials of the Chinese hepatitis B asset AGX-1009 in 2013.

Mr Weston has told Biotech Daily that the clinical trial application to China's State US Food and Drug Administration would be made in 2013.

The error was made by a sub-editor who will spend an indefinite period learning to fill-in clinical trial applications.

Agenix fell 0.1 cents or 2.8 percent to 3.5 cents.

BIODIEM

Biodiem says that commercial partner the Serum Institute of India has progressed plans to allow international export of its live attenuated influenza virus-based vaccines.

Biodiem said that the Serum Institute expected to file documentation in 2013 with both the World Health Organisation and the Drugs Controller General of India to permit the export of seasonal influenza vaccines produced using Biodiem technology to member developing countries of the United Nations.

Biodiem said that it received royalties on sales of its live attenuated influenza virus (LAIV) vaccines to developing countries by the Serum Institute and retained the option to outlicense LAIV for sales to developed countries.

The company said the Institute's acquisition of a Netherlands-based vaccine business signaled plans to access developed markets such as Europe, Australia and the US.

Biodiem said that once export was permitted, target export markets would need to grant approval for new vaccine products and that process was expected to be aided by the regulatory work with the WHO and the DCGI, as well as by new clinical data from a phase II efficacy trial for a seasonal LAIV vaccine, by the non-profit organization Program for Appropriate Technology in Health using vaccine manufactured by the Serum Institute.

Biodiem said the Bangladesh trial of the nasal spray Nasovac for H1N1 ('swine') influenza involved about 300 children who were given the vaccine in a randomized, placebo-controlled study with results analyses underway.

The company said that Nasovac had the benefit of being able to be taken in a single dose and without the need for specially trained staff.

Biodiem chief executive officer Julie Phillips said that the Serum Institute of India was "one of the world's largest vaccine manufacturers with significant international reach".

"We expect that Biodiem's royalty streams will expand significantly when the [Institute] is able to export LAIV 'flu vaccine,'" Ms Phillips said.

The company said that it had partners in India and China and the agreements generated \$1.3 million in revenue in the 2012 financial year in milestone payments and royalties, complementing a diverse development portfolio in the area of infectious disease therapies and vaccines.

Biodiem was up half a cent or 10.9 percent to 5.1 cents.

PRANA BIOTECHNOLOGY

The Prana annual general meeting passed all resolutions but there was up to 24.1 percent opposition against the issue of 9,000,000 options to directors (BD: Nov 9, 2012).

The meeting approved the issue of 4,000,000 options to executive chairman Geoffrey Kempler and 1,000,000 options each to directors Peter Marks, Richard Revelins, Brian Meltzer, Lawrence Gozlan and Dr George Mihaly with the greatest dissent against the issue of options to Mr Marks with 14,537,416 proxy votes (24.1%) against and 45,759,436 proxy votes (75.9%) in favor.

There was a smaller level of dissent against the ratification of previous share issues and the employee share plan, while the remuneration report was passed overwhelmingly, as was the re-election of Dr Mihaly as a director.

The company's most recent Appendix 3B said that Prana had 340,689,928 shares on issue meaning that the largest number of opposition votes to directors' options amounted to 4.3 percent of the company's total shares on issue, not sufficient to requisition extraordinary general meetings.

Prana fell half a cent or 2.3 percent to 21 cents.

CONSEGNA GROUP

Consegna has requested a voluntary suspension to follow the trading halt it requested on December 10, pending a capital raising (BD: Dec 10, 2012).
Consegna last traded at 0.4 cents.

NOVOGEN

Novogen says it has appointed Andrew Bursill as company secretary replacing Steven Coffey.

Novogen said that Mr Coffey remained a director of the company
Novogen fell half a cent or 3.85 percent to 12.5 cents.