



Biotech Daily

Wednesday May 28, 2014

Daily news on ASX-listed biotechnology companies

- * **ASX UP, BIOTECH DOWN: PRANA UP 33%, BENITEC DOWN 8%**
- * **PATRY'S PAT-SM6 COMBINATION FOR MULTIPLE MYELOMA PATIENT**
- * **PRANA PLEADS SCHULTZ, OLDS TO ASX 33% QUERY**
- * **MESOBLAST ACCELERATES LONZA SINGAPORE CELL MANUFACTURE**
- * **MEDICAL DEVELOPMENTS SALES, PROFIT WARNING**
- * **FISHER FUNDS SELL 2m UNIVERSAL BIOSENSORS SHARES TO 5%**
- * **SPINIFEX APPOINTS FOUR ADVISORS**
- * **FEDERAL GOVERNMENT APPOINTS PENNY DOBSON TO ANSTO**

MARKET REPORT

The Australian stock market was up 0.28 percent on Wednesday May 28, 2014 with the S&P ASX 200 up 15.5 points to 5,527.2 points.

Eleven of the Biotech Daily Top 40 stocks were up, 16 fell, eight traded unchanged and five were untraded.

Prana was the best, up 5.5 cents or 33.3 percent to 22 cents with 4.2 million shares traded (see below).

Analytica, Anteo and Universal Biosensors climbed more than seven percent; Neuren and Prima were up more than four percent; both Biotron and IDT rose 2.2 percent; Cochlear, Phosphagenics and Psivida were up more than one percent; with CSL and Mesoblast up by less than one percent.

Benitec led the falls, down 10 cents or 8.2 percent to \$1.12 with 283,925 shares traded.

Medical Developments fell eight percent; Starpharma fell 5.8 percent; Atcor, Cellmid, Circadian, Oncosil and Optiscan fell more than four percent; Antisense was down 3.3 percent; Bionomics and Pharmaxis shed more than two percent; Ellex, Nanosonics, Osprey, Resmed and Sirtex were down one percent or more; with Acrux down 0.6 percent.

PATRYS

Patrys says that a difficult to treat multiple myeloma patient has responded to PAT-SM6 in combination with bortezomib (Velcade) and lenalidomide (Revlimid).

Patrys said that the patient was granted permission to receive PAT-SM6 on an individual treatment basis under the supervision Germany's University of Würzburg Hospital's Prof Hermann Einsele, who led the phase I/IIa trial of PAT-SM6 in multiple myeloma completed earlier this year (BD: Aug 7, 2103; Jan 23, Mar 27 2014).

The company said that the patient was a 61 year-old man with immunoglobulin G (IgG) kappa multiple myeloma diagnosed in 2013 and was treated initially with four cycles of combination chemotherapy pomalidomide (Pomalyst), doxorubicin hydrochloride (Adriamycin), dexamethasone and high-dose melphalan followed by an autologous stem cell transplant.

Patrys said that the patient initially responded well and went into complete remission but at six months after the stem cell treatment, the patient's disease relapsed and he received another four cycles of combination chemotherapy including lenalidomide.

The company said that at the end of the four cycles, the patient suffered another relapse with several tumors appearing outside the bone marrow in multiple soft tissues and the testes, with evidence of tumor in the bone-marrow.

Patrys said that pre-clinical data showed that PAT-SM6, when used in combination with several marketed myeloma drugs, induced specific binding and killing of multiple myeloma cells that were otherwise resistant to drug therapy and PAT-SM6 had been shown to be highly synergistic with proteasome inhibitors, such as bortezomib.

The company said that Prof Einsele decided to treat the relapsed patient with a combination of bortezomib, lenalidomide and PAT-SM6 and after three doses of the combination therapy, a positron emission tomography-computed tomography scan revealed significant shrinkage of lesions both inside and outside the bone marrow.

Patrys said that of particular note was the disappearance of the tumor in the testes and the patient has since gone on to receive additional treatment for his remaining disease.

Patrys chief executive officer Dr Marie Roskrow said that the patient, who had very difficult to treat myeloma, "had an excellent response to PAT-SM6 when it was used with other myeloma drugs".

"The fact that he received a proteasome inhibitor, Velcade, as part of the treatment protocol with PAT-SM6 is particularly important as Patrys' next clinical trial will be using a second generation proteasome inhibitor Kyprolis, [or] carfilzomib, in combination with PAT-SM6," Dr Roskrow said.

Dr Roskrow said the combination trial was expected to begin by the end of 2014.

Patrys was unchanged at 3.5 cents with 17.1 million shares traded.

PRANA BIOTECHNOLOGY

Prana has told the ASX that it is not aware of any information it has not announced which, if known, could explain recent trading in its securities.

The ASX said the company's share price rose 5.5 cents or 33.3 percent from 16.5 cents on May 27 to 22 cents today, May 28, 2014 and noted an increase in trading volume.

Prana said it appointed Prof Ira Shoulson as a director two weeks ago and its most recent Quarterly Report said it had \$41.7 million in cash at April 7, 2014 (BD: May 13, 2014).

Last night on the Nasdaq, Prana climbed 33 US cents or 21.02 percent to \$US1.90 (\$A2.05) with 5,870,565 US shares traded. There are 10 US shares for each Australian share.

Prana closed up 5.5 cents or 33.3 percent at 22 cents with 4.2 million shares traded.

MESOBLAST

Mesoblast says it is accelerating plans for its Singapore-based commercial manufacturing operations in line with expected product launches.

Mesoblast said it would receive incentives from the Singapore Economic Development Board for manufacturing related activities, as well as product development and commercialization.

Mesoblast chief executive Prof Silviu Itescu said that “bringing forward commercial manufacturing operations in Singapore is an important part of our overall global strategy as we prepare for product launches”.

“... Singapore's business friendly environment, focus on cellular therapies and strong scientific base, supported by the [Economic Development Board] and the Agency for Science, Technology and Research are all assets to Mesoblast,” Prof Itescu said.

Mesoblast said that its Singapore operations included clinical manufacturing supply of its mesenchymal products under contract manufacturing agreements with the Basel Switzerland-based Lonza Group.

The company said that it had exclusive access to Lonza's facilities in Singapore for allogeneic stem cell therapy, subject to certain exceptions and it could require Lonza to construct a purpose-built manufacturing facility exclusively for its use.

Mesoblast said that Prochymal, acquired from Osiris last year, was the world's first approved allogeneic stem cell therapeutic and the only allogeneic stem cell therapeutic with both US Food and Drug Administration orphan drug and fast track status and was first being developed for steroid-refractory graft versus host disease (BD: Oct 11, 2013).

The company said that other indications for its mesenchymal products included congestive heart failure, degenerative disc disease and Crohn's disease.

Mesoblast was up two cents or 0.4 percent to \$4.82 with 406,056 shares traded.

MEDICAL DEVELOPMENTS INTERNATIONAL

Medical Developments says that sales for the 2013-'14 financial year are expected to total about circa \$9.3 million.

Last year, Medical Developments posted revenue for the 12 months to June 30, 2013 of \$11,733,000 (BD: Aug 23, 2013).

The company said that it expected the underlying profit after tax for the 12 months to June 30, 2014 to be about \$750,000 compared to last year's net profit after tax of \$2,309,000.

The company said that sales of its respiratory device spacer business had been “negatively impacted” by \$2 million by three external factors including the merger between the New Zealand-based Ebos Healthcare (formerly the Early Brothers Trading Co) and Symbion which had delayed sales until July 2014; sales in New Zealand were affected by an unusually mild winter; and Glaxosmithkline cancelled its respiratory device supply contract (BD: Dec 9, 2013).

Medical Developments said it was confident there was no long term negative impact on the size of the market for its products and sales of its respiratory products were recovering.

The company said that sales for its New Zealand business were at the same levels for the six months ending June 30, 2013, with “strong forward orders”.

Medical Developments said it had a new agreement with Symbion and new initiatives with other trading partners to increase market share in 2014-'15 and deliver long-term growth.

Medical Developments said the underlying profit did not include licence payments for distribution agreements being negotiating, with some expected by July 2014.

Medical Developments fell 10.5 cents or eight percent to \$1.21.

UNIVERSAL BIOSENSORS

New Zealand's Fisher Funds says it has reduced its substantial shareholder in Universal Biosensors from 11,014,077 shares (6.27%) to 9,189,077 shares (5.23%).

Fisher Funds said it sold 1,825,000 shares for \$332,208 or an average price of 18.2 cents a share.

Last week, Fisher Funds said that it acquired shares from August 22, until September 24, 2013 and sold shares between May 13 and May 19, 2014, the day of the largest sales of 874,097 shares for \$146,261 or 16.7 cents a share.

In a previous substantial shareholder notice Fisher Funds acquired 3,066,457 shares for \$2,356,049 or an average price of 76.8 cents a share (BD: Jun 26, 2013).

Fisher Funds began selling, following an 18-page 'Value Drivers Presentation' which included details of a Johnson & Johnson lump sum service fee option to acquire all the rights to the Universal Biosensors blood glucose test strips after Lifescan reached \$US45 million in cumulative quarterly service fees, and believed to have triggered selling that led to a 39.4 percent share price fall (BD: May 12, 2014).

Universal Biosensors was up 1.5 cents or 7.9 percent to 20.5 cents with 4.0 million shares traded.

SPINIFEX PHARMACEUTICALS

Spinifex has appointed chronic pain specialists Prof Thomas Schnitzer, Prof Roy Freeman and Prof Robert Dworkin to its scientific advisory board along with former chairman Dr Declan Doogan.

The company said that the pain researchers' core areas included understanding the basis for pain progressing from acute to chronic, peripheral neuropathy, diabetic neuropathy and improving clinical trials of pain treatments and they would help guide the development of EMA401, a novel angiotensin II type 2 receptor antagonist being developed as a potential first-in-class oral treatment for chronic pain without central nervous system side effects.

Spinifex said it was planning a further phase II study with EMA401 in post-herpetic neuralgia and investigating it in neuropathic and inflammatory pain conditions such as osteoarthritis, chemotherapy induced neuropathy and peripheral diabetic neuropathy. The company said that Prof Schnitzer was a professor of internal medicine, rheumatology at the Chicago, Illinois-based Northwestern University Feinberg School of Medicine. Spinifex said that Prof Schnitzer had a long-standing interest in chronic musculoskeletal pain, understanding how pain progresses from acute to chronic and the development of new therapeutic approaches to pain management.

The company said that Prof Freeman was a Harvard Medical School professor of neurology and director of the Center for Autonomic and Peripheral Nerve Disorders in the Department of Neurology at Beth Israel Deaconess Medical Center in Boston, Massachusetts.

Spinifex said that Prof Dworkin was a University of Rochester School of Medicine and Dentistry professor of anaesthesiology, neurology, oncology and psychiatry.

Spinifex chief executive officer Dr Tom McCarthy said the "addition of these three highly distinguished scientists in their respective areas of chronic pain and Declan joining the [scientific advisory board] reflects Spinifex's ambition to advance our novel pain candidate EMA401".

"We believe these new members will add to our already strong [scientific advisory board] and provide additional guidance ... as we progress our clinical programs for EMA401," Dr McCarthy said.

Spinifex is a private company.

AUSTRALIAN NUCLEAR SCIENCE AND TECHNOLOGY ORGANISATION

The Federal Minister for Industry Ian Macfarlane says Penny Dobson has been appointed as a director of the Australian Nuclear Science and Technology Organisation.

Mr Macfarlane said that Ms Dobson had worked for 35 years in the healthcare sector including in Australia, Japan, New Zealand and the US and was a former senior executive with a Japanese subsidiary of Merck Sharp and Dohme.

“This appointment is happening at an exciting time for ANSTO, with construction beginning soon on the new ANSTO nuclear medicine facility that will be at the heart of the global fight against cancer and heart disease,” Mr Macfarlane said.

The Federal Government media release said that Ms Dobson held a Diploma of Pharmacy from the Central Institute of Technology in Wellington, New Zealand and a Master of Business Administration from Macquarie University.