

Biotech Daily

Thursday July 22, 2010

Daily news on ASX-listed biotechnology companies

* ASX, BIOTECH DOWN: STARPHARMA UP 6%; PHYLOGICA DOWN 7%

* WEHI, NEXPEP DISCOVER PROTEINS FOR COELIAC DISEASE

- * MERCK'S \$3.5m HAWAII BID LEAVES ACUVAX 'AN EMPTY SHELL'
- * GSK PAYS BIOTA LOW \$900k RELENZA ROYALTY; RECORD 12 MONTHS
- * STARPHARMA PROTECTED FROM DUREX OFFER
- * CORRECTION: EDITORIAL
- * CITELINE CLINICAL TRIALS DATABASE OPENS MELBOURNE OFFICE
- * STIRLING TO ACQUIRE TELEMEDCARE FOR \$511K DOCA

MARKET REPORT

The Australian stock market fell 0.86 percent on Thursday July 22, 2010 with the S&P ASX 200 down 38 points to 4374.7 points.

Eight of the Biotech Daily Top 40 stocks were up, 11 fell, 11 traded unchanged and 10 were untraded. All three Big Caps were down.

Starpharma was best, up three cents or 5.8 percent to 54.5 cents with 500,315 shares traded, followed by Biota up four cents or 4.4 percent to 95 cents with 2.1 million shares traded.

Nanosonics climbed 3.45 percent; Chemgenex and QRX both rose 2.86 percent; with Alchemia and Sirtex up more than one percent.

Phylogica led the falls, down half a cent or 6.7 percent to seven cents with 95,451 shares traded, followed by Prima down 4.8 percent to 10 cents with 3.2 million shares traded.

Benitec, Mesoblast and Prima lost more than three percent; Clinuvel, Heartware, Psivida and Tissue Therapies shed two percent or more; with CSL, Resmed and Virax down more than one percent.

WALTER AND ELIZA HALL INSTITUTE FOR MEDICAL RESEARCH, NEXPEP

Walter and Eliza Hall Institute scientists have identified the three protein fragments that make gluten thereby opening a pathway to make people resistant to coeliac disease. In an article entitled 'Comprehensive, Quantitative Mapping of T Cell Epitopes in Gluten in Celiac Disease' published in the journal Science Translational Medicine the researchers lead by Dr Bob Anderson found that "pathogenic T cells in coeliac disease show limited diversity and therefore suggest that peptide-based therapeutics for this disease and potentially other strongly HLA-restricted immune diseases should be possible". The abstract is available at: <u>http://stm.sciencemag.org/content/2/41/41ra51.abstract</u>.

In a media release the Walter and Eliza Hall Institute for Medical Research (WEHI) said gluten was the main protein in wheat, rye and barley and was toxic to people with coeliac disease.

The Institute said the discovery opened the way for "a new generation of diagnostics, treatments, prevention strategies and food tests for the 200,000 Australians with coeliac disease".

The Institute said that when people with coeliac disease ate products containing gluten their immune response was switched on and the lining of the small intestine was damaged, hampering their ability to absorb nutrients.

WEHI's media release said the disease was treated by permanently removing gluten from the patient's diet.

Dr Anderson said it had been 60 years since gluten was discovered to be the environmental cause of coeliac disease.

"In the years since, the holy grail in coeliac disease research has been to identify the toxic peptide components of gluten and that's what we've done," Dr Anderson said.

WEHI said researchers working on the project included Dr Jason Tye-Din, Dr James Dromey, Dr Stuart Mannering, Dr Jessica Stewart and Dr Tim Beissbarth as well as Monash University's Prof Jamie Rossjohn and the University of Melbourne's Prof Jim McCluskey.

The Institute said the study was started by Dr Anderson nine years ago and has involved researchers in Australia and the UK as well as more than 200 coeliac disease patients. WEHI said the patients, recruited through the Coeliac Society of Victoria and the Coeliac Clinic at Oxford's John Radcliffe Hospital, ate bread, rye muffins or boiled barley. Six days later, blood samples were taken to measure the strength of the patients' immune

responses to 2700 different gluten fragments. WEHI said the responses identified 90 fragments causing some level of immune reaction, but three gluten fragments or peptides were revealed as being particularly toxic.

"These three components account for the majority of the immune response to gluten that is observed in people with coeliac disease," Dr Anderson said.

WEHI said Dr Anderson co-founded Nexpep which developed a peptide-based immunotherapy to desensitize people with coeliac disease to the toxic effects of gluten. Nexpep's phase I trials of the therapy were completed in June and final results are expected in coming months.

WEHI said the immunotherapy worked by exposing people with coeliac disease to small amounts of the three peptides, similar to desensitization for allergies.

Dr Anderson said although coeliac disease could be managed with a gluten-free diet, compliance with the diet was challenging and nearly half the people on the diet had residual damage to their small intestine.

"Consequently, the immunotherapy and three other drugs are under development to help people with coeliac disease."

Nexpep is a private company.

ACUVAX, HAWAII BIOTECH, MERCK

Merck & Co Inc's proposed acquisition of Hawaii Biotech's vaccine assets could leave Acuvax without any significant compounds to develop.

The proposed acquisition has been widely rumored but Biotech Daily believes it is able to confirm through sources close to the proposal that Merck was expected to pay \$US3.1 million (\$A3.5 million) for the West Nile virus and Dengue fever vaccine compounds and Dengue fever diagnostic.

No one was available from Merck or Hawaii Biotech was available to comment on the asset acquisition.

Acuvax owned 26 percent of Hawaii Biotech and had hoped to raise funds to buy the assets when the company declared itself bankrupt (BD: Jun 30, 2010).

Separately, former Acuvax director, Dr Richard Opara, held an 11 percent holding in Hawaii Biotech.

Acuvax was previously known as Avantogen and prior to that the Australian Cancer Technology.

In December 2009, Acuvax said Hawaii Biotech had received an initial \$US500,000 cash injection with an additional \$US1 million (\$A1.1 million) for near-term financing needs (BD: Jan 17, 2010).

Acuvax previously said that Hawaii Biotech chief executive officer Dr Elliot Parks was taking steps to file a petition with the US Bankruptcy Court in Honolulu (BD: Dec 14, 2009).

"This is an unprecedented step as Hawaii Biotech Inc has been offered a number of financing alternatives" Acuvax chairman Patrick Elliott said at the time.

In November, Acuvax requisitioned an extraordinary meeting of Hawaii Biotech shareholders to replace two directors including Dr Parks (BD: Nov 9, 2009).

Acuvax chief executive officer Dr William Ardrey said at that time: "I have never seen a bankruptcy proceeding with so much capital available to a company."

Today Dr Ardrey told Biotech Daily that the sale of the assets to Merck effectively left Acuva an empty shell albeit "a clean empty shell and continues to hold a portfolio of nutriceuticals and ancillary biotechnology assets".

Dr Ardrey said Acuvax had invested a total of more than \$6 million in Hawaii Biotech as well as an adjuvant.

"The Hawaii Biotech platform worked very well," Dr Ardrey said.

"Acuvax shareholders put money into a world class asset," Dr Ardrey said. "It's just a shame we couldn't have control of those assets."

"Those who had control of the company took a different direction," Dr Ardrey said. Last year Hawaii Biotech was ready to begin a phase I trial of its monovalent Dengue fever vaccine.

The company said at that time the Dengue subunit vaccine candidate had been developed with financial assistance from the National Institutes of Health, the Department of Defence, and the Bill and Melinda Gates Foundation's Paediatric Dengue Vaccine Initiative (BD: Aug 26, 2009).

In February 2009 the phase I West Nile virus vaccine trial showed a favorable safety profile in 24 subjects across four cohorts (BD: Feb 26, 2009).

In October, Acuvax announced that trials of its RP101 pancreatic cancer drug being developed by Sciclone Pharmaceuticals had been halted following a data monitoring safety committee report.

Acuvax said at that time that it owned 43 percent of Avantogen Oncology Inc, which was in a licencing partnership with Sciclone (BD: Oct 6, 2009).

Acuvax was untraded at 0.3 cents.

<u>BIOTA</u>

Biota expects to receive a royalty payment of \$900,000 from Glaxosmithkline for \$12.8 million sales of Relenza in the three months to June 30, 2010.

Biota said that although the sum compared to \$9.7 million royalties for \$138 million sales in the three months to March 31, 2010, the previous two quarterly royalties of \$32.6 million for the three months to December 31, 2009 and \$24.1 million for the three months to September 30, 2009, made the 12 months to June 30, 2010 total of \$63.7 million its largest annual payment for Relenza since the product was launched in 1999.

Biota said the record sales and royalty were "a result of demand driven by the [2009] H1N1 swine flu pandemic and consequent increased production by GSK".

Biota said that influenza "in both its seasonal and pandemic forms has proven to be quite unpredictable, making future sales or royalty forecasts difficult".

"The increase in annual manufacturing capacity by GSK to 90 million courses should ensure that in future higher peak demands can be met, should the need arise," the company said.

Biota was up four cents or 4.4 percent to 95 cents with 2.1 million shares traded.

STARPHARMA

Starpharma says it does "not foresee any negative implications" from the Reckitt Benckiser Group offer for SSL International.

The London based Reckitt Benckiser Group which primarily markets cleaning materials has made an offer for the London-based SSL International, itself an amalgamation of the London Rubber Company or London International with Seton Healthcare and Scholl. Starpharma said it was in communication with SSL about the offer but did "not foresee any negative implications for Starpharma's commercial arrangement with them for the Vivagel-coated condom".

Starpharma said Reckitt Benckiser marketed a range of health and personal care products with current revenues of GBP1.8 billion (\$A3.1 billion).

The offer values SSL at GBP2.5 billion, a premium of 32.8 percent to the current market price.

Starpharma said it had a full licence agreement with SSL to develop and market a Vivagel coated condom.

SSL manufactures and sells Durex condoms, which Starpharma said was the marketleading condom brand worldwide.

Starpharma was up three cents or 5.8 percent to 54.5 cents.

CORRECTION: BIOTECH DAILY EDITORIAL

Last night's edition reported that Bionomics was the sole commercial partner in the CRC for Cancer Therapeutics when it was granted \$36.7 million.

There were three partners in the CRC for Cancer Therapeutics.

The mistake was made by an unnamed but highly valued member of our team, but we'll blame the sub-editor for not picking it up and preventing the error.

Biotech Daily editor David Langsam owns shares in Bionomics and used them to smack the sub-editor about his ears.

<u>CITELINE</u>

Clinical trials database and information service Citeline has opened its Asia Pacific headquarters in Melbourne.

Citeline's Asia Pacific sales manager Sandrine Gandhi told Biotech Daily that her company provided "a comprehensive and complete resource for clinical trials, drugs, sites and investigators".

"It's a real time web-based data-base with more than 300 editors tracking more than 20,000 web sources including companies, media, medical research and hospitals," Ms Gandhi said.

Ms Gandhi said Citeline provided a comprehensive research interface and could be searched by therapeutic area, patient segments, trial sites, drugs tested, mechanism of action and biological targets, among others.

She said that it would enable companies to know what competition was working on similar projects and what stage of development they had reached.

Ms Gandhi said Citeline was originally developed in San Francisco before being acquired by the London-based Informa science and business information reporting company. Ms Gandhi said the company wanted to "further develop our Asia Pacific footprint and help biotech companies move forward to the clinic".

"The costs are flexible with a modular services system," Ms Gandhi said.

"You can pick and choose what you need," she said.

Ms Gandhi said a typical package of three disease types would cost about \$US25,000 (\$A28,566) a year.

For more information on Citeline go to <u>www.citeline.com</u> or contact Ms Gandhi by email at <u>sandrine.gandhi@citeline.com</u> or call +61 3 8842 2477.

STIRLING PRODUCTS

Stirling says it wants to acquire a controlling interest in Telemedcare Holdings (administrator appointed) and associated companies.

According to Telemedcare's website the company primarily provides a 'health monitor' and ancillary services providing patient data on a patient's weight, temperature, blood pressure, blood oximetry blood glucose, spirometry and electrocardiogram.

Stirling said that subject to creditor approval it proposed that a deed of company arrangement (DOCA) would have Stirling contribute \$511,302 over 12 months.

Stirling said it had indemnified the administrator's costs and advanced \$360,000 to Telemedcare to support its ongoing trading under the administration.

Stirling said the transaction was subject to the approval Telemedcare shareholders of the issue of a 65 percent controlling interest to Stirling.

Stirling said that initial funding for the transaction had been arranged through an 18 month \$1.2 million private funding facility convertible to shares at an average one cent a share. Stirling said it had been approached by an unnamed US fund and an unnamed UK fund seeking convertible investment positions and was in discussion with the two funds. Stirling was unchanged at 0.9 cents with 2.1 million shares traded.

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