



Biotech Daily

Tuesday March 24, 2015

Daily news on ASX-listed biotechnology companies

- * **ASX UP, BIOTECH DOWN: OSPREY UP 12%, PATRYS DOWN 9%**
- * **ACTINOGEN INCREASES PHASE I XANAMEM FOR ALZHEIMER'S DOSE**
- * **PHARMAUST: 'PPL-1 REDUCES P70S6K IN ALL 6 CANCER PATIENTS'**
- * **CORRECTION: INVION**
- * **PHYTOTECH TO ACQUIRE CANADA'S MMJ FOR UP TO \$21m SCRIP**
- * **NARHEX TARGET RESAPP OPTIMIZATION STUDY**
- * **COELIAC CHARITIES DONATE \$40k TO WEHI**

MARKET REPORT

The Australian stock market climbed 0.22 percent on Tuesday March 24, 2015 with the S&P ASX 200 up 13.0 points to 5,969.1 points.

Nine of the Biotech Daily Top 40 stocks were up, 18 fell, 11 traded unchanged and two were untraded.

Osprey was the best, up 7.5 cents or 12.0 percent to 70 cents with 183,500 shares traded.

Phosphagenics climbed 5.1 percent; Nanosonics, Optiscan and Sirtex were up more than three percent; Acrux, Admedus and Avita were up more than one percent; with Cochlear, CSL and Impedimed up by less than one percent.

According to Commsec, Patrys led the falls, down 0.1 cents or 9.1 percent to one cent with 413,000 shares traded, although yesterday Commsec said that Patrys fell 0.2 cents to 0.9 cents. Biotech Daily is making enquiries.

Pharmaxis lost 7.7 percent; Ellex and Viralytics were down more than six percent; Antisense, Atcor, Medical Developments and Tissue Therapies fell more than four percent; Benitec, GI Dynamics, Prana and Prima were down more than three percent; Oncosil and Starpharma shed more than two percent; Alchemia, Mesoblast, Neuren and Resmed were down more than one percent; with Clinuvel down 0.9 percent.

ACTINOGEN MEDICAL

Actinogen says that the independent dose escalation committee has approved the next cohort in its phase I study of Xanamem for Alzheimer's disease.

Actinogen said that the committee was satisfied with the safety, tolerability and pharmacokinetic results in dosing the first cohort of eight participants at 10mg and allowed a dose escalation to 25mg for the next cohort of eight participants, which was expected by the end of this March 2015.

The company said that Xanamem had a novel mechanism of action, blocking the production of the stress hormone cortisol in the hippocampus and frontal cortex, the areas of the brain most affected by Alzheimer's disease.

Actinogen said that there was growing evidence that chronic stress and elevated cortisol levels led to changes in the brain affecting memory and to the development of amyloid plaques and neural death, which were the hallmarks of Alzheimer's disease.

The company said the study of 24 healthy volunteers would be dosed at 10mg, 25mg and 35mg of Xanamem to confirm safety and tolerability of the drug and demonstrate how the body absorbed and metabolized Xanamem and the optimal dose for the drug.

Actinogen chief executive officer Dr Bill Ketelbey told Biotech Daily that the patients were being dosed twice daily with oral Xanamem for a total of nine days.

Actinogen said that the double-blinded, placebo-controlled study was being conducted at Linear Clinical Research at the QEII Medical Centre in Perth, Western Australia.

Actinogen was up 0.3 cents or 3.6 percent to 8.7 cents with 1.8 million shares traded.

PHARMAUST

Pharmaust says that the third and final lowest dose patient in its trial of PPL-1 for cancer has had a 50 percent reduction in the blood marker p70S6K.

Pharmaust said that the lung cancer patient with metastases to the liver, brain and bone received PPL-1 for 28 days at the Royal Adelaide Hospital and demonstrated a 50 percent reduction of p70S6K levels at both days three and seven of treatment.

The company said that aberrant expression of p70S6K was believed to contribute to aggressive features of cancer such as growth, invasion and metastasis and levels of p70S6K in peripheral blood immune cells were expected to correlate with similar changes in the patient's cancer.

Pharmaust said that studies had shown that factors that increased mammalian target of rapamycin (mTOR) and p70S6K signaling, lead to increased metastasis in human breast cancer cells and that activation of p70S6K had been shown to increase viability of colorectal cancer cells.

The company said that some anticancer drugs such as paclitaxel might operate through inactivation of p70S6K and that PPL-1 consistently inhibited p70S6K in all six patients with different cancers.

Royal Adelaide Hospital principal investigator Prof Michael Brown said that the use of surrogate tumor markers in the diagnosis of cancer and assessment of progression was "ubiquitous in clinical oncology".

"Although many cancers have a specific marker association, p70S6K appears to be a common indicator of malignancy," Prof Brown said. "Typically, information on drug efficacy is hard to observe in phase I safety studies, particularly at the lowest doses being tested."

"The results so far indicate that PPL-1 is well tolerated at the lowest dose and it appears to be physiologically active in that it reduces a key indicator associated with malignancy," Prof Brown said.

Pharmaust was unchanged at one cent with 17.7 million shares traded.

INVION

Last night's edition incorrectly concluded the article on Invion's US Food and Drug Administration strategy approvals saying the company's share price fell.

In fact, Invion climbed 1.6 cents or 55.2 percent to 4.5 cents with 39.3 million shares traded on the FDA pre-investigational new drug application meeting which supported its strategy for inhaled INV102, or nadolol, and its two phase I study outlines and proposed toxicology program.

The mistake was made by the Monday sub-editor who was summarily dismissed.

Biotech Daily apologizes for the error.

Today, Invion shed one cent or 22.2 percent to 3.5 cents with 9.2 million shares traded.

PHYTOTECH MEDICAL

Phytotech says it will acquire the Canada-based MMJ Bioscience for up to \$20,685,000 through the issue of up to 68,000,000 Phytotech shares valued at 30.5 cents a share.

Phytotech said the deal included \$15.5 million upfront and \$5,185,000 in milestones and shareholders holding 69.3 percent of the Vancouver, British Columbia-based MMJ had entered into a binding heads of agreement for the acquisition with up to 51,000,000

Phytotech shares on settlement, followed by up to 8,500,000 shares if MMJ was granted a licence to produce under the Marihuana for Medical Purposes Regulations in Canada within 12 months of settlement and a further up to 8,500,000 shares if MMJ and its subsidiaries generated at least \$C5.0 million (\$A5.1 million) in revenue from operating activities within 36 months of settlement, subject to due diligence and shareholder approval, with three MMJ nominees to be appointed directors of Phytotech.

The company said that the two companies would combine in a 'merger of equals' to "form a vertically integrated [medical cannabis] company" from ... cultivation to the development and distribution of pharmaceutical, food additives and cosmetics.

Phytotech said that MMJ had three subsidiaries, the horticultural United Greeneries, the pharmaceutical and food additive developer and distributor in Europe Satipharm and Agrichem Analytical a quality control and testing laboratory for medical cannabis.

The company said the deal brought near and mid-term cash flow from MMJ's subsidiaries, through the sale of a gastro-resistant pill in Europe and sales of medical cannabis to Canadian patients, pending approval of its Duncan facility, south west of Vancouver.

Phytotech said revenues were expected to fund business expansion, including research and development and clinical trials.

Phytotech said it hoped to hold a shareholder meeting on May 18, 2015 and complete the acquisition on May 25, 2015.

Phytotech was up 3.5 cents or 11.5 percent to 34 cents with 5.7 million shares traded.

NARHEX LIFE SCIENCES

Narhex says that acquisition target Resapp Diagnostics has enrolled its first of about 150 patient to optimize its algorithms for pneumonia and asthma (BD: Oct 2, 2014).

Narhex said that the study at the Perth, Western Australia-based Joondalup Health Campus would gather data from patients with a variety of respiratory conditions to optimize the algorithms for pneumonia and asthma as well as broadening the validation to other common respiratory conditions such as bronchitis, bronchiolitis and upper respiratory tract conditions.

The company said that preliminary results were expected within three months.

Narhex was unchanged at 0.9 cents with 1.3 million shares traded.

[THE WALTER AND ELIZA HALL INSTITUTE FOR MEDICAL RESEARCH](#)

The Walter and Eliza Hall Institute says that Coeliac Victoria and Tasmania will donate \$40,000 to support its research into childhood coeliac disease.

WEHI said that the donation would support projects by Dr Jason Tye-Din and his team to improve diagnostics and treatments that would be effective for both children and adults with coeliac disease.

The Institute said that coeliac disease was the most common autoimmune disorder and was caused by an inappropriate immune response to gluten, a protein found in wheat, barley, rye and oats.

WEHI said that coeliac disease affected one in 70 Australians, causing digestive symptoms such as bloating, abdominal pain and diarrhoea, as well as fatigue, anaemia, and an increased risk of cancer, and the only treatment was a gluten-free diet.

Dr Tye-Din, who is also a gastroenterologist at the Royal Melbourne Hospital, said the funding would support studies “to better understand how gluten affects children with coeliac disease, which can be quite different to adult disease, and establishing the mechanism for why symptoms occur, so the disabling symptoms caused by gluten can be better managed”.

The Institute said that the coeliac disease research team had uncovered the parts of gluten that were toxic to people with coeliac disease, contributing to the development of a therapy that could potentially enable people with coeliac disease to eat gluten again.

“The immunotherapy, currently being assessed in clinical trials by biotechnology company Immusant, aims to retrain the immune system to tolerate gluten,” Dr Tye-Din said.

“Results have been encouraging, and the treatment will advance to phase II clinical trials this year,” Dr Tye-Din said.

WEHI said that the research team had developed a potential diagnostic blood test for coeliac disease, highlighted the burden of undiagnosed coeliac disease in the Australian community, and uncovered the immune mechanism for why some people with coeliac disease are unable to tolerate oats.