Biotech Daily

Tuesday February 4, 2014

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: CIRCADIAN UP 12%, ACRUX DOWN 10%**

*** WEHI: 'JAK INHIBITORS POTENTIAL FOR STOMACH, BOWEL CANCER**

*** GENETIC TECHNOLOGIES DR MERVYN JACOBSON COURT DATES**

*** GORDAGEN RAISES $6m FOR VITAMIN E TOCOTRIENOLS**

*** GI DYNAMICS 2013 REVENUE UP 229% TO $2.6m, EXPANSION, TRIALS**

*** ACRUX FALLS ON FDA TESTOSTERONE INVESTIGATION**

*** COLLEGE GROUP BECOMES INSTINCTIF PARTNERS**

*** TGA SPECIAL APPROVAL FOR CALZADA, POLYNOVO NOVOSORB**

*** CE MARK APPROVAL FOR USCOM BP+**

*** UK MINISTER DAVID WILLETTS RESEARCH FUNDING MEETING**

MARKET REPORT

The Australian stock market fell 1.75 percent on Tuesday February 4, 2014 with the S&P ASX 200 down 90.8 points to 5,097.1 points.

Eleven of the Biotech Daily Top 40 stocks were up, 20 fell, eight traded unchanged and one was untraded. All three Big Caps fell.

Circadian was the best, up 2.5 cents or 11.9 percent to 23.5 cents with 50,000 shares traded. Cellmid, Clinuvel, Pharmaxis, Tissue Therapies, Uscom and Viralytics were up more than three percent; Bionomics and Starpharma rose more than two percent; with Optiscan and Osprey up more than one percent.

Acrux (see below) led the falls, down 24 cents or 10.3 percent to $2.08 with 2.85 million shares traded.

Living Cell lost 8.2 percent; both Benitec and Oncosil fell 7.1 percent; Atcor was down 6.9 percent; Universal Biosensors was down five percent; Impedimed and Reva fell more than four percent; Admedus, Antisense, Avita, Prana, Psivida, QRX and Resmed were down three percent or more; Cochlear and Mesoblast shed more than two percent; Alchemia, CSL, Ellex, Medical Developments and Neuren were down more than one percent; with Nanosonics down 0.6 percent.

THE WALTER AND ELIZA HALL INSTITUTE FOR MEDICAL RESEARCH

The Walter and Eliza Hall Institute says that Janus kinase inhibitors used for myelofibrosis could treat stomach and bowel cancers.

The Institute said that research initially conducted at the Melbourne branch of the Ludwig Institute and continued at WEHI found that Janus kinase (JAK) inhibitors reduced the growth of inflammation-associated stomach and bowel cancer in mice.

WEHI said that JAK inhibitors were used to treat the cancer-like condition myelofibrosis, and were being investigated in clinical trials for conditions including leukaemia, lymphoma, lupus and rheumatoid arthritis.

The Melbourne based Cytopia developed the JAK1, JAK2 inhibitor CYT387 which was acquired with the company by YM Biosciences which in turn was acquired by Gilead Sciences (BD: Oct 6, Nov 24, 2009; Dec 14, 2011; Dec 13, 2012).

Cytopia's former drug development vice-president Dr Gregg Smith told Biotech Daily today the CYT387 was developed for myeloproliferative neoplasms and was currently in phase III trials for myelofibrosis.

WEHI said the new research by Dr Emma Stuart, Dr Tracy Putoczki and Prof Matthias Ernst, entitled 'Therapeutic Inhibition of Jak Activity Inhibits Progression of Gastrointestinal Tumors in Mice' was published in Molecular Cancer Therapeutics and an abstract at: http://mct.aacrjournals.org/content/early/2014/01/26/1535-7163.MCT-13-0583-T.abstract.

Dr Stuart said the discovery stemmed from the research team's interest in the links between inflammation and cancers of the digestive tract.

"Recently we have begun to unravel the complex signaling that occurs in inflamed tissues, such as when a person has a stomach ulcer or suffers from inflammatory bowel disease, and how this drives cancer development," Dr Stuart said.

"By understanding the molecules that are involved in promoting the survival and growth of cancer cells, we have been able to identify which of these molecules can be targeted with potential anti-cancer treatments," Dr Stuart said.

"In this case, we determined that proteins called JAKs are involved in cancer formation in the stomach and bowel," Dr Stuart said.

"It was exciting to discover that when JAKs were blocked with existing medications [or JAK inhibitors], bowel and stomach cancer growth in experimental models was slowed, and many of the cancer cells were killed," Dr Stuart said.

Prof Ernst said the findings were significant as JAK inhibitors were already available and had shown success in clinical trials, particularly for treating cancer-like blood conditions.

"Our team's research has uncovered several proteins that could be valuable targets in treating cancers of the digestive tract," Prof Ernst said.

"The reason this discovery is particularly exciting is clinical trials have already shown that JAK proteins can be safely and successfully inhibited in patients," Prof Ernst said.

"We hope this will expedite bringing our research to possible clinical trials that may improve the outlook for people with stomach and bowel cancer," Prof Ernst said.

GENETIC TECHNOLOGIES

Genetic Technologies founder and former major shareholder Dr Mervyn Jacobson will return to Victoria's Supreme Court on April 23, 2014 on charges of market manipulation.

The Commonwealth Director of Public Prosecutions has charged Dr Jacobson with 39 counts of market manipulation and two charges of conspiring to commit a Commonwealth offence, namely market manipulation (BD: Nov 27, 2012; Jun 28, 2013).

An officer of the Supreme Court told Biotech Daily that a court date of April 23, 2014 had been set for preliminary argument and the trial date of June 2, 2014 had been reserved.

GORDAGEN PHARMACEUTICALS

Gordagen says it has raised $6million for the first stage of its over-the-counter and regulatory-directed trials of vitamin E-derived tocotrienols.

Gordagen chief executive officer Dr Glenn Tong told Biotech Daily that vitamin E was composed of both tocotrienols and tocopherols and by removing the tocopherols and administering the tocotrienols sub-lingually, or below the tongue, the company had seen markedly increased pharmacokinetic activity.

Dr Tong said that tocotrienols had shown potential against cancer, inflammatory disease, hypertension and diabetes but the results to date had been “very patchy”.

Dr Tong said that the funds would allow Gordagen to complete trials of tocotrienols, initially for over-the-counter supplements, while identifying compounds for potential regulatory-directed trials.

Dr Tong said the compounds had a very high safety profile and administered sub-lingually could be detected in blood within 15 minutes at higher concentrations than oral delivery.

He said that Gordagen hoped to create supplements that could be marketed for exercise endurance, hypertension and hyperlipidaemia as over-the-counter “heart health products”.

“We are also looking at diabetes and hyperglycaemia,” Dr Tong said.

“While we are doing this we will be creating data for prescription candidates if one shows strong activity for hyperlipidaemia or diabetes,” Dr Tong said.

Dr Tong said the company hoped to generate cash-flow from non-prescription products and identify the best candidates for regulatory directed trials with the first over-the-counter products launched in 2015 and a phase II regulatory trial by the end of 2015.

In a media release, Gordagen said the $6 million was from a sophisticated investor who would have 5,500,000 shares, or 20 percent of the company.

Gordagen said that former Roche Products (Australia) managing director Fred Nadjarian had been appointed non-executive chairman to provide expertise in dietary supplement, prescription medicine and pharmaceutical management.

The company said it would establish an appropriate manufacturing facility for its products.

Gordagen is a private company.

GI DYNAMICS

GI Dynamics says revenue for the year to December 31, 2013 was up 228.6 percent to $US2.3 million ($A2.6 million) as it expanded Endobarrier treatment centres.

In a teleconference, GI Dynamics chief executive officer Stuart Randle said the number of centres providing Endobarrier treatment for obesity and type 2 diabetes increased from 28 in 2012 to 50 in 2013 and the company hoped to have 70 centres by the end of 2014.

GI Dynamics said that sales revenue increased 195 percent in Europe, 75 percent in South America, with initial revenue from Australia and Israel.

GI Dynamics chief commercial officer Mark Twyman said that along with funded studies in Europe the company had begun its US pivotal clinical trial evaluating the efficacy and safety of Endobarrier in the treatment of people with type 2 diabetes and obesity.

GI Dynamics said the net loss for the year ending December 31, 2013 was $US35.6 million compared to $US26.8 million for the prior year, with cash and cash equivalents of $US58.6 million at December 31, 2013 compared to $US41.5 million at December 31, 2012.

Mr Randle said that in 2014, the company’s focus would be to pursue regulatory approval in Brazil, increase the number of Australian centres, continue the US pivotal trial and develop data for European reimbursement.

GI Dynamics was unchanged at 79 cents.

ACRUX

Acrux fell 11 percent following news that the US Food and Drug Administration was investigating cardio-vascular risks in men taking approved testosterone products.

The FDA said it had “decided to reassess this safety issue based on the recent publication of two separate studies that each suggested an increased risk of cardiovascular events among groups of men prescribed testosterone therapy”.

The FDA said it had not concluded that FDA-approved testosterone treatment increased the risk of stroke, heart attack, or death.

“Patients should not stop taking prescribed testosterone products without first discussing any questions or concerns with their health care professionals,” the FDA said.

“Health care professionals should consider whether the benefits of FDA-approved testosterone treatment is likely to exceed the potential risks of treatment,” the FDA said.

“The prescribing information in the drug labels of FDA-approved testosterone products should be followed.”

The FDA said testosterone products were approved only for use in men who lack or have low testosterone levels in conjunction with an associated medical condition, such as failure of the testicles to produce testosterone because of reasons such as genetic problems or chemotherapy or problems with the hypothalamus and pituitary gland that control the production of testosterone by the testicles.

The FDA said that approved formulations included topical gel, transdermal patch, buccal system applied to upper gum or inner cheek and injection.

The FDA said an observational study of older men in the US Veteran Affairs health system published in the Journal of the American Medical Association in November 2013 looked at men with an average age of about 60 years with low serum testosterone undergoing imaging of the blood vessels of the heart to assess for coronary artery disease and the study suggested a 30 percent increased risk of stroke, heart attack and death in the group prescribed testosterone therapy.

The FDA said that a second study reported an increased risk of heart attack in older men, as well as in younger men with pre-existing heart disease, who filled a prescription for testosterone therapy.

The FDA said the study reported a two-fold increase in the risk of heart attack among men aged 65 years and older in the first 90 days following the first prescription and among men younger than 65 years old with a pre-existing history of heart disease, the study reported a two to three-fold increased risk of heart attack in the first 90 days following a first prescription, but younger men without a history of heart disease who filled a prescription for testosterone did not have an increased risk of heart attack.

Acrux fell as much as 26 cents or 11.2 percent to $2.06 before closing for a trading halt to respond to an ASX price fall query, down 24 cents or 10.3 percent at $2.08 with 2.85 million shares traded.

INSTINCTIF PARTNERS (FORMERLY COLLEGE GROUP)

The London-based business communications consultancy College Group, including the public relations company College Hill has changed its name to Instinctif Partners.

Instinctif said in a media relase that other divisions included The College, College Public Policy, Policy Action, Green Issues Communique, Stockheim Media and Instinctif and all would be unified under the single Instinctif brand.

Instinctif said it was backed by private equity firm Vitruvian Partners.

In Australia, College Hill and now Instinctif has a number of biotechnology clients including Brandon Capital, Imugene and Novogen as well as private companies.

CALZADA, POLYNOVO BIOMATERIALS

Calzada says that three plastic surgeons have been authorized to use Polynovo's Novosorb wound implant in free flap donor sites or full thickness surgical wounds.
Calzada said that the Australian Therapeutic Goods Administration had authorized three surgeons at the Royal Adelaide Hospital to use wholly-owned subsidiary Polynovo's Novosorb polymer biodegradable temporizing matrix (BTM) which was implanted in patients with surgical wounds to act as a dermal scaffold allowing tissue regeneration and subsequent skin grafting.
Calzada said the authorization was given under the TGA's early access scheme which allowed surgeons to use the product prior to marketing approval.
Royal Adelaide Hospital specialist plastic surgeon Dr Marcus Wagstaff said that "the positive results to date from the clinical trial give me confidence in the Novosorb BTM's safe use in patients with the aim of improving free flap donor site outcomes."
"This TGA authorized prescriber status permits us to refine the use of BTM under controlled conditions, collect more data and derive more valuable clinical experience with the product," Dr Wagstaff said.
Calzada said that the TGA authorization was valid until January 28, 2015 and while relevant to the three Royal Adelaide Hospital surgeons, other surgeons could apply to be authorised prescribers.
Calzada said it expected to gain more data from this use in patient treatments and that increasing acceptance by a growing number of surgeons would follow.
Calzada said that it expected to submit a 510(k) pre-market approval regulatory submission to the US Food and Drug Administration for Novosorb BTM by April 2014, with other jurisdictions currently being investigated.
Calzada was up 0.3 cents or 4.05 percent to 7.7 cents with 2.3 million shares traded.

USCOM

Uscom says its BP+ central blood pressure diagnostic has Conformité Européenne (CE) mark allowing it to be sold in most European countries.
Uscom said the BP+ had US Food and Drug Administration 510K approval and was in the process of Australian Therapeutic Goods Administration review.
The company said it was developing a European distribution network and volume manufacturing so that the BP+ could be rapidly delivered to meet demand.
Uscom said the BP+ was based on supra-systolic oscillometric technology, directly measuring blood pressure at the heart, rather than at the arm.
The company said that the BP+ provided central pulse pressure waveforms that previously were only acquired using catheters into the heart.
Uscom said the non-invasive central blood pressure measurements were "revolutionizing the way hypertension and heart failure are diagnosed and managed with central [blood pressure] now being proven to be more predictive of outcomes and a better method to guide hypertension treatment".
Uscom executive chairman Rob Phillips said the BP+ technology was "leading the changes in thinking on blood pressure and hypertension globally".
"The confirmation of the completion of the CE mark process means we can now sell the device into European jurisdictions," Mr Phillips said.
"We are also preparing for increased manufacturing of the BP+ to meet current orders and to feed the product into our newly developed European distribution channels," Mr Phillips said.
Uscom was up half a cent or 3.6 percent to 14.5 cents.

BRITISH GOVERNMENT, UNIVERSITY OF MELBOURNE

Britain's Minister of State for Science and Universities David Willetts will discuss "the vital research streams" for government investment at the University of Melbourne.

A media release from the British Consulate-General said that Mr Willetts would present his vision of 'The Critical List' - the vital research streams in which governments need to invest with the Chief Scientist of Australia Prof Ian Chubb and academics from the University of Melbourne.

The British Consulate-General said that the Director of the Royal Institution of Australia Dr Paul Willis would facilitate the discussion on research priorities and the role of government in the research agenda in the UK and Australia.

The reception will be hosted by the British High Commissioner Paul Madden at the Dax Gallery at the Melbourne Brain Centre, University of Melbourne Parkville on February 28, 2014 from 6pm to 7pm.

While the discussion is a free event, a valid ticket is required for entry and registration is through: https://the-critical-list-uk-minister-28-02.eventbrite.com.au.