Biotech Daily

Tuesday June 14, 2011

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: NANOSONICS UP 5%, GENERA DOWN 17%**

*** QRX MOXDUO MIXED EQUAL STRENGTH SAFETY RESULTS**

*** WEHI, GARVAN DIABETES VACCINE ACTS ON IMMUNE RESPONSE**

*** JOURNAL PUBLISHES 2006 AGENIX THROMBOVIEW SAFETY DATA**

*** PETER MACCALLUM COMPLETES PRIMA CVAC POTENCY ASSAY**

*** BIOMD TAKES 90% OF ALLIED MEDICAL, COMPULSORY ACQUISITION**

*** CIRCADIAN LAUNCHES AMERICAN DEPOSITARY RECEIPTS**

*** CBIO EGM FOR 9.1m DIRECTORS, EXECUTIVES PERFORMANCE RIGHTS**

*** PHARMAUST EGM TO CHANGE DIRECTION**

*** BLUECHIIP DIRECTORS IAIN KIRKWOOD, BRETT SCHWARZ TAKE 21%**

*** ORBIS TAKES 18% OF IMPEDIMED**

*** REVA RELEASES 211m ESCROW SHARES**

*** KARMELSONIX APPOINTS MICHAEL THOMAS CEO**

MARKET REPORT

The Australian stock market was up 0.5 percent on Tuesday June 14, 2011 with the S&P ASX 200 up 22.9 points to 4585.0 points. Six of the Biotech Daily Top 40 stocks were up, 20 fell, eight traded unchanged and six were untraded.

Nanosonics was the best, up 3.5 cents or 4.5 percent to 81 cents with 577,162 shares traded; followed by Optiscan and Prana up more than two percent; with Cellestis, Prima and Heartware up more than one percent.

Genera led the falls, down four cents or 16.7 percent to 20 cents with 11,000 shares traded. Patrys lost 9.1 percent; QRX and Viralytics fell more than seven percent; Anteo and Universal Biosensors were down more than six percent; Bionomics, Biota and Virax fell more than four percent; Benitec, Cellmid, Genetic Technologies, Living Cell and Phosphagenics were down more than three percent; Psivida shed 2.5 percent; with Pharmaxis. Phylogica and Resmed down more than one percent.

QRX PHARMA

QRX says its phase III comparison trial shows that Moxduo had a mixed superior safety profile to equi-analgesic doses of either morphine or oxycodone alone.

QRX said that on some measures the superiority was significant but others it was not.

QRX said the Study 022 primary endpoint of respiratory depression as measured by oxygen desaturation was less severe and of shorter duration in patients receiving Moxduo immediate release (12mg morphine and 8mg oxycodone) compared to those receiving either 24mg morphine or 16mg oxycodone alone.

The company said respiratory depression was the leading cause of death from high doses of opioids.

QRX said moderate to severe vomiting was also less frequent in the Moxduo patients when compared to oxycodone.

The company said the double-blind, randomized, fixed dose trial enrolled 375 patients with moderate to severe post-bunionectomy pain at four US clinical research sites.

QRX chief executive officer Dr John Holaday said the study "demonstrated that Moxduo treated patients, while receiving effective pain relief, experienced less severe respiratory depression, which is a major safety advantage".

"The study also provided a wealth of information, enabling us to optimize the designs of future trials to support our comparative safety claim program," Dr Holaday said.

"Moxduo's favorable side effect profile, when compared head-to-head to current standards of care, distinguishes the product from other acute pain opioids in the clinical marketplace," Dr Holaday said.

"To the best of our knowledge, Moxduo is the first opioid product to demonstrate a lower risk of respiratory depression in a clinical study comparing morphine equivalent doses," Dr Holaday said.

QRX said blood oxygen was measures through pulse oximetry (SpO2) and oxygen desaturation SpO2 of less than 90 percent over time was used to assess the severity and duration of respiratory impairment indicating that Moxduo has a significantly better safety profile than oxycodone ($P < 0.02$).

The company said that non-significant beneficial trends for Moxduo also occurred in comparisons to morphine treatment on these same endpoints.

QRX said that secondary endpoints of opioid-related side effects were consistent with previous studies demonstrating that the occurrence of moderate to severe vomiting was significantly ($p < 0.04$) reduced in Moxduo IR treated subjects (32%) compared to patients receiving oxycodone alone (42%) at the same 24 mg morphine equivalent dose.

The company said morphine and Moxduo had comparable rates of moderate to severe vomiting. QRX said that the overall incidence of nausea trended lower in the Moxduo treated subjects than oxycodone and morphine, but the differences were not statistically significant.

QRX said the results provided valuable safety and efficacy information for addressing regulatory requirements for future Moxduo product labeling and would be submitted as part of a 2011 product registration filing with the US Food and Drug Administration and would be supportive of its European marketing authorization application scheduled for submission by July 2012.

The company said it expected to file a new drug application with the FDA for Moxduo IR within the next two months.

QRX said Moxduo IR capsules were a patented three to two fixed ratio combination of morphine and oxycodone that targeted the acute pain market, a $US2.5 billion segment of the $US7 billion spent annually on prescription opioids in the US.

QRX fell 14.5 cents or 7.4 percent to $1.825.

THE WALTER AND ELIZA HALL INSTITUTE FOR MEDICAL RESEARCH

The Walter and Eliza Hall Institute says its phase II intranasal insulin type 1 diabetes vaccine trial shows the vaccine could prevent the development of the disease.

The trial began in late 2006 under the auspices of the Diabetes Vaccine Development Centre (now part of the Garvan Institute) and the first patient was treated in March 2007 (BD: Dec 8, 2006; Mar 27, 2007).

The Walter and Eliza Hall Institute said the 52 patient trial of intranasal insulin (INIT II) for the prevention or delay of type 1 diabetes was conducted by the immunology division's Prof Len Harrison with the Royal Melbourne Hospital's Dr Spiros Fourlanos.

The Institute said the nasal insulin vaccine desensitized the human immune system, suppressing its reaction against insulin.

The Walter and Eliza Hall Institute said the trial results were published in an article entitled 'Evidence That Nasal Insulin Induces Immune Tolerance to Insulin in Adults With Autoimmune Diabetes' in the April issue of the journal Diabetes. An abstract is at: http://diabetes.diabetesjournals.org/content/early/2011/02/07/db10-1360.short?rss=1

The article concluded that "although nasal insulin did not retard loss of residual beta-cell function in adults with established [type 1 diabetes], evidence that it induced immune tolerance to insulin provides a rationale for its application to prevent diabetes in at-risk individuals".

The Institute said the research provided proof-of-principle for the type 1 diabetes prevention trial and previous research by Prof Harrison showed that a nasal insulin vaccine was successful in preventing type 1 diabetes in laboratory mice.

"These latest results encourage us that we are on the right track to finding a vaccine for type 1 diabetes," Prof Harrison said.

The Institute said that type 1 diabetes occurred when the body's immune system attacked and killed the beta cells in the pancreas that produced insulin.

WEHI said that insulin itself was a specific target of the immune attack that killed the beta cells and insulin was a vital hormone that moved glucose from the blood stream into the body's cells, giving them energy.

The Institute said a lack of insulin led to serious health problems and people with type 1 diabetes required daily insulin injections.

The Institute said that although the participants were not at the stage of requiring insulin injections they had evidence of immunity to the insulin-producing beta cells in the pancreas and were given either the nasal insulin vaccine or a placebo weekly for 12 months.

"The results showed that the vaccine allowed the immune system to restore immune tolerance to insulin," Prof Harrison said.

"When subsequently given insulin by injection, the participants who had received the nasal insulin vaccine were found to be desensitized to insulin," Prof Harrison said.

"The nasal insulin vaccine works to desensitize the whole immune system to insulin, so that the white blood cells of the immune system, called T cells, are prevented from attacking insulin in the beta cells," Prof Harrison said.

"The insulin vaccine is not administered orally because it would be broken down in the gut, making the concentration too low to be effective," he said. "This problem is not encountered with direct administration to the nose and the nasal mucosal immune system has special properties that actively promote a protective immune response."

"The nasal vaccine approach, if shown to be successful in human type 1 diabetes, could also be tested with different vaccines for the prevention of other autoimmune diseases such as rheumatoid arthritis and multiple sclerosis," he said.

WEHI said the INIT II trial was halfway through the testing phase.

AGENIX

Agenix says a phase Ib study confirming the safety of its pulmonary embolism diagnostic Thromboview will be published in the journal Heart, Lung and Circulation.

Agenix said the data was collected at seven Australian hospitals during 2005 and 2006 in a study led by Royal Brisbane Hospital deputy director Dr David Macfarlane and the publication was authored by the University of California San Diego's head of pulmonary and critical care medicine Dr Timothy Morris.

The article, entitled 'Pulmonary Emboli Imaging with 99mTc-labelled Anti-D-dimer (DI-80B3) Fab' Followed by SPECT' concluded that Thromboview was "well-tolerated in patients with acute pulmonary embolism and does not induce an immune response".

Agenix was developing the Thromboview technology when it became involved in the failed acquisition of two Chinese pharmaceutical companies and its former chief executive officer Neil Leggett embezzled about $4 million from the company (BD: Jun 13, Jul 24, Sep 15, 2008).

Agenix has been in recovery with new management for the past two years.

The company said Thromboview could offer a nw approach to imaging pulmonary embolism in a clinically acceptable timeframe without exposure to potentially nephrotoxic radiographic contrast agents.

Agenix said the 16-patient, multi-centre, single arm, prospective open-label phase Ib study confirmed evidence from two earlier studies that Thromboview was "safe in patients with acute pulmonary embolism" and showed promise as a "safe, useful and accurate diagnostic for detecting pulmonary embolism."

The study found pulmonary embolisms could be accurately imaged in a clinical setting using a standard hospital gamma ray scan after Thromboview had been administered.

Agenix said none of the patients measured displayed an immune response or side effects from exposure to the radioactive diagnostic drug during a 90-day follow-up period.

The company said the lack of an immune response indicated the test had the potential to be used more than once in the same patient.

Agenix said the study showed that images could be read at a relatively short interval after administration and that considering it was the first Thromboview pulmonary embolism study, the ease of reading Thromboview was encouraging.

The company said Thromboview could bind to thrombi in patients despite the presence of anticoagulants.

Agenix chairman Nicholas Weston said the peer-reviewed article provided "timely validation that Thromboview affords a number of benefits to both patients and the medical professionals who currently have limited options available".

"It also supports our strategy for a diagnostic such as Thromboview to meet the significant demand in the anticoagulation market if it could be shown that new clots or clots that remain hot, persistently contain active fibrin for the agent to bind to, require ongoing anticoagulation treatment beyond the standard three month time course," Mr Weston said.

"This could be a considerable market, since the optimal duration of anticoagulation after unprovoked venous thrombo-embolisms is still very controversial," Mr Weston said.

Agenix said that Thromboview required only a standard hospital gamma camera to take a single photon emission tomography (Spect) image from which the reader could easily identify the presence, absence and location of a blood clot.

The company said pulmonary embolisms were a blockage in a main artery or one of its branches in the lungs and were the third most common cause of death among hospitalized patients in the US.

Agenix was unchanged at 1.5 cents.

PRIMA BIOMED

Prima says Melbourne's Peter MacCallum Cancer Centre has completed the potency assay for the CVac ovarian cancer immunotherapy vaccine.
Prima said the purpose of the potency assay was "to ensure that a given batch of treatment, in this case the CVac vaccine, has a pre-defined minimum level of potential biological activity that will deliver an expected result" and helped demonstrate a batch-to-batch consistency of the treatment, which depended on and reflected biological activity.
Prima said CVac was an autologous cell therapy or a personalized medicine like a bone marrow transplantation and a potency assay development was an important step.
The company said the potency assay gave an opportunity to compare manufacturing across its world-wide facilities and would lead to a validation tool for regulatory purposes once patient data from the upcoming phase III study was available.
Prima said the assay was a key component to establish CVac as a pharmaceutical grade product and would become an integral part of the chemistry manufacturing and controls section of a future registration regulatory package.
The company said the qualification of the potency assay was based on more than 18 months of research and was developed in collaboration with Prima's clinical team and the Peter MacCallum Cancer Centre in Melbourne.
Prima was up half a cent or 1.7 percent to 30.5 cents with six million shares traded.

BIOMD

Biomd says it has more than 90 percent of the public unlisted Allied Medical, has shareholder approval for the backdoor takeover and will move to compulsory acquisition.
On completion of the acquisition, Allied shareholders will have 70 percent of the issued capital of the combined group.
Allied Medical chief executive officer Lee Rodne said the merger offered "both Allied and Biomd shareholders the opportunity to benefit from a new and diversified healthcare company".
Mr Rodne said the new company would be focused on its existing distribution business and the commercialization of new medical technologies.
Biomd said the group would include the DNA vaccine development company Coridon Pty Ltd led by Prof Ian Frazer and Biomd's Adapt tissue engineering and regenerative technologies for use in cardiovascular and soft tissue repair surgery.
Biomd was untraded at 6.2 cents.

CIRCADIAN TECHNOLOGIES

Circadian says it will begin trading level 1 American depositary receipts and have dual quotation on the over-the-counter market (OTCQX) in the US from tonight.
Circadian said one American depositary receipts (ADR) would be equivalent to five ASX shares.
The company said the American depositary receipts program was sponsored by the Bank of New York Mellon and the San Francisco-based Merriman Capital Inc had been appointed as principal American liaison in connection with the OTCQX securities.
Circadian chief executive officer Robert Klupacs said that over the past 12 months "we have been receiving considerable interest from US based investors".
"In particular from US retail-orientated broking houses and institutions who have mandates to invest only in US traded stocks," Mr Klupacs said.
Circadian was unchanged at 59.5 cents.

CBIO

CBio shareholders will vote to issue 9.1 million free performance rights to executives and directors, exercisable, pending conditions, at no charge for seven years.
CBio shareholders will be asked to ratify the prior issue of 15,350,616 shares and 2,169,109 shares to Springtree Special Opportunities Fund along with approval for director Dr Michael Monsour to subscribe for rights offer shortfall shares.
A further 11 resolutions provide for the issue of 1,900,000 free performance rights pending conditions to executives, 500,000 rights for company secretary Ben Graham, 2,000,000 performance rights each to chairman Stephen Jones and chief executive officer Jason Yeates, along with 200,000 performance rights each to directors Dr Göran Ando, Dr Peter Corr, Prof John Funder, Dr Michael Monsour, Dr Terje Kalland and Dr Thomas Lönngren and 1,500,000 performance rights for director and chief financial officer James Greig.
CBio said that no shares would be issued in connection with the performance rights until a vesting event occurred, namely, a major collaboration or licence transaction, or sale of the company's operations, or a shareholder acquiring 19.9 percent of the issued shares of the company, or the achievement of a $1.00 share price.
The general meeting will also be asked to increase the pool of directors' remuneration to $750,000. CBio said directors received $380,760 for the year to June 30, 2010.
The meeting will be held at the East Auditorium of the BTP Technology Conference Centre, 1 Clunies Ross Court, Eight Mile Plains, Queensland, July 15, 2011 at 11am (AEST).
CBio was unchanged at 53.5 cents.

PHARMAUST

Pharmaust shareholders will vote to change the nature and scale of its activities.
Pharmaust has sought shareholder approval to issue 150,000,000 shares and elect Gregory Cunnold a director in relation to the Pela transaction.
Shareholders will also be asked to ratify the issue of 24,000,000 shares and 24,000,000 attaching options and approve the issue of up to 100,000,000 shares.
Pharmaust intends to develop mining interests in the former Yugoslav Republic of Macedonia but retains Epichem as a wholly-owned subsidiary.
Pharmaust fell 0.1 cents or 3.2 percent to three cents.

BLUECHIIP

Bluechiip chairman Iain Kirkwood and managing director Brett Schwarz have filed substantial shareholder notices saying they own 8.9 percent and 11.7 percent, respectively.
Mr Kirkwood said that with related parties Edward Street Consulting and through a put-option with Mr Schwarz he held 6,972,960 shares or 8.9 percent.
Mr Schwarz said that with related parties Rainbow investments and Kermett Pty Ltd and through a put-option with Mr Kirkwood he held 9.172,000 shares or 11.7 percent.
But Mr Schwarz told Biotech Daily that discounting the put-options he held 10.1 percent and Mr Kirkwood held 5.8 percent.
Separately, Dr Stephen Woodford and Patricia Woodford of Woy Woy, New South Wales said they held 12,806,664 shares or 16.362 percent of the company.
Dr Ronald Zmood said that with related party Zalpere Pty Ltd of Orrong Road Caulfield North Victoria held 4,890,160 or 6.25 percent.
Bluechiip fell 2.5 cents or 10.9 percent to 20.5 cents.

IMPEDIMED

Orbis Investment Management has increased its substantial shareholding in Impedimed from 22,683,111 shares (16.71%) to 27,843,273 shares (17.79%).
Impedimed fell half a cent or 0.83 percent to 60 cents.

REVA MEDICAL

Reva says it will release the equivalent to 210,593,310 CHESS depository instruments and 14,700,000 options from voluntary escrow on June 23, 2011.
Reva said 21,059,331 shares equivalent to 210,593,310 CDIs and 1,470,000 options over common shares equivalent to 14,700,000 CDIs were held in voluntary escrow as part of the 2010 initial public offering (BD: Dec 16, 2010).
Reva fell 4.5 cents or 4.15 percent to $1.04.

KARMELSONIX

Karmelsonix has appointment Michael Thomas as chief executive officer.
The company said Mr Thomas had more than 22 years experience in the healthcare industry in various executive positions and was formerly the chief executive officer at Appian Partners, a healthcare advisory firm.
Karmelsonix said that prior to leading Appian Partners, Mr Thomas was president and chief executive officer of US medical device manufacturer Sleep Solutions Inc.
The company said Mr Thomas had held various sales and marketing positions with Merck and Glaxo Wellcome and held a Bachelor of Science degree in microbiology from Cornell University.
Karmelsonix was unchanged at 1.4 cents with 4.2 million shares traded.