Biotech Daily

Wednesday February 10, 2010

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: PATRYS UP 15%; IMPEDIMED DOWN 10%**

*** QRX BEGINS 2nd PHASE III PAIN TRIAL**

*** COMMERCIALISATION AUSTRALIA BOARD BIOTECH-EXPERIENCED**

*** BIOSIGNAL VOTES ON IP SALE; NAME, DIRECTION CHANGE**

*** CLINUVEL SHELVES TWO OF FIVE AFAMELANOTIDE INDICATIONS**

*** HEALTHLINX NAMES AGR2 AS OVARIAN CANCER TEST PROTEIN**

*** NARHEX – ADMINISTRATORS APPOINTED**

MARKET REPORT

The Australian stock market was up 0.18 percent on Wednesday February 10, 2010 with the S&P ASX 200 up 8.3 points to 4513.4 points.

Sixteen of the Biotech Daily Top 40 stocks were up, 14 fell, six traded unchanged and four were untraded.

Patrys was best, up two cents or 15.4 percent to 15 cents with 227,999 shares traded, followed by Phosphagenics up 11.6 percent to 7.7 cents with 1.3 million shares traded.

Mesoblast climbed 7.4 percent; Cellmid and Clinuvel were up six percent or more; Tissue Therapies were up 4.65 percent; Cellestis, Chemgenex, Compumedics, LBT, Living Cell, Nanosonics, Novogen and Pharmaxis rose more than two percent; with Antisense up 1.96 percent.

Impedimed led the falls, down seven cents or 10 percent to 63 cents with 42,500 shares traded.

Benitec and Genetic Technologies lost more than five percent; Alchemia and QRX fell more than four percent; Cathrx, Circadian, Optiscan, Prana, Prima and Viralytics were down more than three percent; with Genera down 1.2 percent.

QRX PHARMA

QRX has begun its second pivotal phase III registration trial to evaluate the analgesic efficacy and safety of Moxduo Immediate Release for post surgical pain.

QRX said Moxduo was a three to two ratio fixed-dose combination of morphine and oxycodone and the two-arm study would compare the effectiveness and safety of a flexible Moxduo immediate release dose regimen to a fixed low dose for managing moderate to severe pain in patients who have undergone total knee replacement surgery.

The company said it expected to complete dosing by October 2010 in preparation for filing a new drug application with the US Food and Drug Administration by the end of 2010.

QRX said Moxduo Immediate Release (IR) targeted the $US2.5 billion acute pain market, a segment of the more than $US7 billion spent annually on prescription opioids in the US.

QRX chief executive officer Dr John Holaday said that clinical trials had "consistently demonstrated Moxduo IR achieves as good or better pain relief with fewer incidences of moderate-severe side effects than morphine, oxycodone or Percocet".

"Based on these data, we are optimistic about the competitive advantages of Moxduo," Dr Holaday said. "With the initiation of the company's second pivotal trial for Moxduo IR, we are one step closer to definitively proving the value of our dual opioid product to potential partners, prescribers and patients".

The company said that in 2009, an open-label pilot study demonstrated improved analgesia of flexible dose Moxduo IR with individual doses up to 24mg morphine and 16mg oxycodone compared to fixed, low dose Moxduo immediate release of 3mg morphine and 2mg oxycodone in patients with moderate to severe pain following total knee replacement surgery.

Based on these results, low dose Moxduo immediate release was selected as the control for this pivotal trial, QRX said.

The company said that the phase III trial was a randomized, double blind trial, hoping to enroll 140 patients with 70 patients in each study arm at eight US clinical research sites.

QRX said that initially, all post-operative patients would receive intravenous patient controlled analgesia morphine until the day following knee replacement surgery, when patient controlled morphine dosing would be stopped.

The company said that when pain became moderate to severe, based on the 10-point numerical pain rating scale, patients would be randomized in equal numbers to receive either a flexible regimen of Moxduo IR (Arm 1) or the low dose control (Arm 2).

For patients assigned to the flexible dose regimen, the initial dose will be based on the company's proprietary algorithm (developed in the prior open label study) that converts PCA morphine to oral morphine equivalents of Moxduo IR.

All Arm 1 patients will start on at least 12mg morphine and 8mg oxycodone, while patients in Arm 2 will receive a loading dose of 6mg and 4mg followed by 3mg and 2mg regardless of their initial patient controlled dosing regimen.

All patients will be dosed every four to six hours over a 48-hour period, the company said.

QRX said the primary endpoint for evaluating the efficacy of flexible dose versus low dose was the difference from baseline in pain intensity scores for each treatment group over the 48-hour treatment period.

Secondary endpoints include efficacy relating to the time to onset of analgesia and global assessment of effect, that is total pain relief, as well as amount of supplemental analgesia used throughout the treatment period and safety as measured by incidence and intensity of opioid-related adverse effects.

QRX said it expected to complete its phase III program by October 2010 and file its application for Moxduo IR by the end of year 2010.

QRX fell 3.5 cents or 4.6 percent to 72.5 cents.

COMMERCIALISATION AUSTRALIA

Innovation Minister Senator Kim Carr has appointed Commercialisation Australia's six-member board including two directors familiar with the biotechnology sector.

Innovation Minister Senator Kim Carr said that the calibre of the appointees showed "just how serious the Rudd Government is about providing a useful tool to help business succeed and generate high-wage, high-skill jobs".

"The board members have a thorough understanding of the commercialization process," Senator Carr said.

"Their collective experience extends right across the research, industry and investment communities," Senator Carr said.

"They have the practical know-how that is needed to assess the diverse range of applications that we are expecting," he said.

The first board meeting is expected to be held in early March 2010.

The chairman of the board is the co-founder and director of IQ Capital Management Dr Laurie Hammond.

The members of the board are Australian Private Equity and Venture Capital Association (AVCAL) chief executive Dr Katherine Woodthorpe; former chairman and managing director of Johnson & Johnson Research Dr Susan Pond; Swinburne (University) Ventures chief executive officer Dr Bruce Whan; Commonwealth Scientific and Industrial Research Organisation's general manager of intellectual property, licencing and technology transfer Jan Bingley; and Australian Manufacturing Workers' Union industry and economic adviser Nixon Apple, a trustee of Australian Super and described by Dr Woodthorpe as "a supporter of venture capital".

A Department of Innovation media release said Dr Hammond was the independent chairman of the committee guiding the establishment of Commercialisation Australia and a member of its interim advisory board.

The media release said Dr Hammond had about 20 years experience as a scientist and research director in biology and environmental science and 10 years as chief executive in a number of organizations financing or applying innovation in Australia and New Zealand.

Dr Woodthorpe has been a director of Agenix, Australian Cancer Technologies, Psivida and Ventracor.

Ausbiotech chief executive officer Dr Anna Lavelle and Bio-Melbourne Network chief executive officer Michelle Gallaher said the board members with whom they were familiar, in particular Dr Hammond, Dr Woodthorpe and Dr Pond were welcome appointments.

BIOSIGNAL

Biosignal shareholders will vote on the backdoor listing of RGM Entertainment Pte Ltd at a general meeting on March 19, 2010.

The meeting will consider nine resolutions including a transaction with Commonwealth Biotechnologies Inc which includes the transfer of Biosignal's intellectual property (BD: Jul 24, Dec 14, 2009).

Other resolutions are for a 25-to-one consolidation of share capital the acquisition of RGM, the election of RGM representatives to the Biosignal board, the approval of a name change to RGM Media, a capital raising, share option plans.

The company said it expected to be reinstated to trading tomorrow February 11, 2010.

The meeting will be held at Middletons, Level 25, 525 Collins Street, Melbourne, on March 2010 at 10.30am.

Biosignal last traded at 2.3 cents.

CLINUVEL PHARMACEUTICALS

Clinuvel says it will shelve programs trialing its photo-protective drug afamelanotide for solar urticaria and photodynamic therapy.

Clinuvel said it made the decision after “positive scientific advice from the European Medicines Agency … relevant to its application for marketing authorization for [erythropoietic protoporphyria] this year”.

Clinuvel said it would focus its resources on the final development of afamelanotide for erythropoietic protoporphyria (EPP), actinic keratosis and polymorphic light eruption (PLE).

The company said the European Medicines Agency’s committee for human medicinal products considered its existing preclinical package, accompanied by ongoing studies, “adequate to support marketing authorization”.

Clinuvel said the committee further acknowledged that afamelanotide could become the first line treatment for EPP and agreed that no other medicinal products were available for treating EPP.

Since the guidelines for clinical trials in small populations would apply, Clinuvel said it expected the ongoing clinical trials should be sufficient for marketing authorization.

Clinuvel said that it was encouraged by the European Medicines Agency to develop the product for children acutely affected by EPP.

Afamelanotide would decrease the intensity of phototoxicity and increase the quality of life for children, the company said.

Clinuvel’s chief scientific officer Dr Hank Agersborg said that in the past two years “the consistently positive responses from physicians and patients suggests afamelanotide may become the first-line treatment for EPP”.

“The potential of afamelanotide is recognised and is being tested by many leading physicians treating skin cancers in organ transplant recipients and most photo-dermatologists treating PLE patients,” Dr Agersborg said.

“These three indications will be the focus of our company,” he said.

He said that recruitment for solar urticaria and photodynamic therapy would be difficult.

Clinuvel chief executive officer Dr Philippe Wolgen said that by concentrating on three indications “Clinuvel will be most effective in filing for a marketing authorization in 2010”.

“The selective melanocortin afamelanotide is a rare find in pharmaceutical development,” Dr Wolgen said.

“We will continue to use the drug only where it is clinically most appropriate,” Dr Wolgen said.

“The criterion of most urgent unmet clinical need is addressed by the severity of both EPP and skin cancer,” he said.

“It will be most rewarding to develop a paediatric product for EPP,” Dr Wolgen said.

“These are children who go through years of anguish and anxiety,” he said.

We expect to complete the development of a new paediatric dosage form by mid 2010,” Dr Wolgen said.

Clinuvel head of communications Lachlan Hay told Biotech Daily that the company’s cash burn for the three months to December 31, 2009 was $1.2 million and the company had about $32 million in cash.

Mr Hay said the company expected erythropoietic protoporphyria phase III results by April 2010.

Clinuvel was up 1.5 cents or six percent to 26.5 cents.

HEALTHLINX

Healthlinx has disclosed the identity of one of its ovarian cancer biomarkers as the anterior gradient 2 protein (AGR2) previously described as HTX005.

Healthlinx said the journal Clinical Science had published online an abstract of the yet to be published paper entitled "Increased plasma concentrations of anterior gradient 2 protein are positively associated with ovarian cancer" by its scientists and collaborators at the University of Liverpool.

The abstract is at: http://www.clinsci.org/cs/imps/abs/CS20090537.htm.

Healthlinx said the manuscript described the identification of HTX005 (AGR2) "as a novel biomarker released into the bloodstream of ovarian cancer patients".

The company said the performance of AGR2 would be further tested in a multi-centre, multi-national study.

Healthlinx said that based on preliminary data it was expected that the biomarker would increase the performance of its Ovplex ovarian cancer diagnostic to greater than 97 percent.

Healthlinx managing director Nick Gatsios said the publication was "a coup for the company".

"Healthlinx has a patent pending for what we view as a unique antibody that allows us to detect the protein in human blood," Mr Gatsios said.

"We have been working with this biomarker for almost two years and have been holding our cards very close to our chest until we were confident about its importance in our programs," Mr Gatsios said.

"When we model AGR2 with some of our existing biomarkers in the Ovplex panel we achieve greater than 97 percent diagnostic efficiency," Mr Gatsios said.

"We are confident that the second larger biomarker study commencing in the very near future will further establish the potential of this biomarker and its relevance to producing the next generation multi-marker panel with significantly improved performance," he said.

Healthlinx fell 0.1 cents or 1.3 percent to 7.8 cents.

NARHEX LIFE SCIENCES

Narhex says David Ross and Richard Albarran of chartered accountants Hall Chadwick have been appointed administrators of the company.

Narhex had been developing drugs for HIV but was suspended from ASX trading on March 3, 2008 for failing to lodge its half-yearly accounts for the six months to December 31, 2007, which were lodged with the ASX on July 16, 2009.

The company was provided with a $350,000 line of credit from executive chairman Dr Michael Cohen who died on November 19, 2009.

Narhex last traded at 1.6 cents.