Biotech Daily

Thursday September 24, 2009

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH UP: OPTISCAN UP 13%; PSIVIDA DOWN 16%**

*** ACRUX ESTRADIOL EURO-DEAL COULD EARN UP TO $25m**

*** PSIVIDA BEGINS SECONDARY MACULAR OEDEMA ILUVIEN TRIAL**

*** QRX SNAKE VENOM ALLIANCE WITH CHINA'S NUOKANG**

*** SUNSHINE HEART RIGHTS ISSUE RAISES $8m**

*** COMPUMEDICS INCREASES GERMAN SALES**

*** BIOPROSPECT APPOINTS LEO 'THE GUN' KHOURI DIRECTOR**

*** FDA CLEARS KARMELSONIX WHEEZOMETER**

MARKET REPORT

The Australian stock market fell 0.69 percent on Thursday September 24, 2009 with the S&P ASX 200 down 32.9 points to 4701.2 points.

Sixteen of the Biotech Daily Top 40 stocks were up, 15 fell, three traded unchanged and six were untraded. All three Big Caps were up.

Optiscan was best, up one cent or 13.3 percent to 8.5 cents with 173,199 shares traded, followed by Prana up 10.3 percent to 21.5 cents with 1.8 million shares traded and Antisense up 10 percent to 5.5 cents.

Cytopia and Impedimed climbed more than nine percent; Viralytics and Universal Biosensors were up more than seven percent; Heartware and Mesoblast were up more than three percent; Biota, Cellestis, Cochlear, Compumedics and Tissue Therapies rose more than two percent; with Clinuvel up 1.5 percent.

Psivida led the falls, down 93 cents or 16.2 percent to $4.82 with 17,856 shares traded, followed by Living Cell down 10 percent to 22.5 cents.

Benitec lost 9.4 percent; Phosphagenics fell 8.7 percent; Nanosonics was down 7.4 percent; Progen fell 6.15 percent; Tyrian fell 4.2 percent; Novogen and Starpharma shed more than two percent; with Acrux, Bionomics, Chemgenex, Genetic Technologies and Sunshine Heart down more than one percent.

ACRUX

Acrux says the Paris-based HRA Pharma will market and distribute its transdermal estradiol spray Ellavie for menopause symptoms in major European countries.

Acrux chief executive officer Dr Richard Treagus told Biotech Daily that Ellavie would be marketed under a different name in Europe due to a similarity to an existing HRA product.

Dr Treagus said Acrux would receive up front fees but the amount was not disclosed.

Acrux said HRA Pharma specialized in reproductive health and endocrinology and would distribute the spray in France, Germany, the United Kingdom, Spain, Italy, Greece, Turkey and Cyprus, with a product launch expected in 2011.

The company said it expected to receive fees of up to €2.1 million ($A3.6 million) in signing, regulatory approval and market launch milestones.

Acrux said it would receive an ongoing distribution fee based on net sales in each country taking total peak sales potential for the eight countries to €15 million ($25.4 million) a year.

The company said Ellavie was marketed in the US as Evamist and was under evaluation by the regulatory authority in Sweden.

Acrux said it was responsible for obtaining marketing approval in Sweden and HRA Pharma would then be responsible for obtaining marketing approval in each country through a mutual recognition procedure.

Dr Treagus said the company was “very pleased to announce the commercialization of Acrux’s first product in the key Western European pharmaceutical markets”.

Acrux fell three cents or 1.9 percent to $1.54.

PSIVIDA

Psivida says it has begun enrollment for a safety and efficacy pilot study of Iluvien in patients with macular oedema secondary to retinal vein occlusion.

Psivida said Iluvien inserts, containing the generic corticosteroid fluocinolone acetonide were designed to provide a sustained therapeutic effect of up to 36 months, for the low dose Iluvien, and up to 24 months, for the high dose of Iluvien.

The company said Iluvien was inserted into the patient’s eye with a 25-gauge needle, allowing for a self-sealing wound similar to an intravitreal injection, a procedure commonly employed by retinal specialists.

Psivida said Iluvien was in pivotal phase III clinical trials for diabetic macular oedema (DME) with 24-month top-line data expected in December 2009 and a new drug application expected to be filed with the US Food and Drug Administration in 2010.

The company said the randomized, double-blind pilot study of Iluvien for macular oedema secondary to retinal vein occlusion would compare two doses of Iluvien - 0.23 micrograms per day and 0.45 micrograms per day. The trial is sponsored by licencee, Alimera Sciences of Alpharetta, Georgia.

Psivida chief executive officer Dr Paul Ashton said retinal vein occlusion was a common disorder of the retina and “one of the leading causes of blindness after diabetic eye disease and age-related macular degeneration”.

Dr Ashton said Iluvien was in phase III clinical trials for DME and was in pilot studies for wet and dry age-related macular degeneration.

Psivida said retinal vein occlusion occurred when the circulation of a retinal vein became obstructed and the occlusion could cause capillary leakage leading to macular oedema, which was the leading cause of visual loss in retinal vein occlusion.

Psivida said it had developed “two of the only three products approved by the FDA for the long term, sustained release delivery of drug to treat chronic back of the eye disease”.

Psivida fell 93 cents or 16.2 percent to $4.82.

QRX PHARMA

QRX says it is creating a strategic alliance with Liaoning Nuokang Medicines of Shenyang, China, to develop and commercialize QRX's venomics assets.
QRX said the alliance involved Nuokang investing $US5.0 million ($A5.7 million) for a controlling interest in a Hong Kong company that holds a licence over two of QRX's lead haemostasis product candidates the anti-fibrinolytic agent Textilinin and the pro-coagulant Haempatch, both derived from Australian Brown Snake venom.
QRX said the transaction should be completed by mid-October 2009 and a minority interest in the Hong Kong company will be held by Venomics Pty Ltd, which is a majority-owned subsidiary of QRX and holds all of QRX's venomics assets.
An affiliated company of Nuokang has subscribed for a 10 percent interest in Venomics.
QRX chief executive officer Dr John Holaday said the strategic alliance was with a Chinese biopharmaceutical company with "extensive experience in the development, manufacture and sale of therapeutics derived from snake venoms".
"Blood loss in surgery and trauma is a significantly under-served market opportunity and Nuokang's capabilities and resources will ensure that Textilinin and Haempatch progress quickly to the clinic," Dr Holaday said.
Dr Holaday said the deal provided "a great opportunity to extract value for QRX Pharma shareholders from the venomics assets without diverting management's attention away from QRX Pharma's main prospect" of its dual opioid pain treatment.
QRX said Venomics would be led by chief executive officer Janette Dixon with Dr Holaday as chairman.
QRX said Ms Dixon had extensive experience in the pharmaceutical and biotech sectors and spent a large part of her career working in Asia and before joining QRX in 2008, was the managing director of New Zealand's Pacific Pharmaceuticals.
QRX said Textilinin was a novel recombinant peptide that inhibited plasmin, a key enzyme in the fibrinolytic pathway and had the potential to reduce blood loss in major surgery.
The company said Haempatch was a novel prothrombin activating protease, with properties similar to the human Factor Xa clotting factor. Haempatch and the native form of Textilinin were isolated from Australian Common or Eastern Brown snake (Pseudonaja textilis) venom by University of Queensland researchers.
A collaborative project has been ongoing since 2003 between QRX Pharma and the University of Queensland research team to further develop Textilinin and Haempatch and screen Australian snake venoms for therapeutic leads.
QRX said a jointly owned pipeline of early stage candidates had been developed.
QRX was up six cents or 7.6 percent to 85 cents with 1.1 million shares traded.

SUNSHINE HEART

Sunshine Heart says its partially underwritten non-renounceable three-for-five rights issue has raised $8.1 million through the issue of 201,406,334 shares at four cents a share.
Sunshine Heart said existing shareholders subscribed for 197,569,471 shares equivalent to $7.9 million and 3,836,863 shortfall shares were placed by RBS Morgans.
The company said the maximum amount of $8.1 million was raised through the rights issue, taking the total amount raised under the placement and rights issue to $9.8 million.
Sunshine Heart's chief executive Don Rohrbaugh said that the support of shareholders was very encouraging and the funds would allow the company to complete enrolment and follow-up in the US Food and Drug Administration 20-patient feasibility trial of the C-Pulse aorta cuff pump and preparation for the Conformitée Européenne (CE) Mark application.
Sunshine Heart fell 0.1 cents or 1.82 percent to 5.4 cents.

COMPUMEDICS

Compumedics says its Germany-based sleep business has won a $325,000 sleep-diagnostics devices contract from Cologne's Malteser Hospital St Hildegardis.
Compumedics said Malteser Hospital was a major sleep-diagnostic facility, serving as a major referral centre for Cologne (Köln) and its surrounding districts, which combined, cover a population of 16 million people.
The company said the sale would allow it to expand its brand through the many sleep-diagnostic facilities in Germany.
Compumedics said it had won $1 million in German business in six months through its direct-sell model, representing major customer facility-penetration only and "these sales contracts displaced a number of incumbent competitors".
"This achievement not only validates the direct-sell model, but also supports the technical superiority and usability of Compumedics' range of sleep-diagnostic devices," the company said.
Germany is the world's third largest medical device market and Europe's largest.
Compumedics was up half a cent or 2.5 percent to 20.5 cents.

BIOPROSPECT, SOLAGRAN

Bioprospect has appointed Leo Khouri as a non-executive director, effective immediately.
Bioprospect said Mr Khouri, also known as Leo 'The Gun' Khouri, was "a longstanding supporter and major shareholder in Bioprospect" and was committed to the successful development of the company's range of natural products.
The company said Mr Khouri had previously provided strategic and financial advice in his capacity as director and owner of Melbourne-based Gun Capital Management.
His experience and expertise in financial management, strategic planning and public company governance will greatly assist Bioprospect for its future success.
Bioprospect is effectively controlled by Solagran with at least two Solagran directors on the board.
A known associate of Mr Khouri, Victoria Police Senior Sergeant Anthony Langdon, was appointed as a director at the same time as Solagran's Charles Pellegrino and the late Peter Stedwell.
Victoria Police confirmed last year that there was an ethical standards investigation into Snr Sgt Anthony Langdon (BD: Sep 22 2008).
"There is an Ethical Standards [Unit] investigation into the matter regarding secondary employment and threats of intimidation," a Victoria Police media officer said in 2008.
Today, Victoria Police representatives told Biotech Daily that Snr Sgt Langdon was still a serving member of the Victoria Police and he was no longer being investigated.
Solagran and Mr Khouri were both caught up in the Opes Prime debacle, with about 43 percent of Solagran's total shareholding handed over to the failing stock broking firm.
About 26 percent of Bioprospect was also handed over to Opes Prime.
Shortly after the Opes Prime collapse was made public, the Takeovers Panel said it would not commence proceedings on an application by Gun Capital Management, Bejjal and Exchange Minerals to prevent the ANZ bank selling Bioprospect shares exposed by the Opes Prime collapse (BD: Apr 18, 2008). The decision (TP 08/28) says the applicants claimed on April 11, 2008 that they were the beneficial owners of 14.63 percent of Bioprospect's shares.
Bioprospect was up 0.9 cents or 42.9 percent to three cents with 8.9 million shares traded.
Solagran fell half a cent or 2.9 percent to 16.5 cents.

KARMELSONIX

Karmelsonix says the US Food and Drug Administration has granted marketing clearance for its Wheezometer for professional use.

The company said the Wheezometer could measure the wheeze rate of patients over a short span of time to document the patient's extent of wheeze and response to treatment.

Karmelsonix said the Wheezometer had been cleared for use in Europe and Australia.

The company said it intended to seek FDA clearance for use of the Wheezometer for home use by patients.

Karmelsonix was up 0.6 cents or 11.1 percent to six cents with 5.7 million shares traded.