Biotech Daily

Thursday September 29, 2011

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH EVEN: CATHRX UP 26%; USCOM DOWN 9%**

*** BIOTRON STARTS PHASE I/II BIT225 HIV TRIAL**

*** ACRUX TAKES 7.5% OF $1.2bn US TESTOSTERONE MARKET**

*** PHARMAXIS COMPLETES PHASE II ASM8 TRIAL ENROLMENT**

*** ISONEA SIGNS $10.6m BERGEN CONVERTIBLE EQUITY FACILITY**

*** IMPEDIMED: 'RED JOURNAL BACKS L-DEX LYMPHOEDEMA TEST'**

*** SENATOR CARR ANNOUNCES MONASH, ANSTO PARTNERSHIP**

*** CATHRX CLOSER TO EUROPEAN LICENCE DEAL**

*** PLACEMENT TAKES NOVOGEN TO 57% OF MARSHALL EDWARDS**

MARKET REPORT

The Australian stock market fell 0.77 percent on Thursday September 29, 2011 with the S&P ASX200 down 31.2 points to 4,008.3 points.

Eleven the Biotech Daily Top 40 stocks were up, 11 fell, 10 traded unchanged and eight were untraded.

Cathrx was the best, up three cents or 26.1 percent to 14.5 cents with 25,242 shares traded, followed by Genera up 8.3 percent to 13 cents with 66,750 shares traded.

Tissue Therapies climbed 6.1 percent; Bionomics was up 5.6 percent; CSL was up 3.7 percent; Acrux and Nanosonics rose more than two percent; Phylogica was up 1.85 percent; with Heartware, Psivida and Sirtex up by less than one percent.

Uscom led the falls, down 1.5 cents or 9.4 percent to 14.5 cents with 10,000 shares traded, followed by LBT down 9.3 percent to 4.9 cents with 100,000 shares traded.

Anteo, Clinuvel and Universal Biosensors lost more than six percent; Circadian and Viralytics were down more than five percent; QRX fell 4.1 percent; Impedimed shed 2.2 percent; Cochlear was down 1.8 percent; with Pharmaxis, Reva and Resmed down by less than one percent.

BIOTRON

Biotron says it has begun a 24-patient, phase Ib/IIa, proof-of-concept, human trial of BIT225 for HIV in Bangkok, Thailand.

Biotron said that 16 HIV-positive, treatment-naive patients would be treated with the drug over 10 days, a further eight patients would be given a placebo and both groups would have a 10 day drug-free follow up.

The company said the oral drug was able to inhibit replication of the HIV virus in monocyte lineage cells, where until now the virus had been able to hide from current drug treatments.

In a media release, Biotron managing director Dr Michelle Miller said she was confident the trial would further demonstrate the ability of BIT225 to reduce HIV loads in HIV-infected reservoir cells.

“Treatment and elimination of this virus reservoir remains a major therapeutic challenge globally,” Dr Miller said.

Dr Miller said the HIV trial was a major milestone for the company and its lead drug candidate, which had also recorded encouraging data in previous trials in healthy volunteers and hepatitis C virus-infected patients.

Dr Miller told Biotech Daily the HIV trial was recruiting patients at the same centres as phase II hepatitis C trial and the hepatitis C results were expected “soon”.

Dr Miller said she hoped to have the phase Ia/IIb HIV trial results by April 2012.

“BIT225 represents an extremely promising first-in-class opportunity and its progress is being keenly followed by the international pharmaceutical industry and investors,” Dr Miller said.

Dr Miller said that while current treatments resulted in reduction of HIV levels in the body, they had not been effective in eliminating virus from underlying reservoirs.

“By specifically targeting HIV in reservoir cells, Biotron's BIT225 offers the potential to stop the on-going cycle of infection in the body,” Dr Miller said.

Biotron said BIT225 was “synergistic with commonly used anti-retroviral therapies” and if successful would potentially be used in conjunction with these treatments.

Biotron fell 0.2 cents or two percent to 9.8 cents.

ACRUX

Acrux says Axiron’s share of the $1.2 billion US testosterone therapy market has grown 1.4 percent to 7.5 percent in one month.

In August, Acrux said it had 6.1 percent of total prescriptions for the male hormone replacement therapy market (BD: Aug 23, 2011).

The company said Axiron had increased its share of new-to-brand prescriptions from 22 percent to 25.5 percent.

Acrux chief financial officer Jon Pilcher told Biotech Daily that Acrux had filed regulatory applications for Australia, Canada and Europe and hoped to have approval in 2012.

Mr Pilcher said the global market for testosterone replacement therapy was $1.5 billion.

In the media release, Acrux chairman Ross Dobinson said that short selling had caused the company’s share price to fall.

“We remain confident about the fundamentals of the business and about Axiron’s market performance, which was presented in detail by Acrux and Lilly on August 23,” Mr Dobinson said.

Acrux chief executive officer Dr Richard Treagus said the company expected marketing approval for the dog pain drug Recuvyra in Europe by January 2012 (BD: May 10, 2011).

Acrux was up seven cents or 2.2 percent to $3.26.

PHARMAXIS

Pharmaxis says it has completed enrolment of all 16 subjects in its Canadian phase II clinical trial of ASM8 for moderate to severe asthma.

Pharmaxis said that ASM8 was a combination product of two RNA-silencing oligo-nucleotides targeted at a number of mediators of inflammation in asthma and had been developed for patients with moderate to severe, persistent, uncontrolled asthma despite existing medications.

Pharmaxis chief executive officer Dr Alan Robertson said that ASM8 was “a new approach to asthma and operates early in the cascade of events that lead to inflammation and hyper-responsiveness in the lungs of asthmatics”.

“We have completed enrolment into this trial smoothly and ahead of schedule,” Dr Robertson said.

“Previous studies of shorter duration have shown ASM8 to be effective in reducing the signs and symptoms of allergic asthma and this trial will give us a better understanding of the performance of the product when administered for two weeks,” Dr Robertson said.

Pharmaxis said the trial was a cross-over design to evaluate the efficacy and safety of two doses of inhaled ASM8 compared to placebo when administered over 14 days and was being conducted in four hospitals in Canada.

Pharmaxis chief financial officer David McGarvey told Biotech Daily the company acquired ASM8 when it bought the Montreal-based Topigen (BD: Jan 17, 2010; Jan 19, 2011).

“The trial is in Canada where Topigen has an existing network of clinical trial centres, specializing in asthma,” Mr McGarvey said.

The company said the data would be available by July 2012 and a successful outcome will allow a dose to be selected for a longer trial.

Pharmaxis said the market was a significant commercial opportunity as there were few treatment options and serious consequences for the patient if disease progression was not halted.

The company said that the prevalence of asthma was about 60 million in the US, Europe and Japan of which about three million had severe, persistent asthma.

Pharmaxis fell half a cent or 0.7 percent to 70 cents.

ISONEA

Isonea (formerly Karmelsonix) has signed a $10.6 million convertible loan equity draw down facility with the New York-based Bergen Global Opportunity Fund.

Isonea said the transaction with a US investor was “a major milestone” as it prepared for the listing of its American depositary receipts on the over-the-counter qulity excellence (OTCQX) market in the United States scheduled to take place before the end of 2011.

On its website OTCQX says it “separates out the credible companies from the large number of economically distressed and questionable companies that trade OTC”.

Isonea said that Viriathus Capital acted as the exclusive placement agent for the transaction.

The company said the facility would provide maximum flexibility and minimize dilution to the shareholder base.

Isonea said the investment had two parallel instruments consisting of a $1 million lump sum investment by way of an unsecured convertible instrument on the execution of the agreement with a face value of $1.12 million and the investment of up to $9.6 million, of which $4.8 million is conditional on a mutual commitment, over a period of about 24 months by Bergen paying for additional share issues.

Isonea fell 0.1 cents or 6.25 percent to 1.5 cents with 2.2 million shares traded.

IMPEDIMED

Impedimed says a critical review of the literature supports the use of its L-Dex technology to detect lymphoedema following breast cancer treatment.

Impedimed said the article entitled 'Breast Cancer Related Arm Lymphoedema: Incidence Rates, Diagnostic Techniques, Optimal Management and Risk Reduction Strategies' was published in the International Journal of Radiation Oncology Biology Physics, known as 'The Red Journal'.

Impedimed said the review found the L-Dex bio-impedance testing superior to traditional techniques to measure arm-related lymphoedema in breast cancer patients.

The article is available at: www.redjournal.org/article/S0360-3016(11)02784-2/abstract.

Impedimed said that the article reviewed the literature on the clinical assessment of unilateral lymphoedema associated with breast cancer patients and treatment modalities and addressed the shortcomings of conventional forms of measurement and the benefits of newer technology like bio-impedance spectroscopy for facilitating risk reduction strategies like pre-emptive care models.

Impedimed quoted the review saying that risk reduction strategies needed to incorporate treatment and patient factors that increased breast cancer-related lymphoedema and include proactive surveillance and diagnosis to increase the percentage of patients diagnosed with sub-clinical disease.

Impedimed said the publication "suggests that bio-impedance spectroscopy be adopted as a standardized method for the clinical assessment of lymphoedema, noting that the L-Dex technology is well positioned with respect to specificity, accuracy, precision, repeatability, and sensitivity".

The review said bio-impedance spectroscopy "has emerged as a potentially disease changing clinical assessment modality that addresses many of the shortcomings of previous traditional assessment measures".

"[Bio-impedance spectroscopy], unlike many traditional assessment tools, provides a true measure of extra-cellular volume and measurements are unaffected by weight changes or changes in the muscle/fat ratio," the review said.

Impedimed chief executive officer Greg Brown said the publication was "a major clinical support for positioning L-Dex as an optimal tool for the pre-emptive care model for breast cancer patients".

Impedimed fell one cent or 2.2 percent to 44 cents.

FEDERAL GOVERNMENT, MONASH UNIVERSITY, ANSTO

Innovation Minister Senator Kim Carr says Monash University and the Australian Nuclear Science and Technology Organisation will partner to boost Australia's research efforts.

Senator Carr said the partnership would help facilitate knowledge sharing and create new training and development opportunities for our researchers.

"With ANSTO and Monash University researchers working together we can expect to see significant developments in key areas such as biomedical imaging, cancer therapy, accelerator and neutron science," Senator Carr said.

ANSTO chief executive officer Dr Adi Paterson said nuclear research opened opportunities to better understand the world around us.

"Experience shows that bringing together researchers from different fields brings together great outcomes for science," Dr Paterson said.

"We're hopeful … that through this collaboration we can do research which will improve existing medical imaging techniques to better understand how diseases affect the body," Dr Paterson said.

CATHRX

Cathrx says it has granted a potential licensee exclusivity for finalizing diligence and a formal agreement to develop and commercialize its catheters in Europe.

Cathrx said it had been negotiating with two potential licencees, had granted one a period of exclusivity and suspended negotiations with the second (BD: Aug 19, 29, 2011).

Cathrx chief executive officer Jeffrey Goodman said the period of exclusivity would "allow us to exchange detailed strategic information with the potential licencee without concerns about future competitive activities".

"Cathrx previously expected the initial phase of diligence would take until the end of September and now believe this next phase of diligence should be completed by end October," Mr Goodman said.

Cathrx was up three cents or 26.1 percent to 14.5 cents.

NOVOGEN

Novogen has increased its holding in US subsidiary Marshall Edwards by investing $US2 million for 1.33 million shares raising its holding from 51.5 percent to 57 percent.

Novogen said it bought the common stock in a private placement and Marshall Edwards would use the funds to continue development of its two different cancer treatment pathways, an oxidase inhibitor and mitochondrial inhibitor, with lead candidates ME-143 and ME-344 advancing in the clinic this year.

Novogen chairman William Rueckert said Marshall Edwards was the company's "most important asset and we are pleased to be able to continue to support its exciting drug development programs".

Novogen was up 1.5 cents or 11.5 percent to 14.5 cents.