Biotech Daily

Thursday November 12, 2009

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: TISSUE THERAPIES UP 10%; BIONOMICS DOWN 10%**

*** BIOTA ACQUIRES $12m OXFORD, BOSTON ANTIBACTERIAL PIPELINE**

*** 5% OPPOSE BIOTA REMUNERATION REPORT; DR JIM FOX APPROVED**

*** TGA UNSATISFIED WITH FDA APPROVAL FOR ACRUX'S ELLAVIE**

*** LEO'S PEPLIN TAKEOVER COMPLETE**

*** SIX PROJECTS WIN $1m AUSTRALIAN STEM CELL CENTRE GRANTS**

*** MEDICAL THERAPIES, YAMASA SIGN JAPAN DISTRIBUTION DEAL**

*** MARK FORDREE SMOOTHES FERMISCAN'S PILLOW**

*** IMPEDIMED APPLIES FOR US INSURANCE CODE**

*** STARPHARMA REQUESTS CAPITAL RAISING TRADING HALT**

*** NEUREN REQUESTS CAPITAL RAISING TRADING HALT**

MARKET REPORT

The Australian stock market fell 0.2 percent on Thursday November 12, 2009 with the S&P ASX 200 down 9.1 points to 4,747.9 points. Twelve of the Biotech Daily Top 40 stocks were up, 15 fell, eight traded unchanged and five were untraded.

Tissue Therapies was best, up 1.5 cents or 10 percent to 16.5 cents with 456,500 shares traded, followed by Phylogica up 9.5 percent to 11.5 cents.

Cathrx climbed 6.35 percent; Novogen and Viralytics were up more than three percent; Alchemia, Avexa and Biota rose more than two percent; with Clinuvel and Living Cell up more than one percent.

Bionomics led the falls, down four cents or 9.9 percent to 36.5 cents with 970,111 shares traded followed by Compumedics and Tyrian down more than five percent.

Antisense, Benitec, Impedimed and Phosphagenics lost four percent or more; Acrux, Circadian and Nanosonics were down more than three percent; Prana and Universal Biosensors shed more than two percent; with Pharmaxis down 1.6 percent.

BIOTA

Biota has effectively created a new pipeline of early stage development anti-bacterial drugs from companies in Oxford UK and Boston Massachusetts for $12.4 million.

Biota said it had acquired the pre-clinical antibacterial assets of Oxford's Prolysis Ltd for $10.8 million as Biota shares, of which 60 percent would be subject to a 12 month escrow period, along with up to a 15 percent share in all milestone and royalties earned on commercialization with Biota retaining all upfront payments on licenced programs.

The company also said it had acquired the assets and preclinical antibacterial drug development programs of Boston's Maxthera Inc, for $US1.2 million ($A1.28 million) in cash and $US300,000 in Biota shares, subject to conditions expected "to be met in the near future".

Biota said Prolysis had two primary projects focused on new antibiotics for multiple drug resistant infections, which "if successfully developed … have the potential to manage the current wave of hospital superbugs that are prevalent in modern society".

Biota said the two programs were a Gyrase program targeting DNA supercoiling in gram positive bacteria; and a cell division inhibitor program targeting staphylococci, blocking assembly of the septum cell wall components prior to cell division, which received significant Wellcome Trust funding over recent years.

Biota said Prolysis was founded on the work of Prof Jeff Errington, previously of Oxford University and now the director of the Institute for Cell and Molecular Biosciences at Newcastle University.

Biota said it intended to invite Prof Errington to join its board as a director.

Biota said it intended "to retain all Prolysis staff and maintain activities at its current laboratory facilities in Oxford" and expected to invest $25 million over the next three years developing the key programs.

Prof Errington said the deal "secures our antibiotic program through clinical trials with a world class partner".

"It also guarantees the future of our Oxford facility and helps to enhance our tradition of antibiotic R & D in the UK," he said.

Biota said the Wellcome Trust had agreed to transfer its funding agreement to Biota.

Biota's chief executive officer Peter Cook said the acquisition was "consistent with our stated strategy of broadening our anti-infective focus [and would] enable Biota to expand its drug development capability by extending its current anti-viral portfolio to include a new pipeline of early stage antibacterial programs".

Biota said Boston's Maxthera had developed "a high quality suite of validated novel bacterial targets and early stage antibacterial programs aimed at developing compounds to treat serious bacterial infections, including those that are resistant to existing antibiotics".

The lead program targets inhibitors of an essential bacterial enzyme in the Coenzyme-A biosynthetic pathway, which is responsible for a large number of metabolic processes in bacteria.

"Maxthera's portfolio of new targets and novel inhibitor structures are highly complementary to Biota's own innovative programs and the two organizations have very similar systems and discovery strategies," Mr Cook said.

Biota said it intended to accelerate the development of the lead Maxthera program and invest up to $US15 million, assuming development milestones were achieved, in equal installments over the next three to five years.

MaxThera's principal scientists Dr Ania Knap and Dr Roger Frechette and main shareholders will maintain their program involvement in Boston.

Biota was up six cents or 2.1 percent to $2.89 with 1.0 million shares traded.

BIOTA

Biota's annual general meeting saw some dissent over the remuneration report but all directors were reelected overwhelmingly as was the capital return to shareholders.
A total of 3,401,006 proxy votes (5.2%) opposed the adoption of the remuneration report with 61,785,687 proxy votes (94.8%).
Dr Jim Fox was appointed a director and chairman this year (BD: Mar 2, Apr 27, 2009) and was elected with more than 64.7 million votes in favor and 402,205 votes against.
Prof Ian Gust and Richard Hill were elected by a similar margin. The return of capital was supported with 67.4 million votes, but 118,318 votes opposed the resolution.
Biota's chief financial officer Damian Lismore told Biotech Daily the annual general meeting was "much quieter then last year's".
In 2008 several shareholders including Biotech Daily's editor David Langsam and Bioshares' David Blake called for then chairman John Grant to resign over his handling of the litigation with Glaxosmithkline (BD: Oct 29, 2008).

ACRUX

Acrux says the Australian Therapeutic Goods Association requires more data on its estradiol spray Ellavie than the US Food and Drug Administration.
Acrux said the estradiol spray to treat the symptoms of menopause and marketed as Evamist in the US, was approved by the FDA in 2007 and has been marketed in the US since early 2008.
The company said the TGA would require additional supporting data that specifically compares the spray to an Australian marketed estradiol transdermal product.
Biotech Daily asked a representative of the Department of Health and Ageing why the call for more data had occurred, given it was the first time this publication was aware of an Australian-developed drug being approved by the FDA and rebuffed by the local authority.
A spokeswoman for the TGA said "it happens all the time" but was unable to cite an example.
Acrux said it was engaging its commercial partners to determine a cost-effective way of addressing this TGA requirement, which would result in a delay in making Ellavie available to women in Australia.
The company said the value of the Australian market for Ellavie is small and the financial impact on Acrux of this regulatory delay is immaterial.
The regulatory process for Ellavie is proceeding as planned in other international markets.
Acrux fell eight cents or 3.6 percent to $2.16.

PEPLIN

Peplin says it has completed its merger with Leo Pharma after obtaining the approval of the majority of Peplin stockholders.
Peplin said the merger consideration of $US287.5 million in cash would be distributed to holders of common stock and CDIs promptly.
Peplin will operate as a US-based Leo subsidiary with Peplin's former chief commercial officer George Mahaffey promoted to lead the company as chief executive officer.
Dr Eugene Bauer will continue as president and chief medical officer and Dr Peter Welburn will maintain his role as Australian general manager and vice-president of research and development.
Peplin will retain other key management and employees in California and Queensland.
Peplin is suspended and will be removed from the ASX official list on November 18, 2009.

AUSTRALIAN STEM CELL CENTRE GRANTS

The Australian Stem Cell Centre says its Strategic Development Fund will provide $1 million in grants for six projects.

The Stem Cell Centre said the projects include stem cell treatments for Alzheimer's disease along with stem cells on contact lenses to treat corneal blindness, pelvic floor regeneration to stem cell manufacturing and bioinformatics.

The Centre said the Strategic Development Fund aimed "to develop and accelerate stem cell projects towards a well-defined commercial, medical or academic goal".

The Centre said it received "more than 60 high quality applications from investigators from over 50 organizations, in six states, reflecting the diversity and depth of Australian stem cell research".

The successful projects include investigating adult stem cells for regenerating the pelvic floor by Monash Institute of Medical Research's Dr Caroline Gargett and Commonwealth Scientific and Industrial Research Organisation's Dr Keith McLean;

A clinical trial to further the utilization of stem cells on contact lenses to treat corneal blindness by University of New South Wales' Prof Nick Di Girolamo and the Prince of Wales Hospital's Dr Stephanie Watson;

Strategies for stem cell therapies for Alzheimer's disease by Monash Institute of Pharmaceutical Sciences' Prof Colin Pouton, Dr John Haynes, Dr Jennifer Short and Dr Joe Nicolazzo;

The Australian stem cell database initiative, a collaboration with Griffith University's Dr Christine Wells, the Walter and Eliza Hall Institute's Prof Doug Hilton and the University of Queensland's Prof Sean Grimmond;

Manufacturing Clinical Grade Mesenchymal Stem Cells a collaboration with Mater Health Services' Prof Kerry Atkinson, Mater Medical Research Institute's Prof Gary Brooke and the University of Queensland's , Dr Nicholas Timmins; and

Utilising mathematical modelling to understand pluripotency by CSIRO's Dr David Winkler.

The Australian Stem Cell Centre said each grant was for a maximum of $250,000 over 18 months, with funding to commence no later than December 1, 2009.

MEDICAL THERAPIES

Medical Therapies has signed an agreement with Japan's Yamasa Corp for the non-exclusive distribution of its anti-midkine antibodies for research purposes.

Medical Therapies said Yamasa would produce and sell certain proprietary anti-midkine antibodies solely to the research market and pay an undisclosed fixed percentage of the net sales revenues.

The company said the distribution agreement was non-exclusive and did not prevent Medical Therapies selling its antibodies through any other agent in any region, including Japan.

Medical Therapies said its "portfolio of high performance anti-midkine antibodies [was] sought after by researchers involved in embryonic cytokine, in particular midkine, research".

Yamasa has expertise in the production and sale of superior grade antibodies and distributes reagents and diagnostic assays to the research market primarily in Japan.

Medical Therapies' chief executive officer Maria Halasz said that Yamasa was "a prominent research reagent supplier in Japan" and including her company's antibodies in their product line was "an important validation of the quality of our anti-midkine portfolio".

Medical Therapies fell 0.1 cents or 3.6 percent to 2.7 cents with 4.8 million shares traded.

FERMISCAN

Fermiscan executive director Mark Fordree is effectively working as an administrator to salvage what he can for shareholders.

Yesterday Fermiscan lost its New South Wales Supreme Court appeal against Prof Veronica James and owes at least $500,000 in costs, with less than $716,000 in cash.

Mr Fordree told Biotech Daily that he was “shutting down all expenses” including cutting all clinical programs while he looked for suitable commercial deals.

Apart from the intellectual property associated with Prof James’ x-ray diffraction test of hair to detect breast cancer, the company is carrying extensive tax losses that could be attractive for a company working in a similar field.

Mr Fordree said his role was to salvage what he could for shareholders.

Mr Fordree was appointed after the directors and executives who began the litigation against Prof James had departed the company.

Fermiscan was untraded at three cents.

IMPEDIMED

Impedimed says it has applied for a category 1 current procedural terminology code (CPT 1) with the American Medical Association.

Impedimed said the application “seeks assignment of a dedicated code that can be used by physicians across the US in billing health insurance providers for their utilization of the company’s L-Dex technology in the prospective management of breast cancer patients at risk of lymphoedema”.

Impedimed chief executive officer Greg Brown said that applying for a category one reimbursement code was an “important milestone”.

“Impedimed’s plan to drive lymphoedema education and adoption of pre-emptive care for all patients will be greatly enhanced should this code be successful,” Mr Brown said.

“Surgeons are the key to facilitating pre-emptive care and it is great to see their support of a category 1 code for the L-Dex test,” Mr Brown said.

“It demonstrates a clear commitment to protecting the quality of life of patients,” he said.

Impedimed said the US current procedural terminology coding process was the mechanism by which new technologies were assigned codes used by US public and private health insurance companies to describe the procedures and services offered by clinicians.

The AMA’s CPT editorial panel considers and evaluates new coding requests three times each year and Impedimed said its coding application would be heard by the panel in their February 2010 meeting.

New codes then go on for the determination of a national reimbursement payment level which is assigned to each new code, which can take a further few months before payment is set.

All new codes become effective on January 1 of the following year.

Impedimed fell three cents or four percent to 72 cents.

STARPHARMA

Starpharma has requested a trading halt pending an announcement “regarding an equity capital raising”.

Starpharma said it expected the trading halt would be extended to a voluntary suspension.

Trading will resume on November 16, 2009 or on an earlier announcement.

Starpharma last traded at 60 cents.

NEUREN

Neuren has requested a trading halt pending an announcement “about negotiations for a material capital raising”.

Trading will resume on November 16, 2009 or on an earlier announcement.

Neuren last traded up half a cent or 10.9 percent to 5.1 cents with 5.7 million shares traded.