# Biotech Daily

Tuesday August 28, 2012

*Daily news on ASX-listed biotechnology companies*

*** ASX UP, BIOTECH DOWN: CELLMID UP 12.5%, IMPEDIMED DOWN 17%**

*** SPINIFEX PHASE II TRIAL: 'EMA401 REDUCES NEURALGIC PAIN'**

*** GENETIC TECHNOLOGIES REVENUE DOWN 66%, PROFIT TURNS TO LOSS**

*** BLUECHIIP, GENTRIS WORK ON PHARMACO-GENOMICS, BIO-REPOSITORY**

*** REGENEUS SETS UP MACQUARIE UNI CLINIC FAT STEM CELLS LAB**

*** HEALTHLINX EGM TO SELL OVPLEX ASSETS**

*** MEDICAL AUSTRALIA REVENUE UP 5% TO $9m, LOSS UP 95% TO $669k**

## MARKET REPORT

The Australian stock market climbed 0.36 percent on Tuesday August 28, 2012 with the S&P ASX 200 up 15.7 points to 4,359.4 points.

Thirteen of the Biotech Daily Top 40 stocks were up, 15 fell, five traded unchanged and seven were untraded.

Cellmid was the best, up 0.2 cents or 12.5 percent to 1.8 cents with 1.9 million shares traded.

Ellex climbed 5.6 percent; Allied Health and Neuren were up four percent or more; Phosphagenics and Phylogica were up more than three percent; Cochlear, CSL, Nanosonics, Prana and Tissue Therapies rose two percent or more; Bionomics was up 1.7 percent; with Heartware, Sirtex and Starpharma up by less than one percent.

Impedimed led the falls, down three cents or 16.7 percent to 15 cents with 45,000 shares traded.

Psivida lost 7.9 percent; Anteo fell 6.7 percent; Benitec was down 5.9 percent; Avita, Genetic Technologies and Prima were down three percent or more; Pharmaxis, QRX and Universal Biosensors shed more than two percent; Acrux, Reva and Viralytics were down more than one percent; with Alchemia and Mesoblast down by less than one percent.

SPINIFEX PHARMACEUTICALS

Spinifex says its 183-patient, phase II clinical trial of EMA401 in post-herpetic neuralgia showed the drug met its primary endpoint of a reduction in mean daily pain score.

Spinifex said that post-herpetic neuralgia was a painful condition that developed in some patients following herpes zoster or shingles and existing therapies did not relieve pain in all individuals.

The company said the clinical trial met its primary endpoint, reduction in mean daily pain score versus placebo over the last week of 28 days of treatment.

Spinifex said the results showed a statistically significant and clinically meaningful reduction in mean pain intensity from baseline to week four for subjects on active treatment when compared to placebo.

The company said that on an-intent-to-treat basis, the mean pain intensity reduction from baseline after four weeks treatment resulted in a reduction of an average of 2.34 points on the zero-to-10 pain level score for EMA401, with placebo achieving a 1.64 points average reduction ($p = 0.006$).

Spinifex said the drug met a key secondary endpoint, in which a significantly greater proportion of patients on active treatment reporting a more than 30 percent reduction in mean pain intensity score compared to baseline, with EMA401 having a 56.5 percent reduction compared to 34.1 percent for placebo ($p = 0.003$).

The company said that EMA401 was generally safe and well tolerated with no serious treatment related adverse events reported.

Spinifex said the double-blind, placebo-controlled, randomized trial was recruited at 29 centres in five European countries and South Africa and enrolled 183 patients.

The trial began in September last year (BD: Sep 20, 2011).

Spinifex said it would present an overview of the clinical development of EMA401 today at the World Congress of Pain in Milan, Italy, with full results of the phase II trial expected to be published in a pain clinical research journal.

Principal investigator Dr Milton Raff of the Christiaan Barnard Memorial Hospital in Cape Town, South Africa, said the headline results “are very promising with a clear reduction in pain versus placebo and a good safety and tolerability profile”.

“EMA401 offers an entirely novel approach to the treatment of [post-herpetic neuralgia] and could represent a valuable new option in an area where there is a clear need for new medicines,” Dr Raff said.

“Current treatments for the condition are effective in some patients but a significant proportion either don’t respond to therapy and are left with debilitating symptoms or suffer significant side effects,” Dr Raff said.

Spinifex chief executive officer Dr Tom McCarthy said the results were “a major step for Spinifex and for the development of EMA401 as a treatment for neuropathic pain”.

“It is tremendously gratifying for the Spinifex team to have taken a scientific discovery through to proof of clinical concept in what is a notoriously difficult field and one where new treatments are clearly needed,” Dr McCarthy said.

“We look forward to advancing EMA401 further in [post-herpetic neuralgia] and other neuropathic pain indications including cancer chemotherapy-induced neuropathic pain and painful diabetic neuropathy,” Dr McCarthy said.

“Ultimately we hope EMA401 becomes a broad treatment for chronic pain in general,” Dr McCarthy said.

Spinifex said the market for neuropathic pain treatments was expected to continue to increase and was projected to reach $US6.2 billion by 2017.

Spinifex is a private company.

## GENETIC TECHNOLOGIES

Genetic Technologies says its revenue fell 66 percent to $6,217,814 in the 12 months to June 30, 2012, taking last year's net profit after tax to a loss of $5,287,523.

Genetic Technologies chief financial officer Tom Howitt told Biotech Daily that the fall in revenue was "mainly attributable to delays in licencing deals and their payment".

Mr Howitt said licencing revenue fell from $13,680,741 in the previous year to $2,526,599 in the year to June 30, 2012 and 2010-'11 was "an exceptional year" but the company was hoping to return to those levels of licencing revenue.

Revenue from genetic testing fell 19.7 percent from $4,594,960 to $3,691,215.

Mr Howitt said that complicating the report was the deconsolidation of Immunaid which provided an accounting gain $5,113,175, based on a recent fund raising at $1 a share.

Genetic Technologies said its diluted loss per share was 1.15 US cents compared to the previous year's earnings of 0.22 cents and it had $8,900,235 in cash and equivalents at June 30, 2012 compared to $5,104,667 for the previous corresponding period.

Genetic Technologies fell 0.3 cents or three percent to 9.7 cents with 1.1 million shares traded.

## BLUECHIIP

Bluechiip will partner with Gentris Corp to include temperature tracking in its pharmaco-genomics and bio-repository support for clinical trials and genomic biomarker programs.

Bluechiip said the North Carolina-based Gentris collaborated with academia and industry to translate pharmaco-genomics innovations into "safer, more effective medicines, aimed at accelerated drug discovery and improvement in clinical treatment outcomes".

The company said that as well as the partnership agreement, Gentris had joined Bluechiip's early adopter program for its temperature sensing and tracking product, assisting with the ongoing validation of the Bluechiip system.

Gentris' vice-president of bio-repository operations Eric Hall said the Bluechiip technology offered bio-repositories and bio-resource laboratories "significant value via its ability to sense sample level temperature".

"This capability will allow Gentris to track the temperature of individual samples from time of collection to analysis, which improves our ability to evaluate and control the integrity of client samples, Mr Hall said.

Gentris chief scientific officer L Scott Clark said that the "ability to understand sample-level temperature changes and trends in temperature across sample collections throughout the process chain and specimen lifecycle over time will be extremely valuable".

"This will lead to enhanced annotation of pre-analytical variables and improved identification of analytical artifacts that may occur due to changes in sample integrity<" Mr Clark said.

"Prospectively measuring sample temperature will increase our confidence in the quality of samples analyzed and improve our understanding of research findings and interpretation of downstream testing, [that is] gene expression and biomarker validation studies," Mr Clark said. "Utilizing the Bluechiip technology has the potential to positively impact research and clinical outcomes, not only in bio-banking but also in pharmaco-genomic trials."

Bluechiip head of strategy and business development Lisa Miranda said that Gentris' "technical and scientific expertise, vision, commitment to driving innovation and support of real-time, evidence-based bio-banking practice was a key driver in its selection both as a strategic partner and as an early adopter to further test and validate our technology".

Bluechiip was up 1.5 cents or 6.7 percent to 24 cents.

## REGENEUS

Regeneus says it has established a cell processing laboratory at Macquarie University Hospital to treat patients with its Hiqcell stem cell therapy for musculoskeletal conditions.
Regeneus said the facility was at the Macquarie University Clinic and technicians would process the cells, taken from patient's own fat tissue, and prepare Hiqcell by separating the regenerative cells and preparing them in for re-injection in osteoarthritic joints such as knees, hips and ankles of that patient.
The company said the processing took about one hour and was performed under the supervision of the treating physician.
Regeneus said the extracted regenerative cells included mesenchymal stem cells and adipocytes, which worked together to reduce inflammation and promote regeneration and repair of tissue.
Macquarie University Hospital chief executive officer Carol Bryant said the Hospital was "committed to providing clinicians and their patients with world-class medical facilities and the latest treatments."
Regeneus said that sports and exercise physician Dr Donald Kuah had pioneered the use of Hiqcell for musculoskeletal disorders and said the Macquarie University Hospital facilities were "world-class and … an ideal location for Hiqcell".
Regeneus said the cell-processing facility built on the established relationship with Macquarie University led by founder Prof Ben Herbert who was also Macquarie's director of regenerative science.
Prof Herbert said that by bringing together "stem cell scientists, clinicians and leading technology partners … we are able to build powerful and integrated knowledge and skills networks that are translating the latest research and technology into new innovative cell therapies for diseases with limited treatment options".
He said the integrated approach delivered "rapid translational medicine outcomes and we will see new conditions being treated with cell therapy in the next few years".
Regeneus is a public unlisted company.

## HEALTHLINX

Healthlinx shareholders will vote on the sale of its major assets to the US-based Mane Cancer Diagnostics primarily in exchange for shares in Mane.
Healthlinx said the San Diego, California-based Mane would acquire the Ovplex ovarian cancer diagnostic, the monoclonal antibody AGR2, the vascular permeability peptide CR014, the adipogenesis inhibiter LAP001, all licencing and distribution agreements and studies performed on those assets.
The company said that it immunoglobulin-Y (IgY) assets were not included in the sale.
Healthlinx said Mane would list on the Nasdaq with a deemed value to Healthlinx of the 30 percent shareholding at $US6,250,000 of the expected listed value of $US20,000,000.
The company said it would also receive $US250,000 in cash.
Healthlinx said the three resolutions were for the approval of a change in nature and scale and the sale of assets to Mane Cancer Diagnostics; approval to dispose of the major asset ; and authority to accept further payments under convertible note issued to La Jolla Cove Investors.
Biotech Daily believes the sale leaves Healthlinx as a shell company suitable for acquiring a new technology or be available for a back-door listing.
The meeting will be held at 576 Swan Street, Richmond, Victoria on September 27, 2012 at 4pm.
Healthlinx was unchanged at 0.3 cents with 2.8 million shares traded.

## MEDICAL AUSTRALIA

Medical Australia says that revenue for the 12 months to June 30, 2012 was up 5.0 percent to $9,211,228 with net loss after tax up 95.0 percent to $668,924.

Medical Australia finance general manager Suraj Sethuram told Biotech Daily that revenue primarily came from the sale of intravenous extension sets and medical consumables

Mr Sethuram said the company expended about $150,000 on legal action that had been finalized and paid off $445,000 in debt.

Medical Australia said its net tangible asset backing per share was 0.14 cents compared to minus 0.0001 cents in the previous corresponding period.

The company said that diluted loss per share was up 66.7 percent to 0.15 cents, compared to 0.09 cents in the year to June 30, 2011.

Medical Australia said it had $578,221 in cash and cash equivalents at June 30, 2012, compared to $828,297 at June 30, 2011.

Medical Australia was unchanged at 1.4 cents.