



Biotech Daily

Friday September 30, 2011

Daily news on ASX-listed biotechnology companies

- * **ASX FLAT, BIOTECH UP: CLINUVEL UP 6%; LBT DOWN 16%**
- * **TISSUE THERAPIES READY FOR EURO SALES, US TRIAL**
- * **CELLMID EGM DEFEATS LA JOLLA COVE NOTE; FUNDING REVIEW**
- * **CIRCADIAN FILES FDA IND FOR VGX-100 LATE STAGE CANCERS TRIAL**
- * **ALLIED PLACES \$2m, TAKES \$3m KODIAK EQUITY DRAW DOWN FACILITY**
- * **COGSTATE'S PROF PAUL MARUFF WINS IG-NOBLE PRIZE**
- * **AGENIX AGM FOR 3m CHAIRMAN RIGHTS, ELECT DIRECTORS**
- * **SOCIAL INVESTMENTS TAKES 7% OF NEURODISCOVERY**
- * **SUNSHINE HEART APPOINTS CM'S DR MARK HARVEY DIRECTOR**

MARKET REPORT

The Australian stock market was flat, edging up 0.01 percent on Friday September 30, 2011 with the S&P ASX200 up 0.3 points to 4,008.6 points.

Fifteen the Biotech Daily Top 40 stocks were up, eight fell, 12 traded unchanged and five were untraded.

Clinuvel was the best, up nine cents or 6.4 percent to \$1.50 with 10,860 shares traded, followed by Tissue Therapies up 5.75 percent to 46 cents with 836,613 shares traded.

Cellmid and Circadian climbed more than five percent; Heartware, Nanosonics and Sunshine Heart were up four percent or more; Pharmaxis and Phylogica were up more than three percent; Impedimed and Viralytics rose more than two percent; Bionomics was up 1.05 percent; with QRX and Starpharma up by less than one percent.

LBT led the falls, down 0.8 cents or 16.3 percent to 4.1 cents with 580,000 shares traded, followed by Optiscan down 9.1 percent to nine cents with 10,000 shares traded.

Prana lost 6.1 percent; Cochlear fell 3.8 percent; Acrux and Sirtex were down more than one percent; with Biota, CSL, Mesoblast and Universal Biosensors were down by less than one percent.

TISSUE THERAPIES

Tissue Therapies says it expects to announce a European distribution deal in November 2011, with sales of the Vitrogro wound treatment expected to begin by July 2012.

Tissue Therapies said that the current global economic conditions made an attractive commercial arrangement more difficult but negotiations were well-advanced and allowed sufficient preparation time for the planned sales launch in the UK and Europe.

The company said the clinical trial required for European Union marketing approval had been completed, with the final report expected in October 2011.

Tissue Therapies said EU regulatory consultant was "confident that the human trial data already announced is sufficient for approval for sale" and the preparation for reimbursement approvals in Europe was also well advanced.

The company said that ideal initial customers were specialist hospital and wound care clinics and sales to these centres did not require reimbursement approvals.

Tissue Therapies said that larger scale manufacturing of Vitrogro had been completed to the good manufacturing practice standard required for human use and final packaging design consistent with regulatory and commercial requirements had been completed and packaging of ready-for-sale Vitrogro was about to start.

The company said it had an expert consulting group review the US Food and Drug Administration request for designation application prior to its submission.

Tissue Therapies said the consulting group included two former FDA directors who were "confident that the [application] will result in a successful device classification".

The company said that preparations for the FDA clinical trial of Vitrogro for venous ulcers were almost complete, with chief clinical investigator and clinical research organization appointed, the protocol finalized, site selection underway and patient recruitment planned to start during December 2011.

Tissue Therapies chief executive officer Dr Steven Mercer said the company was "delighted to now be so close to the start of sales of Vitrogro for the treatment of chronic wounds".

"As part of our preparation for sales, the Tissue Therapies chief scientist Prof Zee Upton and I recently met with more than 20 key wound care opinion leaders in the UK and Europe," Dr Mercer said. "They were unanimous in their praise of the careful, scientific approach we have taken in the development of Vitrogro and are impatient to start using Vitrogro to treat their patients."

Tissue Therapies was up 2.5 cents or 5.75 percent to 46 cents.

CELLMID

Cellmid investors have voted overwhelmingly against a vote to issue a convertible note and shares to La Jolla Cove.

The resolution was lost with 100,731,334 proxy votes against and 8,449,821 proxy votes in favor.

In its most recent annual report Cellmid's top 20 shareholders at September 1, 2010 held 141,072,551 shares of the total 326,581,294 shares and the largest shareholder was Cell Signals with 33,000,000 shares.

Cellmid said that in 2010, La Jolla Cove agreed to provide \$US8 million over three years (BD: Sep 15, 2010) and had issued two of the eight \$US1 million notes.

The company said it could not issue a further note and would "undertake a thorough review of all funding opportunities to ensure that adequate capital will continue to be available for Cellmid's promising product development programs".

Cellmid was up 0.1 cents or 5.6 percent to 1.9 cents.

CIRCADIAN TECHNOLOGIES

Circadian says it has submitted an investigational new drug application to the US Food and Drug Administration for clinical studies of VGX-100 for late stage cancers.

Circadian said the application was made by wholly-owned subsidiary Vegenics and the first phase I trial would involve the treatment of a variety of different cancer types.

The company said VGX-100 was a human antibody that acted against the human vascular endothelial growth factor C (VEGF-C) protein, with glioblastoma and metastatic colorectal cancers the first target indications.

Circadian said it was also developing VGX-100 for a number of other cancer indications, as well as an agent to treat front-of-the-eye diseases.

The company said that pre-clinical animal studies across a wide range of tumor types had shown that when combined with Avastin and chemotherapy, VGX-100 could significantly reduce tumor growth and tumor spread as well as significantly improve tumor inhibition, over and above that of Avastin and/or chemotherapy alone (BD: Jun 16, 2011).

Circadian said that recent studies also implicated VEGF-C as a key mediator of disease progression during Avastin treatment, implying that combination therapy with VGX-100 and Avastin could significantly improve treatment outcomes in cancer patients.

Circadian chief executive officer Robert Klupacs said that VGX-100 had "the potential to significantly improve the treatment of patients suffering from cancer".

"The IND filing is an important milestone for us, as it completes our pre-clinical phase of development and transitions Circadian into a clinical development company," Mr Klupacs said. "We expect to commence our first in man phase I studies as soon as possible after FDA review ... [and] expect to see results from the study in the second half of 2012."

Circadian said that Vegenics owned worldwide rights to an extensive intellectual property portfolio covering the angiogenesis and lymph-angiogenesis targets VEGF- C, VEGF-D and the receptor protein VEGFR-3 and Vegenics had been granted exclusive worldwide rights to intellectual property filed by Schepens Eye Research Institute, covering the use of anti-lymph-angiogenic molecules for the treatment of dry eye disease.

Circadian was up 2.5 cents or 5.6 percent to 47 cents.

ALLIED HEALTHCARE GROUP

Allied Health says it has \$5 million funding through a \$2,006,000 placement and a \$US3,000,000 equity draw down facility with the Dallas Texas-based Kodiak Capital.

The company said the private placement of 71.4 million shares at 2.8 cents a share was to sophisticated and professional investors and related parties of the company, including directors and substantial shareholders.

Allied said that the Metal Group, an entity controlled by Fortescue Mining chairman Andrew Forrest and a substantial shareholder, would subscribe for \$450,000 in the placement, with directors and substantial shareholders other than the Metal Group subscribing for \$463,000 in the placement, arranged and managed by Bell Potter.

Allied said the funds were for its subsidiary Coridon's vaccine development program, to launch Cardiocel and provide further general working capital.

The company said it would issue six million options exercisable at six cents within three years from issue to Bell Potter as a management fee.

Allied said it would seek shareholder approval for that portion of the placement issued to related parties, including directors and substantial shareholders.

The company said the Kodiak Capital facility could be drawn down at Allied's option, subject to conditions, during the next 12 months.

Allied was unchanged at 3.2 cents with 2.6 million shares traded.

COGSTATE

Cogstate says chief science officer Prof Paul Maruff was one of 10 Ig Nobel Prize winners last night at Harvard University for a paper on thinking and micturition.

Organized by Improbable Science for the past 21 years the Ig Nobel Prizes “honor achievements that first make people laugh and then make them think”.

Prof Maruff and co-author Prof David Darby were formerly researchers at Victoria’s Mental Health Research Institute.

Cogstate said that Prof Maruff, Prof Darby and colleagues from the Lifespan Hospital System in Providence, Rhode Island and Yale Medical School, New Haven, Connecticut were recognized for their work which found that an acute urge to void the bladder can result in impairment in cognitive function, the magnitude of which was greater than that found for 0.05 percent blood alcohol concentration or with 24 hours sleep deprivation. The company said that while it sounded unusual, the findings had important implications for people whose work place requires that they operate in demanding environments where there was restricted access to toilets.

Cogstate said the findings could help understand the shared neurologic mechanisms that are involved in both pain perception and in concentration and problem-solving abilities.

Prof Maruff’s paper entitled ‘The Effect of Acute Increase in Urge to Void on Cognitive Function in Healthy Adults’ was published in 2010 in the journal *Neurourology and Urodynamics*.

An abstract is available at: <http://onlinelibrary.wiley.com/doi/10.1002/nau.20963/abstract>.

Cogstate said the study of eight healthy adults who took part in an experiment in which they consumed 250mL of water every 15 minutes.

The company said the researchers used the Cogstate computerized brief battery to measure cognitive function at 45 minute intervals.

Cogstate said the researchers found that the urge to void and pain increased with time and with amount of water consumed and that having an extreme urge to void had a negative effect on attention and working memory functions.

“Receiving an Ig Nobel Prize was completely unexpected and one of the oddest things that has occurred in my scientific career,” Prof Maruff said.

“When we conducted the research, we understood that it may seem a bit quirky, but this study really does have important and practical implications for everyday life,” Prof Maruff said.

Cogstate was untraded at 16 cents.

AGENIX

Agenix’s annual general meeting will vote to issue 3,000,000 free rights at a zero exercise price to executive chairman Nicholas Weston.

Agenix said Mr Weston had been with the company since 2008 and had “undertaken a difficult and challenging task with inherent reputational risk”.

The company said Mr Weston’s fixed cash remuneration of \$150,000 a year was “significantly less than the market rate” and the rights were in lieu of a more substantial cash remuneration.

The meeting will also vote on the re-election of director Christopher McNamara.

The meeting will be held at the BDO Melbourne Boardroom, Level 30, North Tower, Rialto, 525 Collins Street, Melbourne on October 31, 2011 at 11am (AEDT).

Agenix was untraded at 1.6 cents.

NEURODISCOVERY

The Perth-based Social Investments has increased its substantial shareholding in Neurodiscovery from 4,742,171 shares (5.56%) to 6,838,357 shares (7.05%).

The substantial shareholder said Social Investments bought the shares at prices between 3.2 cents and four cents a share.

Neurodiscovery was up 0.1 cents or 3.1 percent to 3.3 cents.

SUNSHINE HEART

Sunshine Heart has appointed CM Capital partner Dr Mark Harvey as a non-executive director effective from September 29, 2011.

Sunshine Heart said that funds affiliated with CM Capital held 29 percent of the shares in the company.

Earlier this year CM Capital's John Brennan resigned as a Sunshine Heart director "for personal reasons" (BD: May 19, 2011). Mr Brennan is no longer with CM Capital.

Sunshine Heart said that Dr Harvey has experience in the formation, fund raising and management of numerous life science companies and was a director of medical technology companies Osprey Medical and Pathway Therapeutics.

CM Capital's website said that Dr Harvey was formerly managing director of Symbiosis Group and life sciences group manager at the University of Queensland's commercialization arm. Uniquist.

The website said Dr Harvey held a Bachelor of Science, Ph D and Master of Business Administration from the University of Queensland.

Sunshine Heart said Dr Harvey would stand for election at the November annual general meeting.

Sunshine Heart was up 0.2 cents or 4.4 percent to 4.7 cents with 2.4 million shares traded.