



Biotech Daily

Thursday November 8, 2012

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH DOWN: CLINUVEL UP 9%, PHYLOGICA DOWN 8%**
- * **DSMB BACKS ALCHEMIA HA-IRINOTECAN COLORECTAL CANCER TRIAL**
- * **CSIRO SOLDIER BEETLE GENE FOR ANTIBIOTIC, ANTI-CANCER DRUGS**
- * **BIONOMICS' IRONWOOD IND FOR ANTI-ANXIETY IW-2143 (BNC210)**
- * **CIRCADIAN VGX-100 COMBO INHIBITS COLORECTAL CANCER IN MICE**
- * **GRIFFITH UNIVERSITY TO EXPAND BODIEM BDM-I DELIVERY VARIANTS**
- * **BIO-MELBOURNE BREAKFASTS ON PAEDIATRIC MARKET**
- * **SIGNIFICANT DISSENT AT INVION (CBIO) AGM**
- * **SMALL DISSENT AT USCOM AGM**
- * **DURBIN SUPER TAKES 6% OF GENERA**
- * **MEI PHARMA CONSOLIDATION CHANGES NOVOGEN DISTRIBUTION**
- * **MEDICAL DEV'S JOHN SHARMAN EARNS 2nd TRANCHE SHARES**

MARKET REPORT

The Australian stock market fell 0.72 percent on Thursday November 8, 2012 with the S&P ASX 200 down 32.7 points to 4,483.8 points. Seven of the Biotech Daily Top 40 stocks were up, 17 fell, seven traded unchanged and nine were untraded..

Clinuvel was the best, up 15 cents or 9.1 percent to \$1.80 with 21,361 shares traded. Neuren climbed 8.1 percent; Anteo and Ellex were both up five percent; Bionomics was up 4.6 percent; with Sunshine Heart up 3.1 percent.

Phylogica led the falls, down 0.2 cents or 8.3 percent to 2.2 cents with 431,970 shares traded. Universal Biosensors lost 7.1 percent; Benitec and Uscom were down more than six percent; Patrys was down 5.3 percent; Tissue Therapies fell 4.1 percent; Pharmaxis and Phosphagenics were down more than three percent; Acrux and QRX shed more than two percent; with Living Cell, Mesoblast, Prana, Resmed, Starpharma and Viralytics down more than one percent.

ALCHEMIA

Alchemia says the independent data safety monitoring board has recommended the phase III, trial of HA-Irinotecan for metastatic colorectal cancer continue.

Alchemia said that the board met for the second time on October 30, 2012 and considered study-specific data as well as background knowledge about the disease, test agent and patient population and reviewed data from 220 patients randomized to receive either HA-Irinotecan or irinotecan, each delivered as part of the 5-fluorouracil, leucovorin and irinotecan or FOLFIRI regimen.

The company said that the board “noted that no safety concerns were identified and it recommended continuing the clinical trial as planned”.

Alchemia chief scientific officer Prof Tracey Brown said that the board’s second recommendation to continue the phase III trial of HA-Irinotecan was “the achievement of another important milestone in the progress of this pivotal trial”.

Alchemia chief executive officer Dr Pete Smith said the study “continues to perform well, with a good rate of recruitment keeping it on track ... [and] we responded rapidly to the higher than expected screen failure rate in the early stages of the trial and the subsequent addition of more trial sites has accelerated patient recruitment”.

Alchemia said the trial would recruit 390 irinotecan naïve second or third line metastatic colorectal cancer patients and the primary endpoint was progression free survival, to be assessed when 350 patients had disease progression, expected by December 2013.

Alchemia fell half a cent or 0.9 percent to 54.5 cents.

THE COMMONWEALTH SCIENTIFIC AND INDUSTRIAL RESEARCH ORGANISATION

The Commonwealth Scientific and Industrial Research Organisation says that three genes providing soldier beetles defence could be synthesized for antibiotic or anti-cancer drugs.

The CSIRO said its staff, with a colleague at Sweden’s Karolinska Institute, published the gene identification breakthrough and potential applications in Nature Communications.

CSIRO Ecosystem Sciences research leader Dr Victoria Haritos said that “for the first time, our team has been able to isolate and replicate the three genes that combine to make the potent fatty acid that soldier beetles secrete to ward off predators and infection”. “This discovery ... opens a new way for the unusual fatty acid to be synthesized for potential antibiotic, anti-cancer, or other industrial purposes,” Dr Haritos said.

CSIRO said that soldier beetles exuded a white viscous fluid from their glands to repel potential attacks from predators, as well as in a wax to protect against infection.

The Organisation said that the team found the fluid contained an exotic fatty acid called dihydromatricaria acid, or DHMA, which was one of a group called polyynes that have known anti-microbial and anti-cancer properties and that while DHMA and similar polyyne fatty acids were found in a wide variety of plants, fungi, liverworts, mosses, marine sponges and algae, they were difficult to manufacture using conventional processes.

CSIRO said Dr Haritos’ team had developed a method to manufacture the compounds.

“We have outlined a method for reproducing these polyyne chemicals in living organisms like yeast, using mild conditions,” Dr Haritos said.

CSIRO said that soldier beetles were the only animals reported to contain DHMA and together with the observation that the beetles forage on plants, such as daisies, which contained a lot of those types of fatty acids, led to previous incorrect conclusions that the DHMA in soldier beetles was derived from their diet.

“Through our research and the gene differences we have discovered, we now know soldier beetles have evolved this same defensive compound entirely independently of its production in plants and fungi,” Dr Haritos said.

BIONOMICS

Bionomics says Ironwood Pharmaceuticals has submitted an investigational new drug application for a US trial of anti-anxiety drug candidate IW- 2143 (formerly BNC210). Bionomics said that its US licensee intended to initiate phase I studies with IW-2143 in healthy volunteers following the filing of the application by the US Food and Drug Administration.

The company said that the initial phase I trial was designed to further assess IW-2143's pharmacokinetics.

Bionomics said that its preclinical studies suggested that IW-2143 had anti-anxiety activity and promoted neurite outgrowth.

The company said that anxiety disorders affected 40 million Americans each year and while there were therapies available, there was a significant unmet need.

Bionomics said IW-2143 had the potential to fill a need in this market as an anxiety drug that might not have the sedation, withdrawal syndrome or memory impairment reported with other therapies.

Bionomics was up 1.5 cents or 4.6 percent to 34 cents.

CIRCADIAN TECHNOLOGIES

Circadian says that VGX-100, combined with three different tyrosine kinase molecules improves colorectal cancer tumor growth reduction in mice.

Circadian said that the mouse data was presented today in a poster, entitled 'Improved inhibition of tumor growth by the novel monoclonal antibody VGX-100 targeting VEGF-C in combination with VEGF-Receptor Tyrosine Kinase Inhibitors' at the European Organisation for Research and Treatment of Cancer conference in Dublin, Ireland.

The company said the data showed that VGX-100, when combined with three different vascular endothelial growth factor receptor (VEGF) tyrosine kinase molecules sunitinib (Sutent), sorafenib (Nexavar) and pazopanib (Votrient) was able to improve tumor growth reduction in a mouse model of colorectal cancer.

The company said that VGX-100 had been shown to improve inhibition of tumor growth when combined with the antiangiogenic agent Avastin.

Circadian said that the data indicated that, if clinically validated, VGX-100 had the potential to improve patient response when combined with other small molecule anti-angiogenic agents.

The company said VGX-100 was a fully human monoclonal antibody targeting the VEGF-C growth factor and inhibited the development of blood vessels required for tumor growth. Circadian said that VGX-100 might inhibit cancer spread or metastasis by suppressing the development of both blood and lymphatic vessels.

Circadian's head of preclinical research and development and senior author of the poster presentation Dr Megan Baldwin said that the data "further indicates that VGX-100 can act in combination with a range of anti-angiogenic approved drugs to slow the growth of tumors, opening up possibilities for VGX-100 to be used in a range of new therapeutic combinations across a range of tumor types".

Circadian said it was undertaking a phase I trial in the US under an investigational new drug application evaluating the safety and tolerability of ascending doses of VGX-100 alone or when administered in combination with Avastin, which was expected to be complete by April 2013.

Circadian said it had created a wholly-owned subsidiary, Ceres Oncology Pty Ltd, to focus on the development of VGX-100 as a cancer therapy.

Circadian was untraded at 37 cents.

BIODIEM

Biodiem says it has an agreement with Griffith University to expand the range of variants of its broad spectrum antimicrobial compound, BDM-I.

Biodiem said that creating new variants of BDM-I with enhanced solubility and preserved antimicrobial ability would increase the range of possible commercial applications of the drug.

The company said the work would use expertise at Griffith University's Institute for Glycomics and be overseen by the Institute's director and research leader Prof Mark von Itzstein.

Biodiem said that Prof von Itzstein led the research group responsible for the design and synthesis of the anti-influenza drug Relenza.

The company said that BDM-I had displayed activity against a wide range of agents responsible for causing serious infectious diseases and increased solubility should enhance the potential for it to be delivered via a wider variety of administration routes such as injections, creams, ointment, gels, topical sprays, eye drops and inhalation.

Biodiem said the potential diversity increased the compound's commercial attractiveness for licencees.

The company said that first stage results should be available by December 2012.

Biodiem chief executive officer Julie Phillips said the antimicrobial program research results had "consistently broadened the potential applications of this compound, so we are pleased to announce this collaboration with Griffith University to develop the commercial profile of BDM-I".

Biodiem was untraded at 4.7 cents.

BIO-MELBOURNE NETWORK

The Bio-Melbourne Network says its November 13 Bio-Breakfast will explore the benefits in developing products for the paediatric market.

Bio-Melbourne Network chief executive officer Michelle Gallaher said the "may be some advantages for companies commercializing products for the paediatric market in terms of capital raising and a faster track through regulatory requirements especially if there is an unmet clinical need".

"Biotech companies may consider entering the paediatric market to then springboard into adult markets," Ms Gallaher said.

The Network said that Allied Healthcare Group chief operating officer Dr Julian Chick would discuss Allied's regenerative tissue engineering product Cardiacel, specifically developed to repair leaking heart valves in paediatric patients.

The Network said that Hatchtech chief executive officer Dr Ross Macdonald would present the commercialization path for its Deovo product as a next generation head lice treatment and Otifex Therapeutics chief operating officer Dr Christopher Wraight would discuss the development of a nasal spray for otitis media with effusion, a common cause of childhood hearing problems.

The Bio-Melbourne Network that the Bio-Breakfast would be held in Cinema 1, Australian Centre for the Moving Image, Federation Square, Melbourne, on November 13, 2012.

Registration is from 7:15am.

For more information and to book go to: <http://www.biomelbourne.org/events/view/254>.

INVION (FORMERLY CBIO)

All Invion annual general meeting resolutions were passed but with significant opposition to several resolutions.

The remuneration report was passed easily with 47,667,545 votes (90.7%) in favor and 4,883,245 votes (9.3%) against.

The issue of 25,000,000 options to directors Dr William Garner, Dr Mitchell Glass, Dr Ralph Craven, Dr James Campbell, Warren Brown and Brett Heading were opposed by about one third of all votes cast, with the most significant dissent against the options for Mr Heading with 39,769,473 proxy votes (60.8%) in favor and 25,649,238 proxy votes (39.2%) against (BD: Oct 5, 2010).

Dr Craven and Mr Brown were re-elected overwhelmingly.

Invion was up 0.2 cents or 3.85 percent to 5.4 cents.

USCOM

All Uscom annual general meeting resolutions were passed, but with some opposition to several resolutions.

Uscom executive chairman Rob Phillips told Biotech Daily that all resolutions were passed “unanimously, on a show of hands”.

The remuneration report was passed with 15,932,614 proxy votes (90.4%) in favor and 1,693,501 proxy votes (9.6%) against.

The re-election of directors Christian Bernecker and Sheena Jack were both supported by 9,717,972 votes (85.6%) and opposed by 1,630,564 votes (14.4%).

One resolution for the approval of a private placement was passed by a similar margin to the directors' votes, as were the issue of shares to Ms Jack and options to Mr Phillips.

The ratification of a private placement had 1,664,902 proxy votes against and 1,629,156 proxy votes in favor with 6.3 million proxy votes available in support of the resolution.

Mr Phillips said the votes against the resolution were cast by two shareholders

Uscom's most recent Appendix 3B share issue announcement said there were 63,159,485 shares on issue, meaning that the strongest opposition came from 2.7 percent of all shares on issue, below the five percent needed to requisition extraordinary general meetings.

Uscom fell one cent or 6.1 percent to 15.5 cents.

GENERA BIOSYSTEMS

Durbin Superannuation has increased its substantial shareholder in Genera from 3,618,899 shares (5.16%) to 4,737,586 shares (6.20%).

The substantial shareholder notice signed by director Graham Durbin did not disclose the price the Hunter's Hill, Sydney-based investment superannuation fund paid for the 1,118,687 shares.

In June, the initial substantial shareholder said the fund acquired 3,618,899 shares for \$800,000 or an average price of 22.1 cents (BD: Jun 7, 2012).

Genera was untraded at 15 cents.

NOVOGEN

Novogen says that its shareholders will receive about six shares of common stock in MEI Pharma for every 35 shares of Novogen.

Novogen said that in its annual general meeting it said it would distribute stock on a one-for-59 distribution which took into consideration a proposed one-for-10 stock consolidation announced by MEI Pharma on September 28, 2012 and which Novogen understood was to be effected at the beginning of November, 2012, before the capital reduction resolution was to be determined by the company's shareholders at the meeting .

Novogen said that it had been advised by MEI Pharma that the proposed consolidation would not be effected before the proposed distribution.

The company said it planned to distribute all of the common stock that it owns in MEI Pharma to its shareholders at about six MEI Pharma shares for every 35 Novogen shares.

Novogen said that all other terms were unchanged.

Novogen fell one cent or 6.1 percent to 15.5 cents.

MEDICAL DEVELOPMENTS INTERNATIONAL

Medical Developments says that chief executive officer John Sharman has subscribed for a further 513,577 shares at 25 cents a share under the long term incentive plan. ("LTIP")

Medical Developments said that under the plan, Mr Sharman was entitled to subscribe for one further tranche of 513,577 shares, at 25 cents a share, once the prices at which all shares in the company bought and sold in the ordinary course of trading on ASX was above a weighted average of \$1.46 during for more than three months.

The company said that after paying for his second tranche shares today, Mr Sharman owned 1,027,154 shares in the company.

Medical Developments said that 60 percent of the shares subscribed for today would be held in escrow for 12 months.

Medical Developments fell six cents or 3.3 percent to \$1.77.