Biotech Daily

Wednesday August 8, 2012

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH EVEN:**
- GENETIC TECHNOLOGIES UP 14%, TISSUE THERAPIES DOWN 10%

*** CE MARK APPROVAL FOR GENETIC TECHNOLOGIES BREVAGEN TEST**

*** UK REGULATORY DELAY FOR TISSUE THERAPIES' VITROGRO**

*** HEARTWARE H1 REVENUE UP 44% TO $53m, LOSS UP 113% TO $39m**

*** EURO PATENT FOR BIODIEM'S BDM-I**

*** ISONEA LAUNCHES NEW ASTHMA SMART-PHONE APPLICATION**

*** CALZADA APPOINTS PROF DAVID MCQUILLAN DIRECTOR**

*** ELLERSTON (PACKER FAMILY) TAKES 7% OF ACRUX**

*** TERRAPINN BIOPHARMA CONFERENCE**

MARKET REPORT

The Australian stock market was up 0.49 percent on Wednesday August 8, 2012 with the S&P ASX 200 up 21.0 points to 4,312.6 points.

Fourteen of the Biotech Daily Top 40 stocks were up, 14 fell, six traded unchanged and six were untraded.

Genetic Technologies was the best, up 1.5 cents or 13.6 percent to 12.5 cents with 1.2 million shares traded, followed by Compumedics up one cent or 13.3 percent to 8.5 cents with 50,000 shares traded.

Antisense climbed 6.7 percent; Alchemia and Patrys were up five percent or more; Anteo and Clinuvel were up more than four percent; Bionomics and QRX rose more than two percent; with Acrux and Viralytics up more than one percent.

Tissue Therapies led the falls, down 4.5 cents or 9.9 percent to 41 cents with 884,096 shares traded.

Avita and Bioniche lost more than six percent; Cellmid and Living Cell lost more than five percent; Prima fell 4.2 percent; Phylogica and Prana were down more than three percent; Impedimed and Sirtex shed two percent or more; with Heartware, Reva and Universal Biosensors down more than one percent.

GENETIC TECHNOLOGIES

Genetic Technologies says its Brevagen breast cancer risk test has received Conformité Européenne (CE) mark approval for sale in the EU and countries that recognize the mark.
Genetic Technologies said that the initial commercial focus would be France and Germany.
The company said that breast cancer is the most common form of cancer in European women and in 2008, annual breast cancer incidence in the European Union was more than 330,000., nearly double the incidence rate in the US of about 180,000 a year.
Genetic Technologies said about 80 percent of women who developed breast cancer had non-familial or sporadic breast cancer, with little or no family history of the disease.
Genetic Technologies chief executive officer Dr Paul MacLeman said that the CE mark for Brevagen product was “a major milestone for the company”.
“Given the significant incidence rate of breast cancer in the EU, there is a critical need for enhanced risk assessment tools, leading to improved preventative management and surveillance,” Dr MacLeman said.
Genetic Technologies said the test was launched in the US in June 2011 and was available in 48 US states.
Genetic Technologies was up 1.5 cents or 13.6 percent to 12.5 cents with 1.2 million shares traded.

TISSUE THERAPIES

Tissue Therapies says its Vitrogro Conformité Européenne (CE) mark application has been referred to the UK Medicines and Healthcare products Regulatory Agency.
Tissue Therapies said the EU notified body, the British Standards Institute, referred the application to the Agency “for a final decision as to which Medical Device Directive rule was appropriate for the classification of Vitrogro ECM - Device Rule 8 or Device Rule 13.
The company said the referral came “despite the earlier written advice … that all examiner queries had been answered … to the satisfaction of [the British Standards Institute] and that a CE mark certificate would be issued shortly. (BD: Jul 16, 2012).
Tissue Therapies said that the British Standards Institute advised that the review would take up to 30 days, plus any additional days necessary for questions and replies.
The company said that once CE mark was received, the device rule under which it was granted made no practical, commercial difference.
Tissue Therapies said that it was possible that the review could result in a further referral to the European Medicines Agency for a review of the Vitrogro manufacturing process.
The company said the new delay was “surprising and frustrating” but it was a regulatory question as to which of two device rules was more applicable.
Tissue Therapies said it remained confident of receiving a final device CE mark approval.
Tissue Therapies fell 4.5 cents or 9.9 percent to 41 cents.

HEARTWARE INTERNATIONAL

Heartware says that revenue for the six months to June 30, 2012, was up 44.4 percent to $US55,398,000 ($A52,554,000), with the net loss after tax up 113.2 percent to $US41,627,000 ($A39,490,000).
Heartware said its diluted loss per share was up 110 percent from $US1.40 at June 30, 2011 to $US2.94 at June 30, 2012 and the company had cash and cash equivalents of $US114,501,000 at June 30, 2012 compared to $US71,257,000 at June 30, 2011.
Heartware fell three cents or 1.3 percent to $2.32.

BIODIEM

Biodiem says it has been granted a key European patent for its synthetic antimicrobial compound BDM-I.

In 2010, Biodiem says it had been issued both US and Chinese patents covering BDM-I, entitled 'Antimicrobial and radio-protective compounds' valid until 2022 (BD: Dec 1, 2010).

Today, Biodiem said that BDM-I was a novel compound active against a range of pathogenic micro-organisms including bacteria, fungi and protozoa and the patent provided protection around BDM-I as a treatment for vulvo-vaginitis, a general term for inflammation of the vulva or vagina.

The company said it had a relationship with the US Army Medical Research Institute of Infectious Diseases which was undertaking preclinical studies to screen for BDM-I's activity in-vitro against a range of disease-causing agents.

Biodiem said it was using a US National Institutes of Health in-vitro assessment to assess BDM-I's activity in vitro and results were encouraging and it would discuss with the NIH the potential to use its animal models of infectious disease service to further evaluate BDM-I's activity.

The company said that the target markets for anti-fungals and anti-bacterials were "extremely large" with the anti-fungals market expected to reach $US11.3 billion in 2014 anti-infectives forecast to exceed $100 billion by 2015.

Biodiem said the continued rise in antibiotic-resistant strains of bacteria such as methicillin-resistant Staphylococcus aureus had led to significant interest in such compounds.

Biodiem chief executive officer Julie Phillips said that Europe was "a major regulatory market and this addition to the BDM-I package helps de-risk the asset as a licencing target, increasing its value to Biodiem".

The company said that vulvo-vaginitis was commonly caused by infection from a range of different micro-organisms and was one of the most common female health complaints across all demographics.

Biodiem said the new patent for BDM-I secured a claim around the compound's activity against the organisms Candida albicans, Neisseria gonorrhoeae and Trichomonas vaginalis, among others, some of the most common causative agents for vulvo-vaginitis, providing more evidence for the breadth of BDM-I's potential applications.

The company said that Candida albicans is one of the most common causes of yeast infections and was commonly referred to as thrush, Neisseria gonorrhoeae caused gonorrhoea and Trichomonas vaginalis was the most common sexually transmitted protozoan infection in industrialised countries.

Biodiem said that Trichomoniasis had been correlated with reproductive issues and increased susceptibility to a range of other health issues including infection with HIV.

Biodiem said that a number of non-clinical studies hade been completed to better characterize BDM-I, which had been manufactured to good laboratory practice standards and preparatory physico-chemical studies had provided formulations that could be used for in-vitro and in-vivo assessment in disease models.

The company said it had completed a first study with the Queensland Institute of Medical Research investigating BDM-I in a proof-of-concept model against schistosomiasis, a parasitic disease that caused impairment of growth and cognitive development.

Biodiem said 200 million people were infected with the parasitic worm disease schistosomiasis, with 600 million people at risk of infection.

The company said it was one of the largest neglected diseases of the developing world.

Biodiem was up 0.6 cents or 11.1 percent to six cents.

ISONEA

Isonea says it has launched an updated version of its asthma management smart-phone application, Asthmasense.

Isonea said the new application had international selection options for emergency telephone numbers and metric conversions for height measurements.

The company said the revised application was available to Apple brand Iphones, Ipads and the Linux operating system-based Android users and was provided at no charge to customers who had downloaded the earlier version.

Isonea said Asthmasense provided "the foundation for a family of future asthma management smart-phone [applications] to be released in the coming months, including one that would combine its acoustic respiratory monitoring sensory technology and diagnostic algorithms into mobile health platforms.

The company said that since the May 31, 2012 launch the application had "attention in consumer print and social media and generating a steady rate of downloads" with Australia accounting for eight percent of downloads in June and July and with downloads from 16 other countries in North America, Europe, and Asia.

Isonea said that the US had 55 percent of downloads to date, helped by a promotion to residents of Memphis, Tennessee, as the US city with the highest risk to asthma sufferers.

Isonea said the latest application version was available from Apple, Google Play and Amazon and would cost initial users $US3.99 and users could input their asthma action plans so that Asthmasense could provide active reminders.

Isonea said the application enabled symptoms, medication usage and lung function testing data to be recorded and displayed trends in a graphic format.

Isonea fell 0.4 cents or 6.25 percent to six cents.

CALZADA

Calzada has appointed Prof David McQuillan as a non-executive director.

Calzada said that Prof McQuillan had experience in product development and commercialization of medical devices, with extensive technical, medical, scientific and regulatory knowledge as well as significant mergers and acquisition expertise.

The company said that in 2000, Prof McQuillan joined Lifecell Corp as research and development vice-president and led the team developing products for reconstructive and plastic surgery applications.

Calzada said that following marketing approval in 2008 for its Strattice reconstructive tissue matrix, Lifecell was acquired by Kinetic Concepts Inc for $US1.8 billion and Prof McQuillan became Kinetic's senior vice-president of advanced research and technology.

The company said that Prof McQuillan was currently a consultant to several US healthcare investment funds focused on regenerative medicine, medical devices and tissue engineering and was also the chief scientific officer of the Durhum North Carolina-based Humacyte Inc.

The company said that Prof McQuillan held Bachelor of Science and Doctor of Philosophy degrees in Biochemistry from Monash University, Australia, had undertaken post-doctoral training at the National Institutes of Health, Bethesda, Maryland and the University of Melbourne and was currently an adjunct professor at the Institute of Biosciences and Technology in Houston, Texas.

Dr McQuillan said he was "very familiar with the portfolio of products that can be developed from the Novosorb family of bio-resorbable polymers and believe that these products can address a number of unmet medical needs".

Calzada was up 0.1 cents or two percent to five cents.

ACRUX

Ellerston Capital has increased its substantial shareholding in Acrux from 8,984,253 shares (5.40%) to 10,962,096 shares (6.58%).

Ellerston became a substantial shareholder in May, 2012, saying the shares were held by HSBC Custody Nominees, Cogent Nominees, JPM Nominees and National Nominees (BD: May 23, 2012).

Today, Ellerston provided a detailed list of "passive substantial holders" related body corporates of the principal person, including Arctic Asia, Australian Financial Times, Conpress (Hong Kong, Malaysia, Cayman, Christchurch, Finance, Holdings, International Finance) and Consolidated Press Property, a raft of Ellerston companies, as well as Hoyts Cinemas (America, Argentina, Chile, Germany, Polska), Park Street Partners Cayman and Perisher Village Developments, among others.

Ellerston's website said that it is a subsidiary of Consolidated Press Holdings, a private company of the Packer media and gambling family.

Acrux was up four cents or one percent to $3.88 with 679,483 shares traded.

BIOPHARMA AUSTRALASIA CONVENTION

Events manager Terrapinn says the first Biopharma Australasia Convention will be held in Sydney, on August 23 and 24, 2012.

Terrapinn said the conference at the Swissotel would have sessions on digital pharma marketing; generics; vaccines; drug discovery and development; market access; partnering and investment; and clinical trials.

Terrapinn said speakers included Merck Sharp and Dohme director of licencing and external research Dr Phil Kearney, Boehringer Ingelheim executive Mark Peterson, CSL's head of research and development product development Dr Simon Green, Biota head of product development Dr Jane Ryan, Bionomics chief executive officer Dr Deborah Rathjen, Phylogica chief financial officer Nick Woolf and Benitec chief executive officer Dr Peter French.

For more information and to register go to www.terrapinn.com/bio.