



Biotech Daily

Tuesday September 23, 2014

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH UP: LIVING CELL UP 13%, CLINUVEL DOWN 20%**
- * **BIONOMICS ACQUIRES DISTRESSED PRESTWICK FOR \$391k**
- * **INVION: 'INTERIM DATA SHOWS INV102 SAFE FOR ASTHMA'**
- * **OPTISCAN RAISES \$750k**
- * **ANTISENSE REQUESTS CAPITAL RAISING TRADING HALT**
- * **US PATENT FOR CIRCADIAN, VEGENICS VEGFR-3 TRAP MOLECULES**
- * **LIVING CELL APPOINTS THREE PROFESSORS FOR NTCELL ADVICE**
- * **VIRAX APPOINTS PROF DOUGLAS JOSHUA TO ADVISORY BOARD**
- * **REGENEUS OPENS SINGAPORE CLINIC, APPOINTS DR PATRICK GOH**

MARKET REPORT

The Australian stock market climbed 0.98 percent on Tuesday September 23, 2014 with the S&P ASX 200 up 52.7 points to 5,415.7 points. Eighteen of the Biotech Daily Top 40 stocks were up, 14 fell, four traded unchanged and four were untraded. All Big Caps rose.

Living Cell was the best, up 0.8 cents or 12.9 percent to seven cents, with 202,143 shares traded, followed by Circadian up 10.5 percent to 21 cents, with 133,611 shares traded.

Analytica and Oncosil climbed more than eight percent; Cellmid was up 7.1 percent; Atcor, Prana and Universal Biosensors were up more than six percent; Impedimed was up 4.5 percent; Admedus, Antisense and Compumedics climbed more than three percent; Mesoblast rose two percent; Cochlear, CSL, Medical Developments, Phosphagenics and Sirtex were up more than one percent; with Benitec, Resmed and Starpharma up by less than one percent.

Clinuvel led the falls, down 99 cents or 20.2 percent to \$3.91 with 547,381 shares traded, followed by Tissue Therapies down 16.7 percent to 35 cents with 1.5 million shares traded.

GI Dynamics lost 6.5 percent; Biotron fell 4.35 percent; Avita was down three percent; Prima shed 2.5 percent; Neuren, Pharmaxis and Viralytics lost more than one percent; with Acrux, Bionomics, Nanosonics, Osprey and Psivida down less than one percent.

BIONOMICS

Bionomics says it has acquired the business assets of the Strasbourg France-based Prestwick Chemical for EUR270,000 (\$A390,589).

Bionomics said that Prestwick had reported revenues for the year to December 31, 2013 of EUR4.29 million (\$A6.21 million) and carried no debt, but Bionomics chief executive officer Dr Deborah Rathjen told Biotech Daily that Prestwick had been through "a difficult time" and had been in administration since April.

In a media release, Bionomics said that Prestwick was a medicinal chemistry company that had worked on the BNC375 cognition drug, which was licenced to Merck & Co in June and the company was co-located with Bionomics earlier acquisition, the central nervous system pharmacology business Neurofit (BD: Jun 24, 2104).

The company said it acquired Neurofit in 2005 and the contract research organization had played a key role in the identification of BNC210 for anxiety and depression and had been involved in the evaluation of compounds in the BNC375 program.

Bionomics said that Prestwick was founded in 1999 by medicinal chemist Prof Camille Wermuth with senior scientists from Strasbourg University.

Bionomics said that Prestwick was "a premium provider of medicinal chemistry services and smart screening libraries ... [specializing in] research and development services in early drug discovery including hit identification and validation, hit to lead, and lead optimization based on its expertise and state-of-the-art computational technology".

The company said that Prestwick had one marketed product from its contract research services as well as several compounds in phase III clinical trials.

Bionomics said it had been a Prestwick customer since 2009, with Prestwick involved in both the pain and the BNC375 programs, both of which were partnered with Merck.

The company said that the Prestwick acquisition "vertically integrates key functions within Bionomics in early stage drug discovery and development in neuroscience and oncology".

Bionomics said that Prestwick's customer list included Glaxosmithkline, Johnson & Johnson, Bayer, Sanofi Aventis, Abbot and EMD (Merck Serono), with several dozen small and mid-size pharmaceutical and biotechnology company clients.

The company said that Prestwick's expertise and customer base were complementary and highly synergistic with those of Neurofit.

Dr Rathjen said that the acquisition was "an important addition to Bionomics' global operations" and her company was "especially pleased to have acquired the Prestwick drug candidate library".

"Bionomics is building a global business with integrated drug discovery and development expertise to support strategic partnerships," Dr Rathjen said.

"Prestwick adds to Bionomics' capacity to rapidly identify and advance high value drug candidates for partnering and development [and it] will continue to provide its existing services and its name will not change," Dr Rathjen said.

"Ownership by Bionomics will bring stability within the board and management and deliver synergies by complementing the existing Bionomics business, cementing the important role of Prestwick in ongoing Bionomics [research and development]," Dr Rathjen said.

Dr Rathjen said Prestwick's assets included the expertise of its staff in drug innovation and direct channels into a large number of pharmaceutical companies.

Dr Rathjen said that the similarities with the 2005 acquisition of Neurofit were apparent and if Prestwick returned a fraction of the benefits of Neurofit, "then it will likely be a very worthwhile investment, for a modest price".

Bionomics said the hand over of assets and management would occur on October 1, 2014.

Bionomics fell half a cent or 0.9 percent to 53.5 cents.

INVION

Invion says that blinded interim data shows that 19 of 21 patients in its phase II asthma trial tolerated the highest dose of the beta-blocker nadolol without severe adverse events. Invision chief executive officer Dr Greg Collier told Biotech Daily that two patients dropped out of the trial “but not because of serious adverse events”.

Invion said that the phase II study of INV102, or nadolol, in patients with mild asthma was funded by the US National Institute of Allergy and Infectious Diseases and the National Institutes of Health and the data related to the treatment of asthma patients with INV102, as well as the titration program designed to minimize broncho-constriction and other negative effects of beta-blocker use in patients with airway hyper-responsiveness.

Invion executive vice-president and chief medical officer Dr Mitchell Glass said that the use of beta-blockers in asthma was currently contraindicated due to safety concerns.

Invion said that patients had shown no pattern of cardiovascular or respiratory effects during the four hours of observation required after each titration dose and during initial titration and through the three months of stable daily dosing, patients demonstrated no requirement to increase rescue medication use, provided either as a short-acting beta-agonist or as an anti-muscarinic agent.

The company said that no pattern of adverse events had emerged, which was significant given that nadolol was contraindicated in patients with asthma due to risks associated with worsening broncho-spasm and the data was relevant to the oral and inhaled INV102 programs underway, with the company providing an update to the US Food and Drug Administration in support of a protocol amendment for its trial in smoking cessation.

Dr Glass said that the safety data was encouraging because nadolol appeared to be following the same pattern seen in early studies of the beta-blocker carvedilol in chronic heart failure, that with careful titration to a maximum tolerated dose, side effects could be avoided, a prerequisite to reversing a contraindication.

Dr Glass said that nadolol was “the first and only drug specifically targeting the airway epithelium” and initial studies at Baylor University showed improvement in patients’ airway hyper-responsiveness after nadolol use.

Dr Glass said that the trial data strongly reinforced that nadolol might be given safely and effectively to patients with asthma after dose titration and the data supported the plan to develop inhaled nadolol for long-term treatment of moderate to severe asthma, which results in the same epithelial derangement seen in patients with smoker’s cough, chronic bronchitis and cystic fibrosis.

Invion said the phase II INV102 asthma trial was being conducted at Baylor, Washington University and Duke University and was due to be completed in 2015.

Invion fell 0.1 cents or 1.25 percent to 7.9 cents.

OPTISCAN

Optiscan says it has raised \$750,000 through a \$450,000 placement at three cents a share and a \$300,000 convertible note.

The company said that the convertible note carried interest of 15 percent a year.

Optiscan said the raising was helped by concluding testing on its disposable sheath for the Carl Zeiss neurosurgical endomicroscopy system (BD: August 27, 2014).

The company said that its three priority projects were pre-regulatory submission work for the Zeiss neurosurgery visualization system; final pre-launch product development work for the second generation research endo-microscopy system; and advanced development of the company’s super hi-resolution mini-probe for gastrointestinal medicine.

Optiscan was unchanged at 3.5 cents.

ANTISENSE

Antisense has requested a trading halt "pending an announcement of a capital raising". Trading will resume on September 25, 2014 or on an earlier announcement. Antisense last traded up half a cent or 3.6 percent to 14.5 cents.

CIRCADIAN TECHNOLOGIES

Circadian says that the US Patent and Trade Mark Office has allowed wholly-owned subsidiary Vegenics Pty Ltd a patent directed at soluble VEGFR-3 trap molecules. Circadian said that the patent was expected to proceed to grant about January 2015. The company said that the allowed composition-of-matter claims covered fusion proteins, such as OPT-302, formerly VGX-300, comprising a vascular endothelial growth factor receptor 3 (VEGFR-3) component, capable of binding to VEGF-C and VEGF-D. Circadian said it was developing OPT-302 for the treatment of wet age-related macular degeneration through its wholly-owned subsidiary Opthea Pty Ltd. The company said that the US patent was expected to extend to 2026 as a result of substantial patent term adjustment being awarded and the equivalent patent had been granted in Europe, Japan, Canada and Australia. The company said that OPT-302 blocked VEGF-C and VEGF-D and inhibited the hallmarks of wet age-related macular degeneration in preclinical models, including blood vessel growth and vessel leakage. Circadian said that wet age-related macular degeneration was the leading cause of blindness for people over 50 years in the US and Europe, was estimated to affect more than 1.5 million people worldwide, with a market of \$5 billion in the US alone. Circadian was up two cents or 10.5 percent to 21 cents.

LIVING CELL TECHNOLOGIES

Living Cell says it has appointed Harvard's Prof Anne Young, Cambridge UK's Prof Roger Barker and the University of Auckland's Prof Richard Faull as advisors for its NTCCell. Living Cell said that the three researchers were "internationally recognized experts on the discovery of new treatments for neurodegenerative diseases". The company said that Prof Young had more than 40 years experience studying functional neuro-anatomy and her current research focused on new therapeutic strategies for Parkinson's and Huntington's diseases. Living Cell said that Prof Barker had experience in evaluating and developing therapies for Parkinson's and Huntington's diseases including cell therapies and his work focussed on disease heterogeneity using cognitive testing, functional imaging and genetic biomarkers. The company said that Prof Faull was the director of the Centre for Brain Research, at the University of Auckland and had more than 40 years research experience in anatomical studies of human brain neuronal growth. Living Cell said that the Centre for Brain Research carried out research and development programs targeting neurodegenerative diseases such as Parkinson's, Huntington's, motor neuron and Alzheimer's diseases. Living Cell chief executive officer Dr Ken Taylor said that the three professors "oversight and expertise will enhance [Living Cell's] ability to develop and market NTCCell therapy for Parkinson's patients failing current therapy". "Their expertise will also prove invaluable as we investigate the potential of our patented cell therapy for other neurodegenerative disorders," Dr Taylor said. Living Cell was up 0.8 cents or 12.9 percent to seven cents.

VIRAX HOLDINGS

Virax says it has appointed Prof Douglas Joshua to its scientific advisory board, effective immediately.

Virax said that Prof Joshua was “one of Australia’s most respected multiple myeloma authorities” and was the current emeritus professor of haematology at the Sydney University Medical School and consultant haematologist at the Royal Prince Alfred Hospital.

Virax managing director Dr Robert Crombie said the appointment was pivotal to help drive the company’s lead oncology programs in multiple myeloma, which was an incurable bone marrow cancer

“This is a valuable and strategic appointment for our company as we move to exploit the clinical and commercial opportunity presented by our lead drug candidate GGTI-2418,” Dr Crombie said.

Virax said that Prof Joshua was a scientific advisor and member of the International Myeloma Foundation and was on the editorial board of numerous journals.

Virax said it was pursuing development of GGTI-2418 as a treatment for breast cancer with clinical trials expected to begin in early 2015.

Virax was unchanged at 0.5 cents.

REGENEUS

Regeneus says it plans to open the Hiqcell Regenerative Medicine Clinic in Singapore, with sports physician Dr Patrick Goh appointed as medical director.

Regeneus said that Dr Goh would provide patients in Singapore with access to the Hiqcell, fat derived stem cell therapy for osteoarthritis, with first treatments expected to by the end of 2014.

The company said that Dr Goh was the chief medical officer for the Singapore team during the 2000 and 2004 Olympic Games and he currently held a number of positions within Singapore’s Ministry of Health, the Singapore Armed Forces and Defence Science Organisation and the National Anti-Doping Advisory Board.

Regeneus said that the Hiqcell Regenerative Medicine Clinic would be located at the Camden Medical Centre on Orchard Road where a cell-processing laboratory had been established.

The company said that Singapore was “a natural first overseas market for Hiqcell as it is recognized as a leading edge medical services hub for both local and international patient treatments”.

Regeneus chief executive officer Prof Graham Vesey said the opening was “a major milestone and highlights the first location for treatment of Hiqcell outside of Australia”.

“It makes good sense for Regeneus from a business perspective to select Singapore as the first international location for the delivery of our Hiqcell treatment, as the regulatory environment is similar to what we’re used to in Australia and the standard of care is very high,” Prof Vesey said.

Regeneus was up one cent or 3.8 percent to 27.5 cents.