



Biotech Daily

Tuesday November 11, 2014

Daily news on ASX-listed biotechnology companies

- * **ASX DOWN, BIOTECH UP: BENITEC UP 17%, GENETIC TECH DOWN 18%**
- * **BIONOMICS TAKES-BACK BNC210 FROM IRONWOOD**
- * **RHINOMED TURBINE WINS CE MARK**
- * **INNATE DOSES 4 MS PATIENTS, APPOINTS DR CLAUDIA MANSELL**
- * **AVITA RECEIVES \$1.4m FEDERAL R&D TAX REFUND**
- * **BENITEC PLEADS SCHULTZ TO ASX 40% QUERY, ASX MISSES 35%**
- * **UP TO 9% OPPOSE ANTEO PLACEMENT CAPACITY, OPTIONS**
- * **IMPEDIMED REQUESTS CAPITAL RAISING TRADING HALT**
- * **ALCHEMIA'S DR TRACIE RAMSDALE REPLACES CEO THOMAS LIQUARD**
- * **DANIEL KENNY TO REPLACE ONCOSIL CEO DR NEIL FRAZER**

MARKET REPORT

The Australian stock market slipped 0.12 percent on Tuesday November 11, 2014 with the S&P ASX 200 down 6.9 points to 5,517.1 points. Thirteen of the Biotech Daily Top 40 stocks were up, 10 fell, 14 traded unchanged and three were untraded. All Big Caps rose.

Benitec was the best for the third trading day in a row, up as much as 34.5 cents or 47.9 percent to \$1.065 before closing up 12.5 cents or 17.4 percent at 84.5 cents with 2.15 million shares traded (see below).

Living Cell climbed 7.7 percent; Psivida rose 6.2 percent; both IDT and Patrys were up 5.88 percent; Admedus, Antisense and Oncosil were up more than four percent; Avita and Medical Developments rose more than two percent; Pharmaxis and Sirtex were up more than one percent; with Cochlear, CSL, Osprey and Resmed up by less than one percent.

Genetic Technologies led the falls, down 0.3 cents or 17.65 percent to 1.4 cents with 310,000 shares traded.

Uscom lost 9.1 percent; Biotron fell 6.1 percent; Alchemia, GI Dynamics and Starpharma fell four percent or more; Universal Biosensors was down three percent; Prima shed 2.6 percent; Mesoblast was down 1.7 percent; with Acrux down 0.9 percent.

BIONOMICS

Bionomics says it has taken back anti-anxiety drug BNC210 from Ironwood and will begin a phase Ib trial this year, with a phase II trial planned to begin by April 2015.

In January 2012, Bionomics said that the Cambridge Massachusetts-based Ironwood Pharmaceuticals had licenced BNC210 to develop the drug for anxiety disorders paying a \$2.9 million upfront fee in a deal worth up to \$US345 million (BD: Jan 22, 2012).

In December 2012, Bionomics said that Ironwood had begun a US phase I trial of BNC210, renamed IW-2143, to assess safety and pharmacokinetics in healthy volunteers, using single and multi-dose administration (BD: Dec 21, 2012).

Bionomics chief executive officer Dr Deborah Rathjen said at that time that the trial was “a strong signal of the progress being made by Ironwood in moving ahead with the study of IW- 2143”.

“As this trial progresses it is anticipated that a \$US2 million milestone payment to Bionomics by Ironwood will be triggered,” Dr Rathjen said at that time.

Bionomics said that Ironwood was responsible for developing and, if approved, commercializing IW-2143 and related compounds, including paying for the costs of clinical development.

The December 2012 announcement was the last mention of BNC210’s development.

Today, Bionomics said the companies “mutually agreed to terminate this arrangement” but Ironwood would retain a royalty interest in BNC210.

Bionomics said it would “progress the clinical development of BNC210 to significantly enhance its value prior to further partnering, building on the substantial progress already made through the Ironwood collaboration”.

The company said it would begin a single-centre phase Ib multiple ascending dose trial to investigate safety, tolerability, pharmacokinetics and pharmacodynamics in healthy male volunteers.

Bionomics said the trial would be conducted by the Rennes, France-based Biotrial International and examine target engagement by BNC210, based on its mechanism of action allowing refinement of BNC210 dose levels to be evaluated in phase II.

Bionomics said that it had secured a \$US10 million (\$A11.6 million) loan to be repaid over 30 months from the Santa Clara, California-based Silicon Valley Bank for the development of BNC210.

“Bionomics is in a strong position to dedicate the necessary internal resources and has secured non-dilutive funding specifically for the purpose of progressing BNC210 into the next stage of development,” Dr Rathjen said.

“Much has been achieved in the past two years in building towards phase II, including formulation and an extensive toxicology program,” Dr Rathjen said.

“In addition Bionomics will present on the novel mechanism of action of BNC210 at the annual Society for Neuroscience meeting in the US next month,” Dr Rathjen said.

Bionomics said the phase I trial’s primary endpoint was safety and tolerability of multiple ascending oral doses of BNC210 in healthy adult male subjects.

The company said that secondary endpoints included preliminary pharmaco-kinetic profile, pharmaco-dynamic profile of multiple ascending oral doses of BNC210 on cognitive functions and the pharmaco-dynamic profile of multiple administrations of the highest dose on nicotine shift.

Bionomics said that four groups of subjects would be enrolled to receive one of each of four doses of BNC210 or placebo, twice a day for eight days.

The company said that subjects would undergo a standard battery of pharmaco-dynamic assessments measuring cognitive parameters.

Bionomics was unchanged at 55.5 cents.

RHINOMED

Rhinomed says it has received Conformité Européenne (CE) mark certification for its sports Turbine nasal plugs.

Rhinomed said that it had completed the testing and technical documentation for the CE mark and the Turbine plugs conform to the regulatory and manufacturing requirements opening the way for the Turbine to be marketed directly in Europe and Turkey.

Rhinomed chief executive officer Michael Johnson told Biotech Daily that the CE mark for the sports Turbine would pave the way for the company's snoring product.

The company said the Turbine nasal dilator increased airflow by an average 38 percent and could assist athletes as a treatment for breathlessness during aerobic exercise.

Mr Johnson said the certification was "an important step in our plans to take the Turbine technology to the one of the world's largest sports and exercise markets".

"Having successfully registered the Turbine with the ... [US Food and Drug Administration] earlier this year, complying with the requirements necessary to gain a CE mark was vital," Mr Johnson said.

Rhinomed said that the quality control systems and processes it had in place not only ensured the Turbine complied with the requirements of American and European regulatory authorities, but would be leveraged to ensure the forthcoming over-the-counter snoring product could achieve registration in these markets as well.

Rhinomed was up 0.2 cents or 7.4 percent to 2.9 cents with 1.3 million shares traded.

INNATE IMMUNOTHERAPEUTICS

Innate says it has begun dosing in its phase IIb trial of MIS416 for secondary progressive multiple sclerosis and has appointed Dr Claudia Mansell as senior research scientist.

Innate said that Perth's West Australian Neuroscience Institute and Melbourne's Nucleus Network at the Alfred Hospital had each dosed their first two patients, with several more patients due to begin treatment this month.

The company said that Brisbane's Wesley-St Andrew's Research Institute would be initiated on November 12, 2014 and start recruiting patients.

Innate said that Dr Mansell was appointed as senior research scientist to lead the analysis of trial subjects' blood samples and would develop tests that could be used to help monitor responses to treatment with MIS416.

Innate said that developing a test would be "a significant achievement" as there were no blood tests available to monitor the effects of disease or treatment in patients with secondary progressive multiple sclerosis.

The company said that Dr Mansell holds a Doctoria of Philosophy from the Düsseldorf, Germany-based Heinrich Heine Universität and the Harvard Medical School and was previously at the University of Auckland, New Zealand School of Biological Sciences.

Innate was up 2.5 cents or 14.7 percent to 19.5 cents.

AVITA MEDICAL

Avita says it has received \$1.4 million from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

The company said that the incentive payment was for the year to June 30, 2014.

Avita interim chief executive officer Tim Rooney said that the payment "provides an important additional resource to innovate new advancements and explore additional applications for our proprietary technology platform, Recell Spray-On Skin".

Avita was up 0.2 cents or two percent to 10 cents.

[BENITEC BIOPHARMA](#)

Benitec has told the ASX that it is not aware of any information it has not announced which, if known, could explain recent trading in its securities.

The ASX said the company's share price rose 29 cents or 40.3 percent from the close of 72 cents on Monday November 10, 2014 to an intraday high of \$1.01 at the time of writing today, Tuesday November 11, 2014 ... [and] noted an increase in the volume of trading".

Benitec closed at 61 cents on November 6 and by early afternoon today had peaked at \$1.065, a 45.5 cents or 74.6 percent increase.

Benitec closed up 12.5 cents or 17.4 percent at 84.5 cents with 2.15 million shares traded.

[ANTEO DIAGNOSTICS](#)

Anteo's annual general meeting passed all resolutions, with up to 9.04 percent opposition to the 10 percent placement facility and director options.

The strongest dissenting vote by percentage was the issue of options to director Richard Martin with 15,941,351 votes (16.2%) against and 82,007,782 votes (83.8%) in favor, with the issue of options to directors Mark Bouris, Sandra Andersen and Dr John Hurrell passed by a wider majority.

But the largest number of votes cast against a resolution was for the 10 percent placement facility, which was opposed by 20,758,167 votes (9.04%) with 208,745,197 votes (90.96%) in favor.

The company's most recent Appendix 3B prior to the meeting said that Anteo had 833,239,493 shares on issue meaning that the opposition to the placement facility amounted to 2.5 percent of the company's total shares on issue, not sufficient to requisition extraordinary general meetings.

Anteo was unchanged at 11.5 cents with 2.9 million shares traded.

[IMPEDIMED](#)

Impedimed has requested a trading halt pending the release of an announcement "in relation to a proposed capital raising".

Trading will resume on November 13, 2014 or on an earlier announcement.

Impedimed last traded at 69 cents.

[ALCHEMIA](#)

Alchemia says Thomas Liquard has resigned as chief executive officer with Dr Tracie Ramsdale appointed executive director "during this transition".

Alchemia said that former non-executive director Dr Ramsdale was a former chief executive officer of the company.

In October, Alchemia announced that the pivotal phase III trial of hyaluronic acid-irinotecan (HA-irinotecan) for metastatic colorectal cancer failed to meet its primary endpoint (BD: Oct 27, 2014).

Alchemia fell 0.4 cents or 4.3 percent to nine cents with 1.6 million shares traded.

ONCOSIL MEDICAL

Oncosil says that Daniel Kenny will replace Dr Neil Frazer as chief executive officer, effective from January 5, 2015.

Oncosil said that Dr Frazer would step down from his position on the company's board, effective from November 28, 2014 and told Biotech Daily would remain in a senior scientific and/or senior medical role.

The company said that Mr Kenny was an experienced biopharmaceutical professional, with almost 30 years' experience in the industry, including senior roles with Roche, Allergan and Baxter.

Oncosil said that Mr Kenny had more than 10 years experience in clinical research in ophthalmology and HIV/AIDS prior to joining the pharmaceutical industry.

The company said that Mr Kenny would be responsible for executing growth plans as it drove towards registration of its localized radiation treatment for pancreatic cancer.

Oncosil said that Mr Kenny was previously the France-based Abivax chief commercial officer and head of business development and prior to Abivax, Mr Kenny was Baxter Vaccines franchise and bioscience head.

The company said that Mr Kenny held a Bachelor of Science from the University of New South Wales.

Oncosil was up half a cent or 4.55 percent to 11.5 cents.