



Biotech Daily

Friday July 19, 2013

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH DOWN: VIRALYTICS UP 19%, BENITEC DOWN 7%**
- * **NSW \$10m FOR 5 MEDICAL DEVICE COMPANIES**
- * **ATP, IGNITION LABS: UK, GRIFFITH HACK, BA ON-BOARD**
- * **VIRALYTICS PHASE II INTERIM MELANOMA SAFETY EFFICACY**
- * **BLUECHIIP SIGNS MITEGEN FOR GLOBAL CRYOPIN TRACKING**
- * **ITC STOPS TAIWAN'S APEX, DRIVE IMPORTING RESMED COPIES**
- * **BENITEC 25-TO-1 CONSOLIDATION, ASX CODE CHANGE**
- * **PSIVIDA REQUESTS CAPITAL RAISING TRADING HALT**
- * **PHYLOGICA'S DR RICHARD HOPKINS, DR PAUL WATT SWAP JOBS**
- * **CATHERINE OFFICER REPLACES USCOM CO SEC SARAH PRINCE**

MARKET REPORT

The Australian stock market fell 0.43 percent on Friday July 19, 2013 with the S&P ASX 200 down 21.3 points to 4,972.1 points. Nine of the Biotech Daily Top 40 stocks were up, 15 fell, nine traded unchanged and seven were untraded. All three Big Caps were up.

Viralytics was the best, up 4.5 cents or 18.75 percent to 28.5 cents with 319,663 shares traded, followed by GI Dynamics up 11 cents or 17.2 percent to 75 cents with 1.2 million shares traded and Tissue Therapies up 12 percent to 14 cents with 133,537 shares traded.

Clinuvel climbed 4.1 percent; Living Cell and Patrys were up more than three percent; Circadian rose two percent; QRX was up one percent; with Cochlear, CSL, Mesoblast and Resmed up by less than one percent.

Benitec led the falls, down 2.5 cents or 6.7 percent to 35 cents (equivalent to 1.4 cents pre-consolidation) with 183,000 shares traded, followed by Pharmaxis down 5.9 percent to 16 cents with 1.8 million shares traded. Acrux, Avita and Universal Biosensors lost more than three percent; Cellmid, Nanosonics, Neuren and Prima shed more than two percent; Allied Health, Anteo, Ellex and Starpharma were down more than one percent; with Heartware and Sirtex down by less than one percent.

NEW SOUTH WALES GOVERNMENT

New South Wales' Minister for Health and Medical Research Jillian Skinner has awarded five grants worth more than \$10.3 million in the first round of the Medical Devices Fund. Ms Skinner said the grants would allow the five companies to bring innovative medical technologies to market, delivering hope for people with a range of medical ailments, from heart valve failure to chronic pain.

"The Medical Devices Fund was a key election commitment," Ms Skinner said.

A New South Wales Government media release said that an independent expert panel chaired by the State's chief scientist Prof Mary O'Kane chose the five recipients from a shortlist of 13, which was drawn from 147 applications.

The media release said that the five recipients would share grants totalling \$10,325,758 to be spent over two or three years.

The media release said that Saluda Medical would be awarded \$5 million to develop an implantable device supplying constant pain relief to people suffering chronic neuropathic pain; Endoluminal would receive \$2,448,883 to develop a breakthrough technology for the treatment of failing heart valves; Elastagen was awarded \$2 million for its development of elastatherapy, using the human protein elastin for skin repair, particularly severe burns; Hearworks would receive \$662,115 for its Hearlab fully-automated test for hearing; and Mobilife was awarded \$214,760 for its Mobidrip portable intravenous pump to allow patients to be treated at home.

Ms Skinner said that "the road from innovation to commercial reality is fraught with challenges, which is why I am delighted to present grants in excess of \$10.3 million today to five companies to help them take their ideas from the bench to the bedside".

Ms Skinner said the New South Wales Government's investment in health and medical research was more than \$200 million a year, with \$5 million to be invested annually in the Medical Devices Fund to help other innovators bring new technologies to market.

Details of the five recipients are at: www.health.nsw.gov.au/ohmr/mdf.

ATP INNOVATIONS

The Sydney based ATP Innovations 'seed accelerator' Ignition Labs has signed Griffith Hack, UK Trade & Investment and British Airways as sponsors.

Last month ATP said that Ignition would provide an initial \$25,000 to each of five health and medical technology startups and today extending the application closing date for its "highly competitive, intensive business development program to July 28 (BD: Jun 4, 2013).

ATP said at that time that it was looking for five health and medical technology startups "that will make a positive impact on personal health, social health and the delivery of modern healthcare ... [and was] the first health and medical technology focused accelerator to be launched in Australia".

Today ATP said that the Griffith Hack would supply intellectual property services to the awardees and British Airways would fly the qualifying applicants to London for the November 2013 Health 2.0 conference.

The commercial arm of the British Government, UK Trade and Investment said that through the partnership with ATP it would be able to provide practical help and expertise to medical technology companies in Australia.

ATP commercialization director and Ignition Labs co-founder Ben Wright told Biotech Daily that two winners of the New South Wales medical device grants Endoluminal and Elastagen (see above) were existing ATP Ignition portfolio companies.

For more information about the program go to: www.ignitionlabs.com.au.

VIRALYTICS

Viralytics says interim results from its phase II clinical trial of Cavatak for late stage melanoma show progress towards the primary endpoint and evidence of tolerability.

Viralytics said that the Salt Lake City, Utah-based Huntsman Cancer Institute lead study investigator Dr Robert Andtbacka presented safety and efficacy data from the first 35 patients at the World Congress of Melanoma in Hamburg, Germany.

The company said that the primary endpoint was immune-related progression-free survival at six months after the first dose of Cavatak, including complete tumor response, partial tumor response or stable disease.

Viralytics said that 23 patients had met the protocol criteria for assessment of the primary endpoint of at six months of which eight patients (35%) achieved the endpoint.

The company said the trial target would be achieved if 10 of 54 patients met the primary endpoint, 30 patients qualified for assessment of the primary endpoint at 12 weeks and 18 patients (60%) achieved the endpoint at 12 weeks, with seven of these patients currently between the 12 week and six months response monitoring points.

The company said that the trial was also assessing Cavatak activity for best overall tumor response in both injected and non-injected tumors and that of the 30 patients who had been in the study for at least 12 weeks, a best response of either a complete or partial tumor response was seen in two and six patients, respectively.

The company said that five patients had entered the extension study and received further doses of Cavatak and two patients had been in the study for a total of 12 months and had completed the extension study with both achieving a partial response.

Viralytics said that follow-up surgery to remove the residual injected tumor tissue resulted in a surgical complete response in both patients.

The company said that Cavatak had been well tolerated by patients with no reports of serious or grade 3 or 4 adverse events related to the Cavatak treatment.

Viralytics said that toxicity was a recognized shortcoming of traditional chemotherapy drugs and some new therapies in development for the treatment of melanoma.

The company said that the independent data monitoring committee had met to review data from the first 35 patients and reported that Cavatak had met the safety and tolerability criteria and the study was progressing to full enrolment.

Viralytics said that 38 patients were enrolled and at current recruitment rates it could be fully enrolled by the end of 2013.

Dr Andtbacka said the interim results were “encouraging and it is pleasing to see activity in both injected and metastatic tumors”.

“Oncolytic immunotherapy is a promising new class of investigational agents with potential future application either as a monotherapy, a pre-treatment prior to surgery or use in combination with other new frontline therapies,” Dr Andtbacka said.

Viralytics chief executive officer Dr Malcolm McColl said the company was “very pleased to present these encouraging interim results to oncologists from the global melanoma community”.

“The results to date are very promising both with regard to tolerability and our solid progress towards the primary endpoint,” Dr McColl said.

“These interim results have been achieved in advanced melanoma patients with 74 percent at stage IV disease and an average of 2.9 prior treatments before the first dose of Cavatak, reinforcing how difficult it is to successfully treat melanoma,” Dr McColl said.

Viralytics said Dr Andtbacka’s presentation was entitled ‘CALM study: A phase II study of intratumoral coxsackievirus A21 in patients with stage IIIC and stage IV malignant melanoma’ and was available on its website: <http://www.viralytics.com>.

Viralytics was up 4.5 cents or 18.75 percent to 28.5 cents with 319,663 shares traded.

BLUECHIIP

Bluechiip says that US manufacturer Mitegen will be the exclusive global distributor of its technology used for the tracking of cryopins used in crystallography.

Bluechiip said that crystallography was the science that examined the arrangement of atoms in solids and last year the two companies signed a joint development agreement to develop a tracking product for synchrotrons.

In December 2012 year, Bluechiip said Mitegen designed, manufactured and distributed products for crystallization, crystallography and x-ray diffraction and supplied crystallography goniometer bases, commonly referred to as cryopins, for crystal mounts used in synchrotrons (BD: Dec 4, 2012).

Today, the company said that its Bluechiip technology provided unambiguous identification and temperature tracking of samples during storage and use at synchrotrons, improving the efficiency and reliability for researchers.

Bluechiip said that a product prototype would be launched at the American Crystallographer Association meeting July 20 to 24, 2013 in Honolulu, Hawaii.

The company said that Mitegen was a major supplier of cryopins, offering a wider range of cryopin designs than any other manufacturer and was better able to meet the varying needs of customers.

Bluechiip commercial director Brett Roberts said there was "general industry consensus that cryo-sample tracking is critical and yet it is either not used or the current systems in place are not satisfactory".

"The Bluechiip product overcomes many problems consistent with current tracking methodologies and provides an alternative for researchers concerned about commonly occurring identity and chain-of-custody issues that surround their cryo-samples, in particular temperature tracking, readability, efficiency, accuracy and reducing the potential for loss," Mr Roberts said.

Mitegen chief executive officer Robert Newman said the Bluechiip technology "holds great promise as more and more beam lines are looking to increase throughput and need a sample tracking methodology that is unaffected by lighting, wear, frost or other issues that can effect traditional bar code readers".

Bluechiip was untraded at 17 cents.

RESMED

Resmed says that the International Trade Commission has determined that Taiwan's Apex Medical should be stopped from the importation and sale of infringing products.

Resmed said it initiated the US Government investigation and filed the action at the ITC in March 2013, asserting patent infringement by two Apex masks and two Apex flow generators.

The company said the ITC case against Apex also named Medical Depot Inc, doing business as Drive Medical Design and Manufacturing.

Resmed said that the same ITC previously determined that the ITC should enter a consent decree against Drive thereby ordering it to stop importation and sales of the Freedom 210 and Freedom 220 masks made by Apex.

Resmed general counsel and chief administrative officer David Pendarvis said that the company appreciated but was not surprised by the swift conclusion of the case against both Apex and Drive Medical Design.

"This result is a testament to the strength of Resmed's intellectual property," Mr Pendarvis said.

Resmed was up two cents or 0.4 percent to \$4.88 with 2.3 million shares traded.

[BENITEC BIOPHARMA](#)

Benitec's shares are trading under the code BLTDA as the company conducts the 25-to-one share consolidation approved at the annual general meeting (BD: Jul 17, 2013).

In the notes to the meeting the company said that the shares and options would be registered on a consolidated basis from July 26, with normal trade-plus-three-business-days beginning on August 2, 2013 under the ASX code of BLT.

Benitec fell 2.5 cents or 6.7 percent to 35 cents.

[PSIVIDA](#)

Psivida has requested a trading halt pending "an announcement to the market in relation to a proposed capital raising".

Trading will resume on July 23, 2013 or on an earlier announcement.

Psivida last traded at \$3.76.

[PHYLOGICA](#)

Phylogica says Dr Richard Hopkins will replace Dr Paul Watt as chief executive officer, effective immediately and chief finance officer Nick Woolf will leave the company.

Phylogica said Dr Hopkins had been with the company since 2006 and was most recently the chief scientific officer.

The company said that Dr Hopkins had worked with the phylomer platform for more than 12 years and was a founding shareholder.

Phylogica said that prior to that, he held senior research roles at the Telethon Institute for Child Health Research, Department of Medicine at the University of Western Australia and Murdoch University.

Phylogica said Dr Paul Watt would retire as a director and become the chief scientific officer.

The company said that Mr Woolf would retire as a director immediately and step-down as chief financial officer at the end of September and be replaced by company secretary Graeme Boden.

Phylogica chairman Dr Doug Wilson said the company management structure had been reorganised "to position it for the on-going contractual obligations and emerging strategic opportunities [and importantly, the changes will decrease the company's cost-base and make the company's aspirations more achievable".

Phylogica was untraded at 1.7 cents.

[USCOM](#)

Uscom says Catherine Officer has replaced Sarah Prince as company secretary, effective immediately.

Uscom said that both Ms Prince and Ms Officer worked as solicitors for Company Matters Pty Ltd and the change was a continuation of the existing engagement.

Viralytics made an identical announcement yesterday (BD: Jul 18, 2013).

Uscom was unchanged at 18 cents.