



Biotech Daily

Tuesday November 10, 2015

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH DOWN: ORTHOCELL UP 8%; OPTISCAN DOWN 10%**
- * **RESAPP 'ACCURATELY DIFFERENTIATES RESPIRATORY ILLNESSES'**
- * **ORTHOCELL FIRST CELGRO DENTAL SCAFFOLDS 'SAFE, EFFECTIVE'**
- * **DR ASSELIN-LABAT, DR GEBHARDT WIN \$2.45m VIERTEL PRIZES**
- * **INVION SHARE PLAN**
- * **ALCHEMIA AGM BACKS FONDAPARINUX SALE**
- * **ONCOSIL AGM TO INCREASE DIRECTOR FEE POOL 150% TO \$500k**
- * **GOLDMAN SACHS BELOW 5% OF NANOSONICS**

MARKET REPORT

The Australian stock market fell 0.4 percent on Tuesday November 10, 2015 with the ASX200 down 20.3 points to 5,099.2 points.

Eight of the Biotech Daily Top 40 stocks were up, 19 fell, 10 traded unchanged and three were untraded.

Orthocell was the best, up four cents or 7.55 percent to 57 cents with 112,149 shares traded.

Acrux climbed 3.9 percent; Bionomics, Pro Medicus, Psivida and Starpharma were up one percent or more; with Medical Developments and Sirtex up by less than one percent.

Optiscan led the falls, down 0.4 cents or 10.3 percent to 3.5 cents with 641,500 shares traded.

Genetic Technologies and Viralytics lost more than six percent; Living Cell fell 4.4 percent; Actinogen, Anteo, Benitec and Biotron were down more than three percent; Atcor, Impedimed, Oncosil, Pharmaxis and Universal Biosensors shed more than two percent; Circadian, Compumedics, IDT, Nanosonics and Osprey were down more than one percent; with Cochlear, CSL and Ellex down by less than one percent.

RESAPP HEALTH

Resapp says its device is able to differentiate particular respiratory diseases from other respiratory diseases with accuracy in the range of 87 percent to 99 percent.

Resapp said that its study at the Perth, Western Australia-based Joondalup Health Campus and Princess Margaret Hospital assessed an updated 338 subject dataset, including 51 subject defined as normal with no respiratory disease, 35 patients with viral pneumonia, 32 patients with bronchiolitis, 17 patients with croup and 20 patients with upper respiratory tract infections (URTI).

The company said that the Resapp algorithm device had 100 percent accuracy for distinguishing bronchiolitis from normal; 99 percent accuracy for distinguishing croup from normal; 96 percent accuracy, with the addition of existence of fever to the algorithm, for distinguishing patients with URTI from normal; and 97 percent accuracy for distinguishing patients with viral pneumonia from normal.

In tables at the end of the media release, Resapp said that in comparing viral pneumonia from URTI the device showed 86 percent sensitivity, 90 percent specificity and an overall 87 percent accuracy.

The company also compared the bronchiolitis group with the URTI group resulting in 100 percent sensitivity, 95 percent specificity and an overall 98 percent accuracy.

Resapp said that a comparison of the croup subset with the URTI group resulted in 94 percent sensitivity, 95 percent specificity and an overall 95 percent accuracy.

The company said that other differential diagnoses between respiratory diseases ranged in accuracy between 85 percent and 99 percent.

Resapp said that it was 99 percent accurate in differentiating between bronchiolitis and viral, pneumonia, and 98 percent accurate in diagnosing pneumonia from croup and bronchiolitis from croup.

Princess Margaret Hospital paediatric emergency physician and Resapp clinical adviser Dr Paul Porter said the results “demonstrate the potential to accurately differentially diagnose respiratory disease in children in a novel way with meaningful consequences for selecting the correct treatment option”.

“The results also point to the possibility to better define lower airway involvement in respiratory disease more accurately than current clinical practice,” Dr Porter said.

The company said that the respiratory diseases covered the majority of respiratory conditions that commonly occur in children.

Resapp said that bronchiolitis was the most common reason for admission to hospital in children under 12 months in developed countries and formed a large proportion of the workload to general practitioners and emergency departments during the winter months.

The company said that croup was a common condition that accounted for about 15 percent of clinic and emergency department visits for paediatric respiratory tract infections.

Resapp chief executive officer Dr Tony Keating said that the additional data was “another significant step forward in our development of a complete respiratory disease diagnostic tool that provides instant answers and seamlessly integrates into tele-health platforms”.

Resapp said that comparative diagnosis was based on the clinical presentations, auscultation, or listening to the internal sounds of the body with a stethoscope, findings and imaging as well as laboratory test results when clinically indicated for the diagnosis of a given respiratory illness.

The company said that as some of the respiratory illness groups did not have a gold standard diagnosis, overall clinical diagnosis was used as a reference standard of comparison.

Resapp was up 1.2 cents or 15.4 percent to nine cents with 72.5 million shares traded.

ORTHOCELL

Orthocell says the first two patients in a pilot study of its Celgro scaffold for use as dental implants shows “bony consolidation and incorporation ... without complication”.

Orthocell managing director Paul Anderson told Biotech Daily that the 30 patient pilot trial was examining the safety and efficacy of Celgro to facilitate the implantation of dental bone substitute grafts.

“The Celgro scaffold covers the bone graft acting as a barrier between the soft tissue and the bone,” Mr Anderson said.

Orthocell said that a post-operative review at 10 days and 20 days of the first two patients showed “no complications and demonstrated that the intra-oral incision was closed and mucosal tissue appeared to have healed well, that the soft tissues were pink and healthy and no membrane exposure reported”.

“Also noted was excellent bony consolidation and bony incorporation of the dental implants, without signs of complication,” Orthocell said.

The company said that the study was being performed in collaboration with the University of Western Australia, the Subiaco, Perth-based St John of God Hospital and maxillofacial surgeon Dr Brent Allan.

Mr Anderson said the initial assessment was “very positive for Celgro as we move to complete this clinical trial for dental applications”.

“This also represents an important step forward in the development of Celgro, which has a range of high value applications in surgery,” Mr Anderson said.

Orthocell said that guided bone regeneration was the main standard of care to support new bone formation at dental implant sites.

The company said that a barrier membrane was often placed over the bone defect to allow the ingrowth of bone without competition from gum tissue, but finding a cell-friendly and strong scaffold to resist soft tissue infiltration while promoting new bone formation was a challenge that had not been universally addressed adequately by other scaffolds.

Orthocell said that each year in the US there were more than three million dental implant procedures, that number was growing by 500,000 a year and many of the implant procedures required guided bone regeneration.

Orthocell said that while its use in dental implants was only one application for the Celgro scaffold, it was a significant market opportunity addressable in the near term.

The company said that Celgro was a biological scaffold which was pure and free from cells and reactive DNA and had been shown to improve tissue ingrowth and repair.

Orthocell was up four cents or 7.55 percent to 57 cents.

SYLVIA AND CHARLES VIERTTEL CHARITABLE FOUNDATION

The Sylvia and Charles Viertel Charitable Foundation says Dr Marie-Liesse Asselin-Labat and Dr Thomas Gebhardt have each won \$1,225,000 research grants.

The Foundation said that the Walter and Eliza Hall Institute’s Dr Asselin-Labat would use the \$245,000 a year for five years to further research in lung development and cancer.

WEHI said the funding would help develop better treatments for premature babies with under-developed lungs, as well as children and adults with lung disease, including cancer.

The Viertel Foundation said that the University of Melbourne Peter Doherty Institute for Infection and Immunity Dr Gebhardt was researching immune cells that guard barrier tissues such as skin and gut where they provide local protection from renewed infection.

The Foundation said it had established a gender equity approach to grants, with one male and one female researcher to be the recipient of the awards.

The Foundation said it had awarded 40 senior medical research fellowships in 20 years.

INVION

Invion says it is offering a share plan at a 10 percent discount to the 5-day volume-weighted average price to the allotment date of December 3, 2015.

Invion said that shareholders eligible at the record date of November 9, 2015 would be able to apply for parcels of shares from \$500 to 15,000.

The company published its letter to shareholders including the application form and said the offer would close on November 30, 2015.

Invion said that the funds would be used for general working capital and applied to costs associated with on-going data analysis from the completed phase II trial of INV102 (nadolol) in smoking cessation, preparation for an end of phase II meeting with the US Food and Drug Administration, on-going business development and partnering discussions for the company's three drug assets and maintenance of its intellectual property portfolio.

In September, Invion said it had raised \$1,001,000 in a placement at 1.4 cents a share to an unnamed US institutional investor (BD: Sep 1, 2015).

Invion fell 0.1 cents or 8.3 percent to 1.1 cents with 2.9 million shares traded.

ALCHEMIA

Alchemia says that all annual general meeting were passed overwhelmingly including the sale of its fondaparinux assets to Dr Reddy's for \$24 million (BD: Sep 25, 2015).

Alchemia said the strongest dissent was against the remunerations report which was passed with 84.6 million votes in favor and 2.0 million votes against.

Alchemia fell 0.1 cents or 1.1 percent to 8.7 cents.

ONCOSIL

Oncosil will vote to increase the directors remuneration 150 percent from \$200,000 to \$500,000.

Oncosil said that the \$200,000 remuneration level was set more than 10 years ago on April 14, 2005 and "as the company enters commercialization phase the board may be expanded to provide additional skills, as appropriate".

The company said that the meeting would also vote on the 10 percent placement capacity, the remuneration report and the re-election of chairman Dr Roger Aston.

The meeting will be held at the Four Seasons Hotel, 199 George Street, Sydney on November 26, 2015 at 1pm (AEDT).

Oncosil fell half a cent or 2.9 percent to 17 cents.

NANOSONICS

The Delaware-based Goldman Sachs Group says it has ceased its substantial shareholding in Nanosonics, yet again.

Goldman Sachs said that subsidiary Rothesay Life returned 748,264 shares "to the counterparty under a repurchase agreement" for no applicable consideration.

Nanosonics fell two cents or 1.3 percent to \$1.565.