# Biotech Daily

Wednesday October 6, 2010

*Daily news on ASX-listed biotechnology companies*

*** ASX, BIOTECH UP: BENITEC UP 24%; PHYLOGICA DOWN 8%**

*** US FDA APPROVES PHARMAXIS ARIDOL ASTHMA TEST**

*** VIRALYTICS RAISES DOSE 10-FOLD IN PHASE I CANCER TRIAL**

*** RESONANCE SIGNS 2-YEAR FERRISCAN AGREEMENT WITH NOVARTIS**

*** SIRTEX CLAIMS 16% SEPTEMBER QUARTER SALES RISE**

*** US GRANTS 3rd TISSUE THERAPIES' VITROGRO PATENT**

*** HELICON SHORTFALL RAISES $1.4m**

*** AGENIX 1-FOR-13.66 RIGHTS ISSUE, SHARE PLAN TO RAISE UP TO $2.4m**

*** TRANSOCEAN INCREASES BUT DILUTED TO 7% OF ANTEO**

*** FLUOROTECHNICS SELLS GEL CO FOR $US150,000**

*** NICHOLAS FALZON REPLACES ANDREW BURSILL AS CELLMID CO SEC**

## MARKET REPORT

The Australian stock market climbed 1.7 percent on Wednesday October 6, 2010 with the S&P ASX 200 up 79.9 points to 4686.8 points. Seventeen of the Biotech Daily Top 40 stocks were up, 12 fell, seven traded unchanged and four were untraded. All three Big Caps were up.

Benitec was best, up 0.8 cents or 23.5 percent to 4.2 cents with 1.8 million shares traded, followed by Tissue Therapies up 10.6 percent to 26 cents with 1.9 million shares traded.

Optiscan and Patrys climbed more than seven percent; Sirtex was up 6.25 percent; Mesoblast, Novogen and Prima were up more than four percent; Genetic Technologies and Viralytics were up more than three percent; Acrux, Biota and Nanosonics rose more than two percent; with CSL, Genera, Immuron, Pharmaxis and Universal Biosensors up more than one percent.

Phylogica led the falls, down 0.4 cents or eight percent to 4.6 cents with 480,000 shares traded, followed by Bionomics down 7.4 percent to 25 cents. Virax lost 6.7 percent; Chemgenex and Starpharma fell more than three percent; with Alchemia, Clinuvel, Phosphagenics and Psivida down more than two percent.

PHARMAXIS

Pharmaxis says the US Food and Drug Administration has approved the marketing of its Aridol bronchial challenge test kit for the diagnosis of asthma.

Pharmaxis acting chief executive officer Gary Phillips said the company was “extremely pleased with this achievement” for Aridol or mannitol inhalation powder.

“An FDA submission is a complex task requiring involvement from almost all divisions of the company and this positive outcome has shown Pharmaxis’ ability to successfully work with the FDA to achieve a positive outcome,” Mr Phillips said.

“Aridol offers a new type of test with improved levels of convenience and efficiency and we believe it will find an important place in the overall assessment of bronchial hyper-responsiveness when asthma is suspected,” Mr Phillips said.

“We are well prepared for a US launch of Aridol with a commercial team in place and pre-marketing activities underway with the respiratory community,” Mr Phillips said.

Mr Phillips said he expected US sales to begin by April 2011.

Pharmaxis said it had approval for Aridol in Australia as well as parts of Asia and Europe.

According to the company’s preliminary final report, Pharmaxis received $828,000 from sales of Aridol in those jurisdictions for the year to June 30, 2010, an increase of 39.2 percent on the previous year.

Mr Phillips told Biotech Daily that in previous years, the Aridol asthma test had been acquired primarily by respiratory laboratories but a growth area was with specialist allergists.

He said that allergists had not previously used challenge tests and in the US there were more than 3,000 doctors specializing in allergies.

Mr Phillips said 150,000 challenge tests for asthma were conducted each year in the US, but the existing test was “complex, expensive and requires specialized equipment”.

Mr Phillips said the Aridol test was a simple, hand-held inhaler used with a spirometer measuring the volume of forced expiratory air over one second.

He said Aridol induced hyper-responsiveness which was a hallmark of asthma.

Pharmaxis said the FDA approved Aridol for the assessment of bronchial hyper-responsiveness in patients six years of age or older who do not have clinically apparent asthma.

The company said Aridol should not be used as a stand-alone tool to assess asthma, but as part of a physician’s overall assessment of asthma.

Pharmaxis said asthma affected more than 23 million people in the US and caused more than 13 million visits to a physician each year with about half a million hospitalizations.

The company said Aridol was endorsed by international organizations and guidelines including the International Olympic Committee Medical Commission's Independent Panel, the US Asthma Management Guidelines and the Global Initiative for Asthma Report on Global Strategy for Asthma Management and Prevention.

Pharmaxis quoted a key opinion leader Colorado-based clinical allergist Dr Bill Storms saying that Aridol was “an important step in the advancement of bronchial challenge testing because it induces constriction through the release of endogenous inflammatory mediators”.

“We believe that indirect challenges such as Aridol, correlate better with airway inflammation, a hallmark of asthma,” Dr Storms said.

Pharmaxis said Aridol was manufactured at its FDA-approved facility in Sydney, which is capable of large scale production of the challenge test.

Pharmaxis closed up three cents or 1.3 percent to $2.35.

## VIRALTYICS

Viralytics says it is increasing the dose of its oncolytic virus Cavatak 10-fold, to the next dose level, in its phase I trial for melanoma breast and prostate cancer.

Viralytics executive chairman Bryan Dulhunty told Biotech Daily that the independent data safety monitoring committee had approved the increase for the dose escalation trial, being conducted at Brisbane's Redcliffe Hospital and Sydney's St George Hospital.

The company said the first patient of the next group was expected to be infused with Cavatak next week, leaving three patients to be recruited to complete the trial.

Viralytics said the completion of the trial and finalization of ongoing preclinical work, in combination with the US Food and Drug Administration review of the scientific, pre-clinical and manufacturing data for its planned phase II intra-tumoral melanoma trial would reduce the time required to lodge investigational new drug applications.

In a media release, Mr Dulhunty said that intravenous delivery of Cavatak, "opened up many new cancer indications" that could potentially be treated by the compound and international recognition of the potential of oncolytic viruses continued to grow.

Viralytics said that compared to available conventional treatments for cancer, numerous studies said that virotherapy was very well tolerated.

Early studies were reinforcing that oncolytic viruses could significantly reduce the size of tumors and in some cases, completely eradicate them, the company said.

Viralytics was up 0.1 cents or 3.2 percent to 3.2 cents with 5.2 million shares traded.

## RESONANCE HEALTH

Resonance says it has signed a two-year agreement with the Basael-based Novartis AG and the US-based Novartis Pharmaceutical Corp for Ferriscan services.

Resonance said the agreement expanded the strategic collaboration which began in 2004 as part of a clinical development program for their iron chelation product.

The company said Ferriscan was approved in more than 100 countries to measure transfusional iron overload.

Ferriscan is a non-invasive, magnetic resonance imaging-based technology that is indicated for the analysis of liver iron concentration in individuals with, or suspected of having, systemic iron overload, the company said.

Resonance said Ferriscan was used to provide a definitive diagnosis of iron overload and for monitoring liver iron burden as part of ongoing clinical management of patients with thalassaemia, sickle cell disease, myelodysplastic syndrome and hereditary haemochromatosis.

The company said Ferriscan received US Food and Drug Administration clearance in 2005 and has regulatory clearance in Australia, Europe, Canada and New Zealand.

Resonance managing director Liza Dunne said the agreement would be "extremely important for the overall management and monitoring of patients with transfusional iron overload disorders and expands our strategic alliance with Novartis".

"Using a non-invasive, validated tool to obtain an accurate assessment of iron levels in the management of these patient populations may help to reduce or eliminate more serious downstream iron-related health complications," Ms Dunne said. "This strategic alliance with Novartis will result in increased awareness of Ferriscan worldwide and will continue to demonstrate the commercial value of the test in key international markets."

The company said Ferriscan was listed in a growing number of clinical practice guidelines was available in more than 20 countries and was delivered as a fee for service through a central image analysis laboratory.

Resonance was up 0.1 cents or 6.7 percent to 1.6 cents.

## SIRTEX MEDICAL

Sirtex says sales of its SIR-Spheres targeted radioactive liver cancer treatment increased 16.4 percent for the three months to September 30, 2010.

A spokesman for Sirtex said dose sales had grown by an average of 26 percent a year for the past five years.

Sirtex said it was the only listed Australian biotechnology company with a cancer therapy sold in global markets, its SIR-Spheres microspheres were used to treat inoperable liver cancer and sales were “a key measure of performance”.

Sirtex said that dose sales in Europe were up 27.1 percent, sales in the US were up 13 percent and sales in the Asia-Pacific were up 6.9 percent for the September quarter.

Sirtex chief executive officer Gilman Wong said the company was encouraged by the strong first quarter result and that management in each regional market was focused on capitalizing on the growing demand for its liver cancer treatment.

“Our global program of technology innovation, new product development and clinical studies in collaboration with other global leaders in the fight to improve the way liver cancer is treated are all making very good progress,” Mr Wong said.

Sirtex said it had revenues of $64.3 million for the year to June 30, 2010 on sales to less than one percent of the addressable live cancer market.

Sirtex was up 30 cents or 6.25 percent to $5.10.

## TISSUE THERAPIES

Tissue Therapies says the US Patent and Trademark Office has granted the third core patent in the Vitrogro family and the deed of letters patent has been received.

Tissue therapies said three Vitrogro patents had been granted in the US and one or more had been granted in Japan, South Korea, India, South Africa, Australia and New Zealand.

Tissue Therapies chief executive officer Dr Steven Mercer said the patent grant was significant because it protected commercially important Vitrogro intellectual property.

Tissue Therapies was up 2.5 cents or 10.6 percent to 26 cents with 1.9 million shares traded.

## HELICON GROUP

Helicon says the 112,972,547 shortfall shares from its rights issue have been placed raising a further $1,412,157 taking the total raised to $1,868,933 (BD: Sep 2, 2010).

Helicon was up 0.1 cents or 7.1 percent to 1.5 cents.

## AGENIX

Agenix hopes to raise up to $1.2 million through a one-for-13.66 share rights issue at 2.5 cents a share, followed by a share purchase plan.

Agenix said the record date for the rights issue was October 14, 2010, the offer opens on October 20 and closes on November 19, 2010.

The company said one free option would come with every five new shares acquired.

Agenix said the funds would be used for ongoing general operating costs and for expenses associated with previously announced activities, including its hepatitis B therapy and the Thromboview diagnostic for deep vein thrombosis and pulmonary embolisms.

Agenix said the company would conduct a further share offer at the same price to raise up to a further $1.2 million, opening on November 19 and closing on February 18, 2011.

Agenix fell 0.2 cents or 6.25 percent to three cents with 2.2 million shares traded.

## ANTEO DIAGNOSTICS

Transocean Securities has increased its investment in Anteo from 37,742,227 shares (9.4%) to 41,060,444 shares but was diluted to 6.8 percent.

Transocean is a company associated with Anteo chairman James Henderson and director Laura Iacusso.

Transocean said it sold 22,000,000 shares for $979,372 or 4.45 cents a share and had exercised 24,318,275 options at 1.2 cent each, raising $303,819 for Anteo.

Separately, Anteo said in an Appendix 3B new issue announcement that 66,168,241 shares had been issued following the conversion of the same number of 1.2 cent options expiring on September 30, 2010, raising a total of $794,019.

Anteo was up 0.2 cents or 4.65 percent to 4.5 cents with 2.1 million shares traded.

## FLUOROTECHNICS

Yesterday, Fluorotechnics said it sold its US subsidiary the Gel Company as part of the scaling back of its operations and selling some or all of its assets.

Fluorotechnics did not disclose the value of the sale at that time, but today said it was sold for $US150,000 ($A154,430).

Fluorotechnics has been suspended from trading and last traded at 3.8 cents.

## CELLMID

Cellmid says Nicholas Falzon has replaced Andrew Bursill as company secretary and financial controller, effective immediately.

Cellmid said Mr Bursill was appointed in December 2008 and was" instrumental in achieving several key milestones … including the restructuring of a convertible note debt, which allowed the recapitalization of Cellmid in early 2009".

Cellmid said Mr Falzon was a director of accounting and consultancy firm Lawler Partners, where he was responsible for a client portfolio including listed and unlisted businesses and had been involved with the company since 2006 as accountant and tax consultant.

The company said Mr Falzon had been responsible for it research and development tax concession submissions, including applications for tax offset.

Cellmid was untraded at two cents.