



# Biotech Daily

Wednesday July 24, 2013

*Daily news on ASX-listed biotechnology companies*

- \* **ASX, BIOTECH UP: ANTISENSE UP 19%, VIRALYTICS DOWN 8%**
- \* **PHOSPHAGENICS: \$5.7m THEFT, DR ESRA OGRU DISMISSED, 5 OTHERS**
- \* **BRAIN DESCRIBES NEW US FDA 'DE NOVO' PATHWAY**
- \* **PATRYS TREATS 3<sup>rd</sup> PAT-SM6 MULTIPLE MYELOMA COHORT**
- \* **BENITEC COMPLETES \$7.9m PLACEMENT**
- \* **COURT REJECTS DISSIDENTS' BIONICHE EGM**
- \* **TWO AUSTRALIAN PATENTS FOR BPH, MOLECULAR DISCOVERY HLS5**
- \* **AUSBIOTECH MELBOURNE, BRISBANE OCTOBER BIO-FESTS**

## MARKET REPORT

The Australian stock market climbed 0.36 percent on Wednesday July 24, 2013 with the S&P ASX 200 up 18.0 points to 5,035.1 points.

Eighteen of the Biotech Daily Top 40 stocks were up, 13 fell, three traded unchanged and six were untraded.

Antisense was the best, up 0.3 cents or 18.75 percent to 1.9 cents with 16.7 million shares traded, followed by Cellmid up 17.2 percent to 3.4 cents with 2.0 million shares traded.

Phylogica climbed 11.1 percent; Patrys was up eight percent; Neuren and Prana were up more than seven percent; Phosphagenics rose 4.55 percent; Atcor, Genetic Technologies and Tissue Therapies were up more than three percent; Bionomics rose 2.8 percent; Acrux, Anteo, Heartware, Medical Developments, Prima and Starpharma were up one percent or more; with QRX up half of one percent.

Viralytics led the falls, down 2.5 cents or 8.2 percent to 28 cents with 65,277 shares traded.

Benitec lost 7.1 percent; Ellex, Impedimed and Reva fell more than six percent; GI Dynamics was down four percent; Clinuvel, Mesoblast, Nanosonics, Pharmaxis and Universal Biosensors shed more than two percent; Alchemia, CSL and Resmed were down more than one percent; with Cochlear and Sirtex down by less than one percent.

## PHOSPHAGENICS

Phosphagenics says about \$5.7 million has been misappropriated with chief executive officer Dr Esra Ogru implicated and dismissed as an employee.

Phosphagenics said that five others, including one recently dismissed employee, were alleged to be involved over eight years through the issue of false invoices.

The company alleged that Dr Ogru had benefited from the misappropriated funds.

Phosphagenics said it had "taken steps to preserve and take security over the assets of the persons involved in, and who benefited from the misappropriations".

Phosphagenics executive director Harry Rosen told Biotech Daily that the company had not contacted police over the matter.

"Our main concern is to get shareholders funds back," Mr Rosen said.

Mr Rosen said he could not confirm a report in Melbourne's The Age that caveats had been placed on several properties owned by Dr Ogru with a collective value of about \$2.3 million, but said that people were free to undertake title searches.

Mr Rosen said there was no specific form of invoicing used to misappropriate the funds. In a media release, Phosphagenics said it expected to recover "a substantial part of the misappropriated funds".

The company said that the timing for the recovery of the funds was unknown, but it would "pursue all available claims against the persons responsible for the misappropriations as expeditiously as possible, including claims for restitution, the cost of the investigation, [by Deloitte Forensic] interest and any other losses resulting from the misappropriations".

Phosphagenics said that Mr Rosen would remain in Melbourne until measures were in place to recover the funds and a new chief executive officer had been appointed.

The company said that clinical programs, product development and marketing activities continued uninterrupted.

Phosphagenics said a review of all systems and authorizations had been commissioned and interim measures implemented to ensure this type of event did not reoccur.

"The company is confident that it will receive substantial restitution and compensation from the various parties responsible for the misappropriations," said Mr Rosen.

"We ... believe we have the appropriate structures and personnel in place to continue the development of our unique platform technology," Mr Rosen said.

"Morale is excellent," Mr Rosen said.

"Further, when restitution is made, our cash resources should increase significantly from the \$14.1 million cash holdings recently announced," Mr Rosen said.

"Despite this, I and my fellow directors cannot aptly describe our profound disappointment in what has occurred," Mr Rosen said

The Sydney-based Allan Gray (Orbis Global) is the company's largest shareholder with 133,609,911 shares or 13.13 percent in March 2012, having reduced its exposure from a high of 178,351,933 shares or 18.85 percent in 2011 (BD: Oct 25, 2011; Mar 22, 2012).

According to ASX data, Mr Rosen owns 64,226,436 shares (6.3%) and Dr Ogru was last recorded holding 5,711,610 direct shares and 215,000 indirect shares.

At today's closing price of 11.5 cents a share Dr Ogru's holding was worth \$681,560.

Phosphagenics website said the board was chaired by independent director Jonathan Addison a former Pricewaterhousecoopers corporate finance director, with Minter Ellison partner Don Clarke, former Colonial State Bank managing-director Stuart James and former Quintiles managing-director Dr Sandra Webb as independent directors.

Dr Ogru has not returned calls from Biotech Daily. Biotech Daily has received numerous emails and phone calls from the industry expressing shock, sadness and disappointment.

Phosphagenics was up 0.5 cents or 4.55 percent to 11.5 cents with 1.2 million shares traded.

## BRAIN RESOURCE

Brain Resource says its approval application for its Depression Treatment Test to the US Food and Drug Administration is under a new approval pathway.

Yesterday, Biotech Daily reported that Brain's test was an automated battery of on-line tasks that measured memory, attention and the accuracy of identifying face emotions.

Today, Brain chief operating officer Dan Segal, told Biotech Daily that the FDA had created the 'De Novo pathway' which was "essentially a new category that sits between a 510k and a pre-market approval".

Mr Segal said that companies did not apply for the pathway "but one which the FDA grants where they think appropriate, [for example] where test is low risk and servicing a major need".

"The new model the FDA is working under is to provide ongoing interactive feedback to companies [so you] no longer just submit one final submission and then spend ages trying to respond to queries under a formal process," Mr Segal said.

"We have been having numerous interactions culminating in what we filed this week, termed 'a pre-sub' under the new FDA model," Mr Segal said.

"This has the core analysis supporting our test and also incorporating all our responses to queries raised by the FDA to date," Mr Segal said.

Yesterday, Brain said it expected feedback from the FDA within three months.

Brain was up two cents or 6.7 percent to 32 cents.

## PATRY'S

Patrys says it has completed initial treatment of the third group of three patients in its phase I/IIa trial of PAT-SM6 for multiple myeloma at the University Hospital of Würzburg. Patrys said that each patient in the group received four doses of PAT-SM6 at a dose level of 3.0mg/kg and to date, no significant safety issues had been observed or reported for any of the three patients treated.

Last December, the first cohort began treatment on 0.3mg/kg and the second cohort completed treatment on 1.0mg/kg in April (BD: Dec 10, 2012; Apr 10, 2013)

Today, Patrys said that one of the treated patients showed laboratory evidence of stable disease at 35 days post-treatment, with a significant reduction in protein M levels in the peripheral blood.

Patrys said that this patient was the second patient to show evidence of stable disease, of eight patients analyzed at 35 days post-treatment, with the ninth patient being analyzed.

Patrys chief executive officer Dr Marie Roskrow said that it was encouraging to see another patient with advanced disease, show stabilization after four doses of PAT-SM6.

"Such patients are resistant to all currently marketed drugs and have a large disease burden, [so] stabilization of their disease is a very clear sign that PAT-SM6 is working," Dr Roskrow said. "This provides great encouragement and once we have received approval we will move forward into cohort 4," Dr Roskrow said.

Patrys said the fourth cohort would receive 6.0mg/kg

Patrys said that the trial had enrolled 12 patients in four dosing groups to receive a minimum of two cycles or four doses of treatment.

The company said that if a patient showed a partial response to treatment an additional cycle of two doses of treatment would be offered.

Patrys said the primary objective was to evaluate the safety and tolerability of escalating doses of PAT-SM6 and the secondary objective was to measure efficacy as determined by a series of well-established laboratory assays.

Patrys was up 0.2 cents or eight percent to 2.7 cents with 32. million shares traded.

### BENITEC BIOPHARMA

Benitec says it has completed its 1.1 cents a share placement raising \$7,900,000 with oversubscriptions of \$900,000 (BD: Jun 6, 2013).

Benitec said that it was in the process of completing a 25-to-one consolidation and 28,727,273 post-consolidation shares were issued through the placement, approved by shareholders earlier this month (BD: Jul 17, 2013).

The pre-consolidation 1.1 cents equates to 27.5 cents post consolidation.

Benitec said it would raise up to an additional \$3,000,000 through a share purchase plan to existing shareholders on the same terms as the placement, with the closing date of July 29, 2013.

The company said that proceeds from the placement and share plan, together with existing cash, would be used to complete its US phase I/IIa hepatitis C trial, planned to begin by the end of 2013, as well as completing preclinical toxicology, bio-distribution and dose-finding studies for Tribetarna for its drug-resistant, non-small cell lung cancer program, and conduct a European-based phase I/IIa clinical trial to begin by the end of 2014.

Benitec fell 2.5 cents or 7.14 percent to 32.5 cents.

### BIONICHE LIFE SCIENCES

Bioniche says that a dissident shareholder group has failed in a court bid to force an extraordinary general meeting to spill the board (BD: Apr 24, Jul 23, 2013).

Bioniche said that the Ontario Superior Court declined the dissident group application to compel a shareholder meeting and granted a declaration that the dissidents were not entitled to proceed with the meeting they called for August 27, 2013.

The company said that as a result it would proceed with its scheduled shareholder meeting on November 5, 2013 and said the judgment allowed the meeting "to proceed in accordance with the normal cycle ... [allowing] shareholders time to consider the issues associated with a contested board election and a proposed sale of the animal health business" and it would provide details about its plans, including director candidates and details of the offer for the animal health business prior to the November meeting.

Bioniche was up two cents or 6.7 percent to 32 cents.

### BPH ENERGY, MOLECULAR DISCOVERY SYSTEMS

BPH Energy says that 20 percent subsidiary Molecular Discovery Systems has been granted two Australian patents relating to the tumor suppressor gene HLS5.

BPH said that the issued patents were entitled 'Agent for the treatment of hormone-dependent disorders and uses thereof' and 'Transcription Factor modulator' and were valid to March 2027 and April 2027, respectively.

The company said that the two patents complimented the patents 'Tumour suppressor factor', which had been granted in the United States and Australia, and the Australian patent entitled 'Sumoylation control agent and uses thereof'.

BPH said that Molecular Discovery Systems had an extensive patent portfolio for HLS5 which encapsulated the gene both as a potential cancer therapeutic target and also underpinning its involvement in a variety of other diseases.

BPH said that patent applications relating to the HLS5 gene were progressing in Australia, Europe and the US.

BPH was untraded at 1.5 cents.

## AUSBIOTECH

Ausbiotech will host a two-day investment conference in Melbourne, ahead of its major conference to be held in Brisbane from October 30 to November 1, 2013.

Ausbiotech chief operating officer Glenn Cross said that with Beacon Events, the industry organization would host a biotechnology investment and capital raising entitled 'Australia Biotech Invest' at the Melbourne Convention Centre on October 28 and 29, 2013 to bring biotechnology innovators together with Australia's investment community "to discover and fund the future of biotech".

Mr Cross said that the industry could suggest topics, case studies or speakers as well as provide "views on the challenges and opportunities in the biotechnology investment space in Australia and Asia" by emailing them to Hayley Laing at: [hlaing@ausbiotech.org](mailto:hlaing@ausbiotech.org).

For more information go to: [www.ausbiotechinvest.com](http://www.ausbiotechinvest.com).

Ausbiotech said that the main conference would follow the Melbourne investment meeting and be held at the Brisbane Convention and Exhibition Centre from October 30 to November 1, 2013.

Ausbiotech said that its conference attracted more than 1,200 delegates from across the world every year and was "a stellar opportunity to mix among the brains trust of the biotechnology innovation sector, build contacts and share challenging and informative ideas".

The industry organization said that this year's theme, 'Bio-economy in transition', was an opportunity to explore the transformation of the Australian industry "as it evolves and adapts to current global forces".

Ausbiotech said that the term bio-economy was coined more than 15 years ago to describe the emerging economic activity derived from biotechnologies and was at the heart of promoting progress in this sector.

Ausbiotech said that companies and individuals working within the biotechnology and innovation sector were connected by a single common goal to improve and extend human life, an admirable and intriguing mission and the conference "hones in on the many ways that sector leaders are bridging the way between ideas and commercial success, and the hurdles they face along the way".

Topics to be discussed at the conference include: changing international laws and regulations on a global scale, including patent law; the influence of social and digital media in developing biotechnology; the global economic landscape; techniques to successfully source capital and fund good ideas; and government policy that supports the development of the bio-economy.

Ausbiotech said that the program was available at: <http://ausbiotechnc.org/program>.

The industry organization said that the conference included the Business Matching Program, where delegates could request and accept meetings with other delegates and the event would encompass the one-day Agriculture and Food Biotechnology Symposium, on November 1, 2013.

To register go to: <http://ausbiotechnc.org/registration>.