



# Biotech Daily

Friday May 29, 2009

*Daily news on ASX-listed biotechnology companies*

- \* **ASX UP, BIOTECH DOWN: LIVING CELL UP 17%, PRANA DOWN 8%**
- \* **BIOGUIDE BRIEF: DIA-B, PALLANE MERGE INTO '\$100m VIRAL TEST CO'**
- \* **BIONOMICS' PHASE I BNC105 TRIAL 'SHOWS SAFETY, SOME EFFICACY'**
- \* **US PAYS CSL \$230m TO SUPPLY NOVEL H1N1 FLU VACCINE**
- \* **AUSTRALIA UPS BIOTA RELENZA STOCKPILE BY 1.6m COURSES**
- \* **VENTRACOR ASSETS TO BE SOLD**
- \* **AVEXA RAISES FURTHER \$1m FROM US INVESTOR**
- \* **EASTLAND PLACEMENT RAISES \$585k**
- \* **IMMURON CUTS US COSTS: DR ZEIL ROSENBERG, DR OREN FUERST GO**
- \* **CEPHALON HAS 75% OF ARANA**
- \* **MYER FAMILY TAKES 19% OF COGSTATE**

## MARKET REPORT

The Australian stock market climbed 1.66 percent on Friday May 29, 2009 with the S&P ASX 200 up 62.4 points to 3,818.1 points.

Twelve of the Biotech Daily Top 40 stocks were up, 14 fell, eight traded unchanged and six were untraded. All three Big Caps were up.

Living Cell was best, up three cents or 16.7 percent to 21 cents with 110,000 shares traded, followed by Cytopia up 13.25 percent to 9.4 cents.

Impedimed climbed 5.3 percent; Starpharma was up 4.7 percent to 33.5 cents; Acrux, Arana, Biota, Peplin, Pharmaxis and Viralytics rose more than two percent; Cochlear was up 1.62 percent; Cellestis, CSL, Resmed and Sirtex up less than one percent.

Prana led the falls, down 1.5 cents or 7.9 percent to 17.5 cents with 10,000 shares traded.

Benitec, Genera and Optiscan lost six percent or more; Labtech was down 3.85 percent; Antisense and Tissue Therapies shed more than two percent; with Chemgenex, Clinuvel, Heartware and Novogen were down more than one percent.

## [MARC SINATRA'S BIOGUIDE BRIEF: DIA-B TECH, PALLANE MEDICAL](#)

Pallane Medical is an unlisted company focused on the development of its Rapid Enhanced Tissue Culture Immunofluorescence (Reticif) test for diagnosing active viral infections. Dia-B Tech intends to acquire Pallane Medical and is raising funds to solidify the acquisition and provide working capital for the entity.

### **Offer Details**

Price: 25 cents; Funds sought: \$12.5 million; Market cap at offer price: \$100 million.

### **Directors (Post Capital Raising)**

Executive chairman and CEO, Peter King; non-executive directors: Dr Michael Wooldridge, Santino Di-Giacomo and Dr Jaydeep Biswas.

The prospective board has strong sales experience and knowledge of the listed life science sector, but lacks expertise in diagnostics and, in particular, the American diagnostic virology industry.

### **Business Segments**

Reticif: This technology is a reconfiguration of existing virology methods, where the major differences are that the cell layers are grown in microtitre plate wells, rather than in tubes or on cover slips and a specialized medium is used. The medium is patent protected. Reticif can be marketed in the US on the basis that it is a cell culture method and, as such, is exempt from FDA review.

Existing Dia-B Tech Projects: ISF-402 is a putative insulin sensitizer for type 2 diabetes. It has completed a phase Ia/Ib study; CDA1 is a protein thought to be important in diabetic nephropathy and atherosclerosis.

The combination of Reticif with the diabetes projects doesn't make much sense, but the future of the diabetes projects is uncertain, making this is largely irrelevant.

### **Competitive Environment**

Other more rapid tests for the identification of certain viral infections do exist, but Reticif is aimed at improving, consolidating and standardizing the more time consuming, higher precision and broader testing that is done, often in conjunction with the rapid testing. Reticif's target area has been somewhat of a backwater for product commercialization.

### **Comment**

The RETCIF concept seems like a good idea and is supported by scientific literature.

Whether the technology is suitable as a commercial venture is the more pertinent question, given the less than ideal nature of the intellectual property protection, the difficulties involved in introducing transformational technologies and the staff and cash the company will need to do these tasks.

For the investors taking part in the \$12.5 million capital raising - as part of the total \$100 million market cap of the proposed entity – it seems there is too little upside to balance against these risks.

Dia-B was up 0.3 cents or 21.43 percent to 1.7 cents.

**Marc Sinatra**

## BIONOMICS

Bionomics says its phase I dose escalation trial of vascular disrupting agent and cancer cell proliferation inhibitor BNC105 has shown safety, tolerability and some efficacy.

Bionomics said the data on BNC105 was presented to the American Society of Clinical Oncology Conference in Orlando, Florida.

Bionomics chief executive officer Dr Deborah Rathjen told Biotech Daily that the clinical trial showed safety, general tolerability and some efficacy in the small number of patients in the trial.

Dr Rathjen said BNC105 was shown to reduce the blood flow in tumors and in some patients "halted tumor growth".

In a media release to the ASX the company said the BNC105 trial was being conducted on patients with advanced cancers in Melbourne at the Peter MacCallum Cancer Centre, the Western Hospital, Austin Health and the Royal Melbourne Hospital under an investigational new drug application approved by the US Food and Drug Administration. Bionomics said seven male and two female patients with a median age of 60 years with advanced solid tumors have been enrolled in the trial.

The objectives of the trial were to determine safety, tolerability, maximum tolerated dose and pharmacokinetics of the drug given intravenously over 10 minutes on day one and day eight every 21 days.

Lead author and principal investigator for the Royal Melbourne Hospital site Dr Jayesh Desai said the trial design was "very efficient allowing us to achieve our objectives quickly using minimal patient numbers".

"The drug appears to be well tolerated by patients and can be administered rapidly compared with other chemotherapies, minimizing patient discomfort," Dr Desai said.

Bionomics said the dose escalations in the trial increased from 2.1 mg/m<sup>2</sup> to 18.9 mg/m<sup>2</sup>. The company said one patient was treated at each of the dose levels 2.1 mg/m<sup>2</sup> and 4.2 mg/m<sup>2</sup>.

At 8.4 mg/m<sup>2</sup>, one patient experienced grade two mucositis.

Bionomics said that observation led to a design switch where three patients were enrolled at each subsequent dose escalation to check for adverse side effects.

No dose limiting toxicities were observed at 12.6 mg/m<sup>2</sup> or 18.9 mg/m<sup>2</sup>.

At doses of 8.4 mg/m<sup>2</sup> and above, direct contrast enhancement magnetic resonance imaging showed reductions in tumor blood flow within three to six hours and 24 hours following BNC105 treatment.

Drug levels achieved in patients to date, correlate with drug exposure required for activity in preclinical experiments.

Two out of nine treated patients had stable disease and received additional cycles of treatment.

One patient with mesothelioma treated with 8.4 mg/m<sup>2</sup> had stable disease up to week 22 of treatment.

A second patient suffering from renal cell cancer, treated at the 12.6 mg/m<sup>2</sup> dose level, had stable disease for nine weeks.

Bionomics' vice-president of discovery research Dr Gabriel Kremmidiotis said the company was "delighted with the progress of the trial".

"The early indications of drug activity, albeit in very small patient numbers, are very encouraging," Dr Kremmidiotis said.

"We anticipate establishing a recommended dose for future studies and are well down the track in designing our phase II trial, scheduled to commence later this year," Dr Kremmidiotis said.

Bionomics was unchanged at 25.5 cents.

## CSL

CSL says US subsidiary CSL Biotherapies Inc has a contract with the US Department of Health and Human Services to provide bulk vaccine antigen for A (H1N1) influenza. CSL said the vaccine would be manufactured at the Parkville Victoria facility and will support the Department of Health and Human Services pre-pandemic influenza preparation efforts.

The company said the new vaccine would be tested in clinical trials funded by the Department of Health and Human Services.

The initial order under the contract will be for an amount of \$US180 million (\$A230 million).

The contract also provides the Department of Health and Human Services with the opportunity to use CSL's antigen filling and finishing capability at the company's manufacturing plants in Kankakee, Illinois and in Marburg, Germany.

CSL said it would maintain its commitment to supply seasonal influenza vaccines to Australia, the US and other markets.

Consistent with the media release issued by the Australian Minister for Health and Ageing on May 28, 2009, CSL said it would also supply its Novel A (H1N1) vaccine to Australia.

CSL chief executive officer Dr Brian McNamee said his company's partnership with the Department of Health and Human Services "to address the serious threat to public health that the A (H1N1) virus represents, is confirmation that we are a leader in the global influenza vaccines market".

"In doing so, CSL will be applying more than 40 years of experience in developing and manufacturing influenza vaccines," Dr McNamee said.

CSL was up 17 cents or 0.59 percent to \$29.20 with 13.4 million shares traded.

## BIOTA

Biota says the Federal Government has purchased an additional 1.6 million courses of Relenza for the National Medical Stockpile to bolster supplies for pandemic influenza. Biota said the purchase cost was \$43 million and the company would earn a 10 percent royalty on all Australian sales of Relenza.

The company said Glaxosmithkline Australia had confirmed that the purchase reflects a supply contract recently signed with the Federal Government.

Biota said that on completion of the supply contract, the Australian National Medical Stockpile would include 3.4 million courses of Relenza, comprising 33 percent of the total stockpile of influenza antivirals.

Biota climbed 3.5 cents or 2.55 percent to \$1.41 with 2.6 million shares traded.

## VENTRACOR

Ventracor creditors have voted "by a clear majority" to adopt a general deed of company arrangement and sell the company's left ventricular assist device and related assets.

Ferrier Hodgson administrators' director of corporate communications Michael Cave told Biotech Daily that the votes at the meeting were not unanimous and said he was unable to produce a list of resolutions.

Mr Cave said a resolution for a shareholder deed of company arrangement was withdrawn following the failure to find a cornerstone investor.

Mr Cave said that after payment of the administrators' fees, the funds would be paid to creditors and if there were any funds remaining they would be dispersed to shareholders.

## AVEXA

Avexa says it has raised a further \$1 million through a placement to an unnamed US institutional investor of 15,000,000 shares at seven cents a share.

Avexa said the placement completed its "current capital raising activities" which raised a total of \$18 million from the 2009 rights issue and subsequent placements (BD: Apr 30, 2009).

The company said Blueprint Life Science Group was the corporate advisor for the placement to the US investor.

Avexa chief executive officer Dr Julian Chick said the addition of the US institutional life science investor to the company's registry, along with the support from existing shareholders, "speaks to the potential of Avexa's programs and, in particular, the near-term apricitabine, or ATC opportunity".

"In June, we expect to announce the result of the [data safety monitoring board] analysis of the 16-week phase III data and with our improved balance sheet we can maintain the development timelines for the company's programs while continuing to explore the best options for ATC's path to commercialization," Dr Chick said.

Avexa was unchanged at 13 cents.

## EASTLAND MEDICAL SYSTEMS

Eastland Medical has raised \$585,000 through the placement of 19,500,000 shares at three cents a share to clients of Patersons Securities.

The funds raised will be used for ongoing working capital requirements.

Eastland was up 0.3 cents or 7.14 percent to 4.5 cents.

## IMMURON

As cost-saving measures Immuron has not renewed the contracts of chief executive officer Dr Zeil Rosenberg and business development vice-president Dr Oren Fuerst. Immuron said the contracts would expire at the end of May 2009 and as cost saving measures the company was reducing the size of its US operation.

The company said Prof Colin Chapman will be the executive chairman until a replacement chief executive officer is appointed

Director Arie Nudel has been reappointed manager of investor relations and Dr Grant Rawlin continues as general manager and head of research and development.

Immuron said it would undertake an executive search for a new chief executive officer and there were "no changes planned to the company's present business program".

A review of the program and strategies would be one of the first functions undertaken by the new chief executive officer.

Immuron said its agreement to acquire the rights to patent technology from Hadasit Medical Research Services & Development to develop novel methods in the treatment of certain chronic diseases required shareholder approval for the issue of shares to Hadasit. Post issue Hadasit would hold 19.99 percent of Immuron's shares (BD: Apr 20, 2009).

The meeting will be held on July 9, 2009 and the notice of meeting and explanatory statement will be forwarded to shareholders within the next two weeks.

The company said the management changes would have "no impact on the proposed research to be conducted in Australia and Israel".

Immuron was untraded at 3.6 cents.

### ARANA

With one trading day until the close of the takeover offer, Cephalon has acquired more than 75 percent of Arana investor

The number of acceptances for the Cephalon offer increased from 158,973,750 shares (69.73%) to 171,106,871 (75.05%) at the close of business on May 28, 2009.

Today's acceptances are not included in this figure.

Cephalon said it would pay \$1.40 a share with more than 50.1 percent of acceptances by the close of business on June 1, 2009 or \$1.45 if it reached the compulsory acquisition target of 90 percent of acceptance.

Arana climbed 3.5 cents or 2.57 percent to \$1.395 with 1.6 million shares traded.

### COGSTATE

Myer Family Office and associates have increased their substantial shareholding in Cogstate from 10,485,192 shares (15.97%) to 12,500,000 shares (19.04%).

The substantial shareholder notice was filed in the name of Martyn Myer citing the Myer & Myer ATF Whereabouts Superannuation Fund, MF Custodians for The Myer Family Office for Mpyer Investments and the MK Myer Family Settlement.

Cogstate was up half a cent or 2.13 percent to 24 cents.