



Biotech Daily

Friday September 18, 2009

Daily news on ASX-listed biotechnology companies

- * **ASX DOWN, BIOTECH UP: PSIVIDA UP 18%; GENETIC TECHNO DOWN 14%**
- * **LATE NEWS: TGA APPROVES CSL H1N1 INFLUENZA VACCINE**
- * **PHARMAXIS 2nd PHASE III CYSTIC FIBROSIS TRIAL 'FULLY RECRUITED'**
- * **BIOPHARMICA TAKES THE MINING OPTION**
- * **CORRECTION: ACUVAX PLACEMENT RAISES \$488k**
- * **FEDERAL GOVERNMENT CALL FOR R&D TAX CREDIT CONSULTATIONS**
- * **DR TERRY CUTLER APPOINTED CSIRO DEPUTY CHAIR**
- * **BIO-MELBOURNE: RESEARCH INSTITUTION MERGERS AND RESULTS**
- * **UNITED BIOSOURCE CEASES SUBSTANTIAL IN COGSTATE**
- * **STARPHARMA RELEASES 7.2m ESCROW SHARES**

MARKET REPORT

The Australian stock market fell 0.46 percent on Friday September 18, 2009 with the S&P ASX 200 down 21.7 points to 4693.2 points. Twenty of the Biotech Daily Top 40 stocks were up, seven fell, nine traded unchanged and four were untraded. All three Big Caps were down.

Psivida was best, up 85 cents or 17.9 percent to \$5.60 with 16,664 shares traded, followed by Living Cell up 12.2 percent 23 cents.

Phosphagenics climbed 9.1 percent to 12 cents with 1.6 million shares traded; Antisense was up 8.7 percent; Nanosonics was up 7.7 percent; Biota and Prana climbed five percent or more; Novogen, Phylogica and Tyrian were up more than four percent; Clinuvel, Cytopia, Labtech, Mesoblast and Sirtex were up more than three percent; Genera and Pharmaxis rose more than two percent; with Circadian up 1.35 percent.

Genetic Technologies led the falls, down 0.8 cents or 13.8 percent to five cents with 220,500 shares traded.

Cathrx and Progen lost more than three percent; Tissue Therapies shed 2.4 percent; with Acrux, Chemgenex, Cochlear, CSL, Resmed and Universal Biosensors down by more than one percent.

CSL

CSL says the Australian Therapeutic Goods Administration has approved its H1N1 Influenza vaccine (BD: Sep 17, 2009).

PHARMAXIS

Pharmaxis says its second pivotal phase III clinical trial of Bronchitol for cystic fibrosis has passed its recruitment target of 300 subjects.

The company said efficacy data from the trial was expected by July 2010.

Pharmaxis said it was the second of two cystic fibrosis trials, required by the US Food and Drug Administration, before a marketing application could be submitted in the US.

Pharmaxis said that when completed, more than 600 cystic fibrosis patients would be recruited into the two Bronchitol phase III clinical trials.

The company said the double-blind, placebo-controlled, randomized study was comparing 400mg of Bronchitol twice a day to placebo at 58 sites in seven countries.

The trial includes a 26-week efficacy and safety component, with an optional 26 week open-label Bronchitol safety extension.

Pharmaxis chief executive officer Dr Alan Robertson said the recruitment had gone well and the compliance rate was good.

"My expectation is that this trial and the one that has gone before will show that Bronchitol has the opportunity to fundamentally impact the way people with cystic fibrosis manage the disease," Dr Robertson said.

The company said the primary efficacy end-point was change in lung function from baseline as determined by forced expiratory volume in one second, over 26 weeks.

The company said that about two thirds of the subjects in the study were being treated with recombinant human deoxyribonuclease (rhDNase or Pulmozyme)

Pharmaxis said the trial was being conducted under the FDA's special protocol assessment scheme, with FDA orphan drug designation and fast track status.

More than 75,000 people in the major pharmaceutical markets are affected by cystic fibrosis and no products have been approved to improve lung hydration.

Pharmaxis said it would file a marketing application with the European Medicines Agency by the end of 2009 based on the first pivotal trial reported in May (BD: May 4, 2009).

Pharmaxis was up seven cents or 2.94 percent to \$2.45.

BIOPHARMICA

Biopharmica says it has signed an options agreement for between 9.7 percent and 19.4 percent of Advent Energy at 50 cents a share (BD: Sep 11, 2009).

The company said the option was subject to shareholder approval at the annual general meeting expected to be held on November 12, 2009.

Biopharmica fell one cent or 6.25 percent to 15 cents.

ACUVAX

Last night's edition said Acuvax hoped to raise \$488,000 through the placement of 24,400,000 shares to sophisticated investors at two cents a share.

In fact the placement was completed, raising the \$488,000.

Biotech Daily apologizes. The sub-editor has been transferred to the pre-clinical trials division for research purposes.

Acuvax fell 0.6 cents or 19.35 percent to 2.5 cents.

FEDERAL GOVERNMENT

Treasurer Wayne Swan and Innovation Minister Senator Kim Carr have called for consultation on the detailed design of the Research and Development Tax Credit. Releasing the Research and Development Tax Incentive Consultation Paper, Mr Swan and Senator Carr urged business and other stakeholders to make their voices heard on reforms to the scheme.

Mr Swan said the R&D Tax Credit was “the biggest reform to business innovation support for more than a decade”.

“It will boost investment, support jobs and strengthen Australian companies so they can take full advantage of new opportunities as the economy recovers,” Mr Swan said.

“From July 1, 2010, the Government will replace the complex and outdated R&D Tax Concession with a simplified R&D Tax Credit which cuts red tape and provides a better incentive for all businesses to invest in research and innovation,” Mr Swan said.

Senator Carr said that under the new system, “eligibility criteria will be tightened to ensure the best return for the taxpayers’ investment”.

“All businesses stand to benefit, in different ways, from the reformed scheme,” Senator Carr said. “The aim of the new Tax Credit is to provide more predictable, less complex support to business.”

Senator Carr said the consultation paper worked from the principle that the reformed scheme would provide more generous support for research and development to build a more innovative economy.

“The paper also poses a range of questions to business about how the Government could approach certain aspects of the scheme’s design,” Senator Carr said.

The Government press release said submissions were required by October 26, 2009.

The consultation paper and information about submissions are at www.treasury.gov.au.

The Government media release said public forums would be held during September and October 2009 with details at www.ausindustry.gov.au.

COMMONWEALTH SCIENTIFIC AND INDUSTRIAL RESEARCH ORGANISATION

The Minister for Innovation Senator Kim Carr has appointed Dr Terry Cutler deputy chairperson of the Commonwealth Scientific and Industrial Research Organisation.

A Department of Innovation media release said Dr Cutler had been on the CSIRO board since 2002 and was appointed deputy chairperson following the end of Prof Suzanne Cory’s term on June 25, 2009.

The 206-page Cutler review of the national innovation system (BD: Sep 9, 2008) entitled ‘Venturous Australia – building strength in innovation’ was described by its lead author as “a working blueprint to reposition Australia’s innovation system”.

The report showed a general decline in Australian Government expenditure on science and innovation from 1996.

While biotechnology was only mentioned four times in the entire document and not until page 92 did it receive its first mention, the review acknowledged that “many start-up firms too large to qualify for the tax offset endure tax losses for the best part of a decade, particularly in sectors like biotechnology”.

“Waiting this long to access the concession hugely degrades its commercial value, particularly for firms engaging in high risk research. And of course many start-ups are unsuccessful and so never access the concession.”

The Cutler review described biotechnology as a key industry and the panel recommended “a dramatic lift in the threshold for refundable credits” and that the incentive should apply to “any research activity in Australia regardless of firm ownership”.

BIO-MELBOURNE NETWORK

The Bio-Melbourne Network October 6 Bio-Breakfast will examine the rationale and outcomes of the mergers that created the Baker IDI and the Burnet Institute.

Baker IDI director Prof Garry Jennings and the Burnet's head of the centre for immunology Prof Mark Hogarth will discuss their respective organizations creations from the 2008 combination of the Baker Heart Research Institute with the International Diabetes Institute and the 2006 Macfarlane Burnet Institute merger with long-time partner the Austin Research Institute.

The process of organizational and cultural change is often fraught and considering the history and sense of identity that the four original organizations had, this will be an interesting point of discussion, the Network said.

The Bio-Melbourne Network said the establishment of the Baker IDI was "a significant step forward in addressing the growing number of patients suffering from cardiovascular disease and diabetes".

"The Baker IDI brings together the strength of the Baker's cardiovascular research reputation and skill with the outstanding diabetes research, education and patient care that IDI has offered for years," the industry organization said.

The Bio-Melbourne Network said the creation of the Burnet Institute as a "super-institute" benefitted from the combined strength of the Burnet's focus in public health and infectious disease and Austin Research Institute's focus in oncology and immunology widening the research and public health strategy of the newly formed Burnet Institute.

Both presenters will describe how the mergers have translated into new collaborative research strategies and what the post-merger measures of success are for each organization.

For more information go to <http://www.biomelbourne.org/events/view/58> or contact Anita Petris on +613 9667 8182 or mobile +613 (0) 417 559 123.

COGSTATE

The Maryland-based United Biosource Corp has ceased its substantial shareholding in Cogstate through the sale of 10,846,463 shares at 22 cents a share or \$2,386,221.86. Cogstate was untraded at 23 cents.

STARPHARMA

Starpharma says 7,203,413 shares will be released from escrow on October 18, 2009 following the end of a 36-month voluntary escrow.

Starpharma said there were no more shares remaining in escrow.

These shares are part of the company's total share issue of 207,218,113 shares.

Starpharma was unchanged at 45 cents with 1.2 million shares traded.