



# Biotech Daily

Wednesday July 30, 2008

*Daily news on ASX-listed biotechnology companies*

- \* **ASX, BIOTECHS UP: PHYLOGICA UP 21%, PEPLIN DOWN 10%**
- \* **THE LANCET NEUROLOGY PUBLISHES PRANA'S ALZHEIMER'S EFFICACY**
- \* **RTI LOSES OMI SYRINGE PATENT CASE; BEGINS US PROCEEDINGS**
- \* **AUSTRALIAN STEM CELL CENTRE SACKS CEO PROF STEPHEN LIVESEY**
- \* **IMPEDIMED 2007-08 SALES UP 109%; PREMIUM PLACEMENT; CASHED UP**
- \* **AGENIX REQUESTS CHINA ACQUISITION TRADING HALT**
- \* **AVANTOGEN CASH BURN NEEDS PROPOSED BBY PLACEMENT**
- \* **RIGHTS ISSUE SAVES PORTLAND**
- \* **LOANS SAVE DIA-B**
- \* **CIRCADIAN DIRECTOR JAMES MACKENZIE RESIGNS**

## MARKET REPORT

The Australian All Ordinaries Index climbed 1.7 percent on Wednesday July 30, 2008, up 85.4 points to 5,008.7 points.

Fifteen of the Biotech Daily Top 40 stocks were up, 10 fell, seven traded unchanged and eight were untraded.

Phylogica was best, up 1.7 cents or 21.25 percent to 9.7 cents on modest volumes, followed by Psivida up 14.7 percent to \$3.20.

Chemgenex climbed five percent; Biota was up 4.48 percent; Clinuvel and Viralytics were up more than three percent; Living Cell, Optiscan, Pharmaxis, Prana, Resmed and Sunshine Heart rose more than two percent; with Cochlear and Starpharma up more than one percent.

Peplin led the falls, down 3.5 cents or 10.29 percent to 30.5 cents on modest volumes, followed by Labtech down 9.09 percent to 20 cents.

Cytopia and Sirtex lost more than five percent; Bionomics and Novogen fell more than four percent; Mesoblast was down 2.27 percent; with Antisense down 1.45 percent.

## [PRANA](#)

Prana says its 12-week phase IIa clinical trial of early stage Alzheimer's disease patients has shown PBT2 to have statistically significant efficacy in some cognitive measures. The results to be published in *The Lancet Neurology* journal and to be delivered at the International Conference on Alzheimer's disease in Chicago overnight, show improved executive function, reduced levels of amyloid beta in spinal fluid, with no serious adverse events and no withdrawals from the trial due to adverse events.

Prana said executive function was "an important aspect of cognitive performance in patients with early stage Alzheimer's disease".

Prana said that amyloid beta or Abeta was a key protein associated with Alzheimer's disease.

The senior author of the publication and Prana's chief European clinical advisor Dr Craig Ritchie said the published clinical data was "very encouraging, especially when coupled with PBT2's strong preclinical efficacy data, as recently published in *Neuron*".

Prana said preclinical research demonstrated that PBT2 reduced amyloid beta in Alzheimer's disease animal models, with a corresponding cognitive improvement.

"The observed reduction of Abeta levels in the spinal fluid and improvement in signals of executive function in the clinical trial has similarities to the pattern of improvement observed in the animal models," Dr Ritchie said.

Prana said that in the aged brain, amyloid beta interacted with abnormally distributed levels of zinc and copper, making the amyloid beta toxic.

PBT2 prevents this interaction, restoring copper and zinc to normal levels in the brain.

Prana chief executive officer Geoffrey Kempler said *The Lancet Neurology* was "a prestigious peer reviewed journal".

"We have very high hopes for PBT2 and are delighted with its progress to date," Mr Kempler said.

"We believe that PBT2 offers a unique mechanistic strategy for the treatment of Alzheimer's disease and is well positioned to enter larger clinical trials and advance towards commercialization," Mr Kempler said.

Prana said 78 early stage Alzheimer's disease patients took either PBT2 (50mg or 250mg) or placebo once daily for 12 weeks, in a randomized, double-blind clinical trial.

The safety and tolerability profile of PBT2 was similar to that of placebo.

There were no study withdrawals related to adverse events, nor any serious adverse events in PBT2-treated patients.

In the 250mg dose PBT2 produced a highly significant reduction in amyloid beta 42 of 13 percent in the spinal fluid, compared to placebo ( $p=0.006$ ).

The effect of PBT2 was dose related ( $p=0.023$ ).

In the cognitive tests, patients on the 250mg dose performed significantly better than placebo in two tests of executive function.

In the 'Trail Making Part B' test, patients completed the task in an average of 42 seconds faster than they had at the beginning of the trial.

In contrast, the placebo group was an average six seconds slower.

The difference between PBT2 250mg and placebo was statistically significant ( $p=0.009$ ) and the effect of PBT2 was dose-related ( $p=0.031$ ).

In the 'Category Fluency test', patients improved their word generation response in 60 seconds by an average of 2.4 more words than at the beginning of the trial.

This compared with a decrease of 0.3 words in the placebo group.

The difference between PBT2 250mg and placebo was statistically significant ( $p=0.041$ ), Prana said.

Prana was up one cent or 2.13 percent to 48 cents.

## OCCUPATIONAL & MEDICAL INNOVATIONS

Occupational & Medical Innovations says the Australian Federal Court has found its syringe does not infringe Retractable Technologies' patent.

In May 2006, Occupational & Medical said the US-based Retractable Technologies had claimed among other things that Occupational & Medical had "constantly and intentionally interfered with the contractual relationship between Retractable Technologies and Double Dove", Retractable Technologies' Chinese manufacturer and that Retractable Technologies had made threats of infringement proceedings under the Commonwealth Patents Act 1990.

Occupational & Medical strongly disputed the claim and began proceedings in the Federal Court of Australia seeking declaratory relief and injunctions restraining Retractable Technologies from making further unjustified threats.

On August 31, 2007, the Federal Court found in favor of Occupational & Medical in those proceedings and made a declaration that Retractable Technologies' threats of infringement proceedings were unjustifiable.

Occupational & Medical said that on July 29, 2008 the Federal Court of Australia gave judgment on the balance of Occupational & Medical's claim, that its syringe device (Australian Patent Number 775427) did not infringe Retractable Technologies' patent (Australian Patent Number 701878).

A formal declaration and the Court's decision on costs will be made in the next few weeks.

In April Retractable Technologies began US court proceedings against Occupational & Medical alleging theft of confidential information; intentional interference with contracts engaging in false advertising; infringement of US Patent No 6,572,584 B1 (granted June 3, 2003) and US Patent No 7,351,224 B1 (granted April 1, 2008).

These proceedings were issued in the US District Court for the Eastern District of Texas, on April 1, 2008.

Occupational & Medical said these proceedings had not been formally or properly served and in any event, Occupational & Medical has previously said it rejects the claims, has confirmed that the claims will be strongly defended and has said it would be successful in any such defence.

The company said the substance of many of the allegations has already been raised by Retractable Technologies in the Federal Court of Australia.

The Federal Court has previously found that Retractable Technologies did not have reasonable cause to believe it had or may have the right to obtain relief from Occupational & Medical in respect of the allegations of misappropriation of confidential information, or interference with contractual relations.

The Federal Court of Australia has given judgment that Occupational & Medical's patent 775427 does not infringe Retractable Technologies' patent 701878.

Occupational & Medical said it had US patent protection for its syringe device covered by patent 775427 and the patent infringements now claimed by Retractable Technologies relate to US patents which embody central claims equivalent to Retractable Technologies' patent 701878.

As previously advised, the only substantially new matter raised by Retractable Technologies' US proceedings is the question of false advertising.

Occupational & Medical said that all claims made in its advertising material were based on expert independent testing. Accordingly, Retractable Technologies' claims in this respect are also rejected.

Occupational & Medical rejects all of Retractable Technologies' claims in the US proceedings.

Occupational & Medical was up nine cents or 32.14 percent to 37 cents on small volumes.

### AUSTRALIAN STEM CELL CENTRE

The Australian Stem Cell Centre says chief executive officer Prof Stephen Livesey has departed the company.

In a media release the Australian Stem Cell Centre said "over the past few months differences have arisen between the board of the ASCC and Professor Livesey as to the future direction of the ASCC".

"The board formed the view that these differences could not be resolved," the centre said. The board has appointed chief operating officer David Collins as acting CEO.

### AGENIX

Agenix has requested a trading halt pending an announcement regarding its acquisition of two Chinese Pharmaceutical companies.

Agenix told the ASX it had "received advice in regard to the acquisition in China of our business which the board needs time to analyze and seek further advice before taking appropriate action to address".

Agenix has previously said it would replace its Chinese chief executive officer Jonathan Zhang and chief operating officer Richard Wang following the failure to complete a \$16.5 million corporate takeover (see Biotech Daily; July 28, 2008).

Last week Agenix said a local government authority had failed to provide a waiver to complete the share transfer for takeover of Shanghai Rui Guang Bio-Pharma Development and 96 percent of Shanghai Yi Sheng Yuan Pharmaceutical.

The landlord and four percent shareholder is the Economic Association of Zhou Pu Town, the township in which YSY's factory and operations are located.

Trading will resume on August 1, 2008 or on an earlier announcement.

Agenix last traded at 1.9 cents.

### IMPEDIMED

Impedimed says its unaudited sales revenue for the 12 months to June 30, 2008 was up 109 percent from \$1.1 million to \$2.3 million.

Impedimed chief executive officer Greg Brown told Biotech Daily that sales for the three months to June 30, 2008 were \$873,000 compared to \$311,000 in the previous period.

Mr Brown said Impedimed had raised \$4.2 million in a placement to Orbis Managed Investment Scheme and Telstra Superannuation at 75 cents a share, a premium to its trading price of 71 cents a share. The \$4 million Orbis investment takes its shareholding in Impedimed to 13 percent, Mr Brown said.

Including the \$8.5 million cash reported at June 30, 2008, the company has \$12.7 in cash. The cash burn for the three months to June 30, 2008 was \$2,271,000.

Impedimed was untraded at 71 cents.

### ATCOR

Atcor says revenue for the 12 months to June 30, 2008 was up 47 percent to \$6.5 million, with second half sales up 70 percent compared to the previous period.

Atcor said US sales of its Sphygmocor central blood pressure measuring device were up 46 percent for the full year and 138 percent for the second half of the year.

The cash burn for the three months to June 30, 2008 was \$409,000 with cash at the end of the quarter of \$3,316,000.

Atcor was up one cent or 10 percent to 11 cents.

### AVANTOGEN

Avantogen has less cash in the bank than its last quarter cash burn.

Avantogen it had a total operating and investing cash burn of \$376,000 for the three months to June 30, 2008 and cash at the end of the quarter of \$225,000.

Yesterday Avantogen chief executive officer Dr William Ardrey told an investors meeting that a placement to BBY stockbrokers (formerly Burdett Buckeridge Young) at five cents a share was being negotiated (see Biotech Daily; July, 29, 2008).

Avantogen was untraded at 7.5 cents.

### PORTLAND ORTHOPAEDICS

Portland Orthopaedics' rights issue has raised \$1.9 million providing the company with cash for more than two quarters at its current cash burn.

Portland reported a total operating and investing cash burn of \$1,025,000 for the three months to June 30, 2008 and cash at the end of the quarter of \$176,000.

But a rights issue offering 162,581,336 shares received acceptances of 66,057,427 shares with a further 10,203,459 shares subscribed under an underwriting agreement with GBS Venture Partners as trustees of GBS Bioventures II.

Portland said the gross amount of capital raised was \$1.91 million.

Portland was untraded at 2.4 cents.

### DIA-B TECH

Dia-B Tech has reported a total operating and investing cash burn of \$695,000 for the three months to June 30, 2008 and cash at the end of the quarter of \$926,000.

Dia-B said it had loan facilities of \$3,500,000 with \$1,748,000 used.

Dia-B climbed 0.2 cents or 6.67 percent to 3.2 cents.

### CIRCADIAN

Circadian says James MacKenzie will resign as a director effective on July 31, 2008.

The company said Mr MacKenzie was resigning after six years with the company "having seen it through to its recent transition from a biotech incubator to a biologics drug development company".

Last month Circadian appointed Carlo Montagner as a non-executive director (see Biotech Daily; June 13, 2008).

A Ludwig Institute nominated director will be appointed when the Vegenics acquisition closes early in August

Circadian fell half a cent or 0.61 percent to 81 cents.