



Biotech Daily

Monday November 8, 2010

Daily news on ASX-listed biotechnology companies

- * **ASX DOWN, BIOTECH UP: PRANA UP 15%; PATRYS DOWN 8%**
- * **BIOTECH DAILY 5th BIRTHDAY EDITORIAL**
- * **PRANA SAYS \$15m LABOR PROMISE 'CRUCIAL' FOR ALZHEIMER'S**
- * **MESOBLAST RECEIVES \$1.2m OBAMACARE TAX CREDIT**
- * **BENITEC SAYS US GRAHAM '099 RNAi PATENT 'IMMINENT'**
- * **WEHI'S DR ROSS DICKINS WINS \$975k FELLOWSHIP FOR LEUKAEMIA**
- * **QRX WINS THIRD OBAMACARE TAX CREDIT OF \$241k**
- * **SMALL DISSENT AT QRX AGM ON DIRECTOR OPTIONS**
- * **SAFETY MEDICAL EGM APPROVES RETURN TO TRADE**
- * **JASPER HILL TAKES 8% OF SELECT VACCINES**
- * **PHARMAUST REQUESTS CAPITAL RAISING TRADING HALT**
- * **NOVOGEN LOSES DIRECTORS GEOFF LEPPINUS, PROF PAUL NESTEL**

MARKET REPORT

The Australian stock market fell 0.46 percent on Monday November 8, 2010 with the S&P ASX 200 down 22.2 points to 4778.4 points. Thirteen Biotech Daily Top 40 stocks were up, 12 fell, 10 traded unchanged and five were untraded. All three Big Caps were up.

Prana was best, up two cents or 15.4 percent to 15 cents with 745,750 shares traded, followed by Alchemia up 10.9 percent to 61 cents with 597,820 shares traded and Virax up 10.7 percent to 3.1 cents with 252,859 shares traded. QRX climbed 5.95 percent; Nanosonics was up four percent; Acrux, Advanced Surgical, Heartware, Optiscan, Tissue Therapies and Universal Biosensors rose more than two percent; with CSL, Impedimed, Pharmaxis and Resmed up more than one percent.

Cellmid led the falls, down 0.4 cents or 7.1 percent to 5.2 cents with 53.5 million shares traded, followed by Clinuvel down 5.6 percent to 17 cents with 146,100 shares traded. Genetic Technologies fell 3.7 percent; Benitec, Genera, Immuron and Living Cell shed more than two percent; with Mesoblast and Phylogica down more than one percent.

BIOTECH DAILY

Biotech Daily has met an important milestone – today we are five years old with about 1,250 editions published.

It was one of my personal goals to reach this date without missing a single edition and by inference not missing a single important life sciences announcement to the ASX. The Holiday Catch-Up editions ensure that news posted on Christmas Eve or over the Summer break is reported in the first edition of the New Year.

The publication has grown both in subscriptions and readership, as well as its mission. Initially, Biotech Daily was intended to be a straightforward journal of record, vanilla in flavor, translating business and scientific jargon into reasonably plain English and removing public relations spin, in order to faithfully report the activities of the sector.

Over the years, the publication has also taken an advocacy role, firstly on transparency and disclosure, as well as a range of other regulatory and ethical practices, and most recently in taking a stance on Government policies that affect the sector.

As just one example, Biotech Daily is not certain that the Federal Government's 45 percent research and development tax credit is the best way to fund the sector – although companies in receipt of the Obamacare 50 percent tax credits might have a different view. In the absence of any other meaningful funding program, we have no choice but to support the Bill being reintroduced to the Australian Parliament. We also welcome the Government's \$80 million for the Innovation Investment Funds (BD: Nov 5, 2010).

Biotech Daily has had informal conversations with the Greens, imploring them to support commercialization of innovation, demonstrating the common ground between our sector and the pro-environment sector (as well as other new technologies) in requiring funds for basic education and science, through research and development to commercialization.

Biotech Daily has taken issue with either the absence of regulation or the bizarre quasi-regulation by the ASX and ASIC, which do not seem able to investigate what appear to be serious regulatory concerns, while demanding answers from companies with exemplary records on why a director's interest statement was one-day late or in the celebrated case of Mesoblast two months ago, why its share price had suddenly climbed to about the midpoint of the valuation in an independent expert's report (BD: Sep 10, 2010).

In that same edition, Biotech Daily returned to the theme of transparency and disclosure, calling on the Federal Department of Innovation, its Minister Senator Kim Carr and Commercialization Australia's board to disclose publicly all potential conflicts of interest.

Like everything else done by this publication, standing up to the Federal Government or any other body we judge to be harming the greater long-term interests of the biotechnology sector, it can only be done because we have the strong support of the industry through you, our subscribers.

Thank you all.

David Langsam, Editor
Marc Sinatra, Analyst

PRANA BIOTECHNOLOGY

Prana says a Victorian Labor Party promise of \$15 million for the Mental Health Research Institute is "crucial" for a 525-patient phase IIb trial of PBT2 for Alzheimer's disease.

The Victorian Labor Party made the announcement last week as part of its campaign for re-election on November 27, 2010 (BD: Nov 5, 2010) saying the funds for the Mental Health Research Institute and Prana would come from the \$55 million biotechnology 'action plan' announced at Ausbiotech in October (BD: Oct 19, 2010).

The funding is dependent on the Labor Party forming Government after the election and was made by the Labor Party while the Government is in 'caretaker' mode during the election campaign.

Prana said the Mental Health Research Institute was its long-standing partner in Alzheimer's research and PBT2 was its lead compound for the treatment of Alzheimer's and Huntington's disease.

Prana said the grant would go towards the further development of PBT2 including the phase IIb clinical trial of 525 patients with mild to moderate Alzheimer's Disease, treated for 12 months.

Prana said it was seeking further funds for the trial which was intended to confirm the results in an earlier phase IIa trial.

In 2008 Prana reported results published in the Lancet Neurology journal and presented at the Chicago conference on Alzheimer's disease that its 12-week phase IIa clinical trial of 78 early stage patients showed PBT2 to have statistically significant efficacy in some cognitive measures (BD: Jul 30, 2008).

Prana said at that time that the results showed 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.

Today, Prana chief executive officer Geoffrey Kempler said PBT had "delivered positive results and has generated a great deal of interest in the global scientific community".

"The funding will come at a very important time for Prana and it is another vote of confidence in the promise of this drug," Mr Kempler said.

"This grant money would be used in a crucial stage of the development of PBT2," Mr Kempler said. "It would enable Prana to proceed with the planned phase IIb trial in a larger clinical setting."

Prana said that PBT2 worked by correcting an imbalance of metals in the ageing brain. Scientists believe this imbalance is one of the underlying causes of Alzheimer's disease and other neurodegenerative conditions.

Prana was up two cents or 15.4 percent to 15 cents.

MESOBLAST

Mesoblast's US associate company Angioblast Systems has been awarded a \$1.2 million tax credit grant credit under the US Qualifying Therapeutic Discovery Project.

The Project is a grant and tax credit scheme operated by the US Internal Revenue Service as part of the US Health Care Reform Bill of 2010 to foster medical, life science and biological innovation in the US.

Mesoblast chief executive Prof Silviu Itescu told Biotech Daily that the merger of the two companies had been approved by both sets of shareholders and the merger was awaiting final US regulatory approval.

Mesoblast said the tax credit payment was for its work on mesenchymal precursor cells for congestive heart failure, cardiac arrest, oncology, eye and diabetes indications.

Mesoblast fell five cents or 1.8 percent to \$2.70.

[BENITEC](#)

Benitec says the US Patent and Trademark Office has issued a “notice of intent to issue an ex-parte re-examination certificate” for its main the ‘099 Graham patent.

Benitec said the US patent (number 6,573,099) was a “wide-ranging platform technology patent covering the use of expressed RNAi in human therapeutic applications”.

The company said the notice formally closed the long-running re-examination proceedings on the patent and the certificate would be issued shortly.

Benitec chief executive officer Dr Peter French said the long re-examination process reflected “the importance of this patent in the global field of gene silencing using RNA interference”.

Last week, Benitec said a UK objection had been lodged against the British equivalent to the ‘099 Graham patent and said it was ready for the fight with the objector (BD: Nov 5, 2010).

“We are continuing to advance a broad pipeline of expressed RNAi-based therapeutic programs in oncology and infectious disease with particular focus on hepatitis B, lung cancer and cancer-associated neuropathic pain,” Dr French said.

Benitec said it had exclusive rights to key claims in expressed RNAi for humans in most major jurisdictions including the US, the UK, Japan and China.

The company said the Commonwealth Scientific and Industrial Research Organisation exclusively licenced the patent to Benitec for human therapeutics and also welcomed the notice.

Benitec fell 0.1 cents or 2.9 percent to 3.3 cents with 6.7 million shares traded.

[THE WALTER AND ELIZA HALL INSTITUTE FOR MEDICAL RESEARCH](#)

The Walter and Eliza Hall Institute says researcher Dr Ross Dickins has been awarded a five year \$975,000 fellowship to study short hairpin RNA for leukaemia .

The Institute said Dr Dickins was the head of one of its molecular medicine laboratories and won the Sylvia and Charles Viertel Charitable Foundation Fellowship to further investigate the genes involved in cancer development, particularly leukaemia, using short hairpin RNA (shRNA) techniques he developed that help identify the function of genes by switching the genes on and off.

“The techniques harness a natural process of gene silencing known as RNA-interference and allow us to quickly and effectively study multiple cancer genes in new ways,” Dr Dickins said.

Dr Dickins said Charles Viertel was “a hugely generous Australian philanthropist, yet during his lifetime he sought little public recognition”.

Dr Dickins said that the research supported by the fellowship aimed to better understand the genetic changes that bring about leukaemia and with that knowledge new therapeutic targets for cancer could be identified.

“We are examining several genes that are known to be altered in human leukaemia, along with a new set of genes that are thought to be involved but whose functions in normal blood cells and leukaemia cells remain untested,” Dr Dickins said.

“Ultimately, we hope that shRNA technology will accelerate cancer drug discovery by identifying genes that could be targeted by new therapeutic agents, in particular for leukaemias and lymphomas,” Dr Dickins said.

“In an ideal future, the research will help match the genetic profile of a tumor with the best possible therapeutic agent to treat that particular tumor,” Dr Dickins said.

WEHI said the Sylvia and Charles Viertel Charitable Foundation was one of the largest in Australia, awarding about \$9 million in grants each year.

QRX PHARMA

QRX says it has been awarded a third tax credit grant credit under the US Qualifying Therapeutic Discovery Project worth \$US244,479 (\$A241,165).

Last week QRX was awarded two grants totaling \$US488,958 (\$A486,464) taking the total to \$727,629 (BD: Nov 4, 2010).

QRX was up 5.5 cents or 5.95 percent to 98 cents.

QRX PHARMA

QRX shareholders approved all annual general meeting resolutions with small but significant dissent over directors' options.

The greatest division was on the issue of options to chief executive officer Dr John Holaday with 2,292,932 proxy votes (6.7%) against and 31,787,148 proxy votes (93.4%) in favor of awarding the options.

There was a similar level of opposition to the issue of options to directors Michael Quinn, Dr Gary Pace, Peter Campbell and Dr Peter Farrell.

Most resolutions, including permitting Mr Campbell, Dr Pace and Mr Quinn to participate in a placement were carried by majorities of more than 48 million proxy votes, while the re-election of Dr Pace and Mr Quinn was supported by more than 52 million proxy votes.

SAFETY MEDICAL

Safety Medical shareholders have approved resolutions required to return to ASX trading with significant dissent over the issue of shares to Trident Capital.

The issue of new shares to Trident Capital was opposed by 1,109,694 proxy votes (24.8%) against, with 3,358,958 proxy votes (75.2%) in favor.

Resolutions on a one-for-five reduction of capital, the right of directors to participate in a share issue were passed by clear majorities.

The company said its securities would remain suspended until the capital raising was completed.

Safety Medical last traded at 3.7 cents.

SELECT VACCINES

Jasper Hill Resources says it has become a substantial shareholder in Select Vaccines with the acquisition of 71,750,461 shares or 7.61 percent of the company.

Jasper Hill said it acquired the shares between September 14, 2010 and November 4, 2010 for \$146,834 or an average price of 0.21 cents share.

Select Vaccines was unchanged at half a cent with 18.2 million shares traded.

PHARMAUST

Pharmaust has requested a trading halt pending an announcement "in relation to a proposed capital raising".

Trading will resume on November 10, 2010 or on an earlier announcement.

Pharmaust was up 0.4 cents or 19.05 percent to 2.5 cents with 1.1 million shares traded.

NOVOGEN

Novogen posted two Appendix 3Z final director's interest notices today implying that directors Geoff Leppinus and Prof Paul Nestel had resigned.

The company did not make a formal announcement of their departure but a Novogen spokesman told Biotech Daily that it had been mentioned in the chairman's address to the annual general meeting.

On the last page of the four page address, chairman William Rueckert said Mr Leppinus joined the board in 2005 and chaired the audit committee while Prof Paul Nestel had been with the company for more than 10 years.

Novogen was unchanged at 11.5 cents.