Biotech Daily

Monday June 6, 2011

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: PHARMAXIS UP 8%; CLINUVEL DOWN 6%**

*** OTIFEX DEVELOPS SPRAY FOR OTITIS-RELATED HEARING LOSS**

*** WHY AUSTRALIAN ETHICAL INCREASED IN PHARMAXIS**

*** LIVING CELL EARLY DATA INDICATES LOW DOSE PIG CELL EFFICACY**

*** NEUREN PAYS SPRINGTREE, PREPARES RIGHTS ISSUE**

*** LLOYDS & CASSANOVE TAKES 7.5% OF CYCLOPHARM**

*** DIRECTOR FRED BART, SECURITY & EQUITY CEASE IN GENETIC TECH**

MARKET REPORT

The Australian stock market fell 0.31 percent on Monday June 6, 2011 with the S&P ASX 200 down 14.0 points to 4569.1 points.

Eight of the Biotech Daily Top 40 stocks were up, 19 fell, 10 traded unchanged and three were untraded. All three Big Caps fell.

Pharmaxis was the best, up 8.5 cents or 7.6 percent to $1.21 with 3.5 million shares traded, followed by Uscom up 6.8 percent to 23.5 cents with 48,994 shares traded.

LBT was up 4.35 percent; Sunshine Heart was up 3.9 percent; with Biota and Phylogica up more than one percent.

Clinuvel led the falls, down 12 cents or 6.3 percent to $1.78 with 6,191 shares traded.

Impedimed, Psivida and Viralytics lost more than five percent; Patrys and Virax fell four percent or more; Cellmid, Phosphagenics, QRX and Starpharma were down more than three percent; Alchemia, Benitec, Genetic Technologies and Tissue Therapies shed more than two percent; with Acrux, Living Cell, Nanosonics, Prima and Resmed down one percent or more.

OTIFEX THERAPEUTICS

University of Melbourne spin-out Otifex Therapeutics says it has raised $1.1 million to develop a nasal spray for otitis media with effusion, or fluid in the middle ear.

Otifex said the funds were provided by the Medical Research Commercialisation Fund and Uniseed.

The company said otitis media with effusion was the most common cause of childhood hearing problems with no effective medication available and often managed with surgical implantation of tympanostomy tubes or grommets.

Otifex said it intended to develop an easy to use, safe and effective nasal spray to assist in the clearance of fluid from the middle ear, which was the cause of otitis-associated hearing loss.

The company said the active drug was the H1 histamine agonist and H3 histamine antagonist, betahistine which appeared to better open the Eustachian tube in animal experiments.

Otifex said its founding scientists University of Melbourne's Prof Colin Anderson and ear nose and throat physician Dr Burkhard Franz discovered that betahistine administered into the nasopharynx improved the functioning of the Eustachian tube in experiments on animals and could have the potential to effectively treat otitis media with effusion in children.

The company said it planned to test the nasal spray in collaboration with the Murdoch Children's Research Institute at Melbourne's Royal Children's Hospital.

Otifex said it had appointed former Antisense Therapeutics research director Dr Christopher Wraight as chief operating officer.

The company said Dr Wraight held a PhD in biochemistry and a Masters of Business administration and had overseen early stage drug development programs from the laboratory to clinical proof of concept.

"Otifex Therapeutics' strategy is to reformulate a well established and safe oral tablet drug, which has a long history of use in 130 million adults, into a safe and convenient nasal spray for children," Dr Wraight said.

"We hope to provide the first, effective, non-surgical treatment option for the most common cause of acquired hearing loss in children," Dr Wraight said.

Otifex said the $1.1 million investment would be used in reformulation for nasal delivery, pharmacology and safety experiments, manufacture and a phase I clinical trial to confirm the nasal formulation's safety.

Otifex said it would then seek additional investment to advance to phase II clinical efficacy trials in children with otitis media with effusion.

Otifex said the $30m Medical Research Commercialisation Fund managed by Brandon Capital Partners provided early stage funding for its member medical research institutes, supported by Statewide and Westscheme Superannuation funds and the State Governments of Victoria, New South Wales and Western Australia.

The company said Uniseed was a $61 million commercialization fund operating at the University of Queensland, New South Wales and Melbourne and supported by Western Australia non-government superannuation fund, Westscheme.

Otifex is a private company.

PHARMAXIS

Australian Ethical Trusts took the decision to increase its exposure to Pharmaxis as it plunged from $2.93 to 76 cents on the negative European trend vote on Bronchitol for cystic fibrosis.

Australian Ethical Smaller Companies Trust's portfolio manager Andy Gracey explains why.

We were disappointed to hear European authorities are now set to vote down the new drug application for Bronchitol in its existing form, but Pharmaxis does have the right of appeal and in all likelihood will modify its application and appeal this decision.

While Pharmaxis is now a riskier investment proposition, Australian Ethical Investment added to its positions on the day of the negative trend vote announcement, primarily because we think Bronchitol will eventually win approval and we thought the market had oversold the stock.

The Committee for Medicinal Products for Human Use concerns with Bronchitol revolve around the drug's efficacy, as well as the variability of results seen in adolescents.

We take a small positive in that no safety issues were highlighted.

The Pharmaxis combined phase III clinical studies of 643 patients demonstrated a 7.3 percent improvement in forced expiratory volume in one second (FEV1) as a measure of lung function, from baseline over 26 weeks.

The more relevant statistic however in any phase III pharmaceutical study is performance against placebo or control, where FEV1 was a less impressive 3.8 percent improvement.

This divergence between FEV1 improvement versus baseline and against control is explained by a strong placebo response, particularly present in adolescent patients, which dragged down the overall clinical efficacy of Bronchitol to 3.8 percent.

The Committee for Medicinal Products for Human Use is quite rightly questioning whether this 3.8 percent improvement is enough and why adolescent patients had such variability in their response to Bronchitol.

We believe Pharmaxis will appeal any negative final decision, with the most conservative Pharmaxis strategy being to modify their new drug application and ask for drug approval in adult cystic fibrosis populations only.

We understand that Bronchitol's clinical data in 341 adult patients or 53 percent of the combined study patients is stronger, with FEV1 improvement above placebo of about seven percent, with statistical significance.

The strategy of focusing on adult cystic fibrosis patients allows Pharmaxis to present stronger clinical efficacy data and removes criticism about variability seen in the adolescent data.

This still leaves the issue of what is enough lung function improvement or efficacy to warrant drug approval in Europe.

Bronchitol rehydrates mucous on the lungs and facilitates a productive cough.

The two therapies used in cystic fibrosis treatment that are most similar to Bronchitol are saline and the Roche-owned Pulmozyme.

Pulmozyne thins the mucous allowing a more productive cough and was approved in 1994 having demonstrated a 5.8 percent improvement in FEV1 over 26 weeks.

But Pulmozyme gained marketing approval on the back of demonstrating a 27 percent reduction in infections requiring antibiotic use and not the FEV1 improvement.

Bronchitol is often also linked to nebulised hypertonic saline, which has a similar method of action.

In 2006, researchers published a report which demonstrated an average 3.2 percent improvement in FEV1 against placebo when saline was taken twice daily over 48 weeks.

This result was considered credible, while falling marginally short of Bronchitol's overall 3.8 percent result.

The 3.2 percent result is a useful data point in an efficacy discussion although saline is not an approved therapy.

It remains difficult to gauge what is a clinically meaningful improvement in lung function, but when put into the context of a nearly two percent annual FEV1 decline seen in cystic fibrosis adults, a seven percent improvement feels enough to get Bronchitol approved for adults in European on appeal in late 2011.

Andy Gracey
Portfolio Manager
Australian Ethical Smaller Companies Trust

Pharmaxis closed up 8.5 cents or 7.6 percent at $1.21 with 3.5 million shares traded.

* Biotech Daily Editor David Langsam holds Pharmaxis shares and his superannuation holdings are with Australian Ethical.

LIVING CELL TECHNOLOGIES

Living Cell says that early trial data presented at the International Pancreas and Islet Transplant Association meeting shows low dose Diabecell efficacy a year after dosing.

Living Cell said the New Zealand phase II trial data was presented at the meeting in Prague by medical director Prof Robert Elliott and research and development director Dr Olga Garkavenko.

Living Cell said the average weekly number of unaware hypoglycaemia events dropped from 3.2 before treatment; to 1.5 up to week 12; and 0.8 from week 12 to week 52 along with falls in the weekly average insulin dose and hypoglycaemia severity indicators.

Living Cell chief executive officer Dr Ross Macdonald told Biotech Daily that it was the first time his company had given an oral presentation at the International Pancreas and Islet Transplant Association meeting.

The company said Diabecell was encapsulated neonatal porcine pancreatic islets that were implanted into the abdomen of patients in a laparoscopic procedure.

Dr Macdonald said the early data indicated that lower doses were more effective than higher doses of Diabecell which had been given in doses ranging from 5,000 to 20,000 islet equivalents per kilogram of body weight.

Dr Macdonald cautioned the company was still collating the data, but there was a possibility that the higher doses were triggering an immune response but said it would be a good outcome if a lower dose was the most effective as it would save resources.

Living Cell said Prof Elliott's presentation entitled 'Microencapsulated neonatal porcine islet implants alleviate unaware hypoglycaemia without immune suppression' showed a dramatic reduction in severe and unaware hypoglycaemia after low dose islet xeno-transplantation procedure without immune suppression, despite only modest reduction in insulin dose.

Living Cell said the benefit could be related to the post-implant hormonal changes measured.

The company said Dr Garkavenko's presentation entitled 'Managing potential zoonotic infections in swine-to-human islet xenotransplants' discussed a key safety aspect of the xeno-transplantation project.

Living Cell said that it had 14 years experience in developing and implementing a comprehensive xeno-safety program that included donors' microbiology evaluation and recipient follow-up, with a particular focus on potential pig endogenous retrovirus infection.

The company said that to date the follow-up of its 27 patients treated with pig islet cells shows no evidence of pig endogenous retrovirus or other pig viruses transmission.

Living Cell said Dr Garkavenko was scheduled to speak at the Berlin Symposium on Xeno-transplantation on June 9, 2011 on a presentation entitled 'The first clinical xeno-transplantation trial in New Zealand: efficacy and safety'.

The company said it had completed the treatment phase of its phase II dose-seeking clinical trial in New Zealand and had approval to begin a clinical trial in Argentina.

"Our data supports the long term safety of Diabecell and dramatic efficacy in improving the management of patients suffering from a life threatening complication of type 1 diabetes," Prof Elliott said.

The company said diabetes control was assessed by seven times a day blood glucose determinations with intermittent periods of continuous glucose monitoring, as well as HbA1c measurements and a standardized record of hypoglycaemic episodes.

No significant adverse events were encountered except in one individual receiving the highest dose of encapsulated islets who presented with a transient possible allergic reaction seven to 10 days after implantation.

Living Cell fell 0.1 cents or 1.2 percent to 8.3 cents.

NEUREN PHARMACEUTICALS

Neuren says it has completed its $2 million placement and terminated its convertible loan with Springtree Special Opportunities Fund.

Neuren said that it received shareholder approval for last month's placement of 153,849,001 shares to interests associated with Lang Walker as well as clients of brokers Taylor Collison and Southern Cross Equities (BD: May 4, 2011).

The company said Springtree had converted the remaining note of $281,400 to 20,844,444 shares and following termination of the convertible loan agreement, Neuren has no remaining convertible debt on issue.

The company said it was preparing for a one-for-one rights issue at 1.3 cents a share to shareholders with registered addresses in Australia and New Zealand, with further details expected in the next two weeks.

Neuren fell 0.1 cents of five percent to 1.9 cents with 1.2 million shares traded.

CYCLOPHARM

Lloyds & Cassanove Investment Partners has increased its substantial shareholding in Cyclopharm from 9,965,180 shares (5.8%) to 12,633,680 shares (7.5%).

The London-based Lloyds & Cassanove said it acquired the 2,668,500 shares for $133,718 or an average price of 5.01 cents a share.

Cyclopharm was up 0.1 cents or two percent to 5.1 cents.

GENETIC TECHNOLOGIES

Security & Equity Resources and Fred Bart have ceased their substantial holding in Genetic Technologies with the sale of 6,250,850 shares for $1,291,692 or an average price of 20.7 cents a share.

The ceasing substantial shareholder notice said there had not been a previous notice since January 28, 2000.

ASX data said that at September 20, 2010 Mr Bart held 25,281,364 shares or 6.25 percent of the company and Mr Bart is believed to continue to hold about 4.6 percent of the company.

Genetic Technologies fell half a cent or 2.2 percent to 22 cents.