



Biotech Daily

Monday October 25, 2010

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH UP: GENETIC TECHNOLOGIES UP 7%; PRIMA DOWN 7%**
- * **PHARMAXIS RESPECT IN BALTIMORE, BUT PLENTY OF CF COMPETITION**
- * **SUNSHINE HEART HAS ONE QUARTER CASH; \$3.7m PLACEMENT**
- * **VIRALYTICS VOTES ON 2m M-D OPTIONS**
- * **DR DILLON NOMINATION HERALDS DIVISIVE ITL AGM**
- * **PHARMAUST'S EPICHEM WINS WA EXPORT GONG**
- * **OBJ SAYS GSK CONTINUES MAGNETIC TRANSDERMAL DEVELOPMENT**
- * **STIRLING APPOINTS CRUCIBLE CAPITAL TO RAISE TELEMED \$10m**

MARKET REPORT

The Australian stock market climbed 1.3 percent on Monday October 25, 2010 with the S&P ASX 200 up 61.8 points to 4710.0 points.

Seventeen of the Biotech Daily Top 40 were up, six fell, 12 traded unchanged and five were untraded.

Genetic Technologies was best, up 0.2 cents or 7.4 percent to 2.9 cents with 26,500 shares traded, followed by Antisense up 7.1 percent to 1.5 cents with 884,980 shares traded.

Patrys and Phylogica climbed more than six percent; Acrux was up 5.3 percent; Genera and Universal Biosensors were up four percent or more; Mesoblast, Psivida and Starpharma were up more than three percent; Cellestis, Clinuvel, Impedimed and Optiscan rose more than two percent; with Biota and Nanosonics both up 1.1 percent.

Prima led the falls, down one cent or 6.7 percent to 14 cents with two million shares traded, followed by Benitec down 5.1 percent to 3.7 cents with 1.3 million shares traded.

Living Cell and Pharmaxis fell more than three percent; with Heartware and QRX down more than one percent.

PHARMAXIS. AUSTRALIAN ETHICAL TRUSTS

Australian Ethical portfolio manager Andy Gracey went to the North American Cystic Fibrosis Conference in Baltimore, Maryland last week to learn more about the debilitating illness.

Mr Gracey's Australian Ethical Smaller Companies Trust has taken a large, but below substantial, stake in Pharmaxis and he reports that although Bronchitol was well received by "an eager practitioner and researcher audience" there was plenty of competition in cystic fibrosis market place. This is his report:

The 24th annual cystic fibrosis conference was attended by about 4000 healthcare professionals and academic researchers from the US and Europe and the three days I spent at the Baltimore Conference was illuminating.

The conference organizers, the US Cystic Fibrosis Foundation is particular focused on methodically improving the standard of care in their cystic fibrosis centres as well as ultimately finding a cure for this dreadful disease. The Foundation is an extremely strong and motivated patient advocacy body with an impressive fund raising ability and has partly funded some of the leading new cystic fibrosis drugs in development.

There was particular excitement at the conference surrounding Vertex's gene therapies (VX-770 & VX-809) which have the potential to correct faulty cystic fibrosis genes and open-up chloride ion transport, which may ultimately promote better mucus clearance.

But these drugs are focused on a small-subset of the global 70,000 cystic fibrosis population and require more scientific validation.

Inspire Pharmaceuticals novel therapy Denufosal, which is also an ion transport therapy received some attention, particularly for child and adolescent cystic fibrosis patient groups.

The real surprise for me was the emergence of hypertonic saline as a credible and cheap option for cystic fibrosis treatment. It has a very similar mode of action to Pharmaxis Bronchitol (Mannitol) for clearing mucous, but lacks the same level of scientific validation. The downside for saline appears that it is most effective if nebulised four times daily, with tolerance and compliance issues consequently flagged.

Pharmaxis principal investigator, the University of Washington's Prof Moira Aitken presented the Bronchitol data in a 20 minute slot to an eager practitioner and researcher audience (BD: Oct 22, 2010).

Pharmaxis attributes the miss in statistical significance in their second pivotal study the 302 study (BD: Jun 22, 23, 2010) to the fact that between the time control patients took their Mannitol tolerance screening test (four to six weeks before baseline for trial commencement) and the time they took their base-line lung function tests, lung function had declined a whopping three percent.

The three percent decline is in the context of the average cystic fibrosis patient having a one to two percent lung decline annually.

Pharmaxis presented their cystic fibrosis 302 study data at the conference showing that if one averaged lung function between screening and baseline for their control group, statistical significance ($p=0.0075$) would have been achieved.

The combined data from the two phase III studies similarly demonstrated significant and sustained improvement in lung function ($p<0.001$).

Prof Aitken said that the sustained improvements in lung function as measured by forced expiratory volume of air over one second (FEV1) was unprecedented in phase III cystic fibrosis clinical studies she has seen.

We should also remember that the Pharmaxis trials enrolled patients with a wide range of lung function, while Vertex's and Inspire Pharmaceutical's drug therapies are targeted to particularly cystic fibrosis mutations or lung function ranges, or age groups.

Researchers asked Prof Aitken a spray of questions on whether Mannitol has the potential to feed the growth of certain bacteria that reside naturally in the lungs. This would be a major concern with the question emerging because Mannitol is used as a base by laboratory researchers to grow bacteria. In favor of Pharmaxis, data exists to show there was no significant difference in key bacteria levels between Mannitol and control.

Overall Mannitol appeared to come through the conference with its scientific credentials intact. The importance of FEV1 as the primary target for all cystic fibrosis therapies came though loud and clear. Mannitol continues to have a low but increasing profile amongst cystic fibrosis therapies.

It would be fair to say Pharmaxis and Bronchitol doesn't get the profile that the more innovative therapies developed by Vertex and Inspire enjoy.

The ease of use gives Mannitol clear time savings over nebulised therapies but cystic fibrosis patients may still need to nebulise a combination Pulmozyme, anti-inflammatories, steroids and antibiotics on a regular basis.

The emergence of cheap hypertonic saline was a surprise while it appears the largest selling cystic fibrosis product Pulmozyme (about \$US450 million in 2008) has a solid following and sales are unlikely to be dented in the near future.

Out-of-pocket expenses for cystic fibrosis families in the US was \$US48,000 with hospitalization accounting for half of this cost.

Pharmaxis next assignment will be to convince US insurers that their Mannitol data will translate to solid hospitalization cost savings, and then agree pricing with insurers.

Andy Gracey
Australian Ethical Trusts

Pharmaxis fell 11 cents or 3.9 percent to \$2.74.

SUNSHINE HEART

Sunshine Heart says its net operating cash burn for the three months to September 30, 2010 was \$1,805,000 with cash at the end of the quarter of \$2,027,000.

Sunshine Heart announced last month that it had commitments for a \$3.7 million placement and was hoping to raise \$11 million in a non-renouceable rights issue. Sunshine Heart was untraded at 2.7 cents.

VIRALYTICS

Viralytics shareholders will vote on the issue of 2,000,000 options to managing director Bryan Dulhunty.

Viralytics said the options would vest in four tranches and be priced at the higher of 60 percent above the 60-day volume weighted average price or five cents.

The meeting will also vote on the prior issue of 28,650,000 shares and 12,095,448 shares and the reelection of director Dr Phillip Altman.

The meeting will be held at the Royal Automobile Club of Australia, 89 Macquarie Street, Sydney on November 24, 2010 at 11am (AEDT).

Viralytics was unchanged at 3.4 cents.

ITL

ITL shareholders will vote on the reelection of existing board members and the election of dissident shareholder and co-founder Dr Jagmohambir Singh Dillon.

A statement by Dr Dillon published with the meeting notice said he had more than 20 years experience in healthcare and was "integral in developing the vision, strategic direction and business plans for the group".

Dr Dillon said the company listed at 50 cents but was now trading at six cents, he owned 14.6 million ITL shares (about 11 percent) and was concerned with its diminishing value.

Dr Dillon made a number of proposals to change the company's fortunes.

The ITL directors recommended against his election and said they were searching for an appropriate board member and said Dr Dillon could "participate in this selection process".

The meeting will vote on the election of chairman William Mobbs, Julian Gosse and Sanjay Sehgal as directors.

The meeting will be held at Unit 1, 63 Wells Road, Chelsea Heights, Victoria on November 26, 2010 at 2pm (AEDT).

ITL was untraded at five cents.

PHARMAUST, EPICHEM

Pharmaust says its wholly-owned subsidiary Epichem has won the Small Business Export Award category of the 2010 Western Australian Industry and Export Awards program.

Pharmaust said Epichem was exporting to 18 countries after recently completing its first sale to Denmark and the award, coordinated by the Western Australia Department of Commerce recognized the best of that state's export businesses.

The winners of each of the 12 export award categories from each State and Territory progress to the 2010 Australian Export Awards.

Epichem managing director Dr Wayne Best said his company exported active pharmaceutical ingredient impurities, "to establish regulatory standards for ingredients to the world's most demanding markets including Europe, the US, Japan and India".

Pharmaust was up 0.1 cents or 6.25 percent to 1.7 cents.

OBJ. GLAXOSMITHKLINE

OBJ says that Glaxosmithkline Consumer Healthcare will proceed with the company's field-in-motion magnetic transdermal development program.

OBJ said Glaxosmithkline would continue to develop the transdermal technology "in a major consumer healthcare sector following a sequence of successful technology evaluations".

"Glaxosmithkline Consumer Healthcare has reported statistically significant levels of enhancement in an in-vitro testing model by the OBJ technology in a global consumer healthcare application," OBJ reported Glaxosmithkline saying.

"These results are the outcomes of the short term evaluation agreement with GSK announced to shareholders on February 18, 2010," Glaxosmithkline was quoted saying. OBJ said it and Glaxosmithkline were in discussions for the next steps of the program which would include a technology integration program and in vivo human efficacy testing to quantify the business opportunity.

OBJ fell 0.2 cents or 9.1 percent to two cents with 9.7 million shares traded.

STIRLING PRODUCTS

Stirling says it has appointed New York Crucible Capital to raise \$US10 million for an equity position in the Telemedcare vital sign monitoring group.

Stirling said the raising would be non-dilutive to Stirling shareholders and was expected to close before the end of 2010.

Stirling was unchanged at 0.8 cents.