



Biotech Daily

Thursday May 22, 2008

Daily news on ASX-listed biotechnology companies

- * **ASX UP, BIOTECHS DOWN:
PROGEN UP 16.5%; TISSUE THERAPIES DOWN 11%**
- * **STEM CELL DEVELOPS INHIBITOR MEDIA FOR PURER CELLS**
- * **PORTLAND MEETING TO RAISE \$8m**
- * **QRX OPTS FOR 12mg MORPHINE, 8mg OXYCODONE FOR Q8003IR**
- * **EASTLAND TAKES 78% OF STAR MEDICAL**
- * **BIODIEM'S DR ANDREW O'BRIEN APPOINTED CEO**
- * **ANZ DOWN TO 18% OF OP'S BIOPROSPECT, HOLDS 42% OF SOLAGRAN**

MARKET REPORT

The Australian stock market fell as much as 1.4 percent before closing up 0.1 percent on Thursday May 22, 2008 with the All Ordinaries up 3.6 points to 5,920.0 points.

Seven of the Biotech Daily Top 40 stocks were up, 20 fell, three traded unchanged and 10 were untraded.

Progen was best, up 22 cents or 16.54 percent to \$1.55 on moderate volumes, followed by Psivida up one cent or 9.09 percent to 12 cents.

Bionomics climbed 5.97 percent; Starpharma was up 4.62 percent; with Acrux and Stem Cell up more than two percent.

Tissue Therapies led the falls down 1.5 cents or 11.11 percent to 12 cents on small volumes, followed by Novogen down 14 cents or 8.54 percent to \$1.50 and Cathrx down nine cents or 8.26 percent to \$1.00.

Phosphagenics lost 7.41 percent; Prana fell five percent; Optiscan and Peplin both fell four percent; Circadian, Cochlear and Proteome fell more than three percent; Antisense, Clinuvel, Pharmaxis, Polartech and Resmed shed more than two percent; with Agenix, Alchemia, Arana, Avexa, Cytobia and Mesoblast down more than one percent.

STEM CELL SCIENCES

Stem Cell Sciences has launched an inhibitor stem cell media product Culticell Istem that maintains cells in their basal, pluri-potent state.

Stem Cell says Culticell Istem is a new, serum-free, feeder-free, embryonic stem cell research media product, providing researchers with a purer starting point for investigating the biological potential of embryonic stem cells.

Stem Cell's scientific program manager Dr Paul Bello told Biotech Daily that the Istem inhibitor stem cells had a combination of signals that dictate the cellular path and inhibit the cell from differentiating in unwanted directions.

The company said the development of Culticell Istem was based on the "pioneering work" of Stem Cell scientific founder Prof Austin Smith and his team at the Wellcome Trust Centre for Stem Cell Research at Britain's Cambridge University.

A paper on the research entitled 'The ground state of embryonic stem cell self-renewal' was published as a letter in today's issue of Nature (Vol 453, No 7194).

An abstract is at: www.nature.com/nature/journal/v453/n7194/full/nature06968.html.

Stem cell said the research found that self-renewal properties of embryonic stem cells were innate and could be maintained by providing a neutralized culture environment, without needing to add external stimulation from cytokines and growth factors.

Since mouse embryonic stem cells were first described more than 26 years ago, they have been cultured and derived using combinations of feeder cells, cytokines, growth factors, hormones and serum.

The company said the research suggests these additives were shielding the true nature of the embryonic stem cells and are not required to maintain pluripotency.

The research also demonstrated that embryonic stem cells with greater purity can be cultured by blocking external signals in the culture environment to phosphorylated extracellular signal-regulated protein kinase (pERK), a protein that triggers differentiation, instead of providing an external stimulus to activate the signaling protein signal transducer and activator of transcription (STAT3) to block differentiation.

The company says its Culticell Istem "provides all these elements in one product".

Stem Cell chief scientific officer Dr Tim Allsopp said Prof Smith's research was "a major step forward in embryonic stem cell research" and elucidated some of the early mechanisms involved in self-renewal and differentiation.

"We have now leveraged this significant advance into our novel media product Culticell Istem, which we believe will help provide researchers with a more pure starting point for embryonic stem cell research," Dr Allsopp said.

Stem Cell was up one cent or 2.86 percent to 36 cents.

PORTLAND ORTHOPAEDICS

Portland Orthopaedics will hold a general meeting to approve a capital raising of up to \$8 million through the issue of shares or convertible notes.

Portland said the funds were "primarily to expand inventory and marketing budgets to meet growing US and Australian demand".

Portland chief executive officer John Brassil said approval would provide the company with "an opportunity to expand sales and marketing efforts through maintaining full inventory levels and pushing through to the 100 surgical cases a month level in the next nine months".

The meeting will be held on June 25, 2008 at Level 17, 383 Kent St, Sydney at 2pm.

Portland was unchanged at 4.2 cents.

[QRX PHARMA](#)

QRX Pharma says phase III trial data has established a 12mg morphine and 8mg oxycodone combination in Q8003IR as the preferred dose for efficacy and tolerability. QRX chief executive officer Dr John Holaday said the initial phase III efficacy data demonstrated statistically significant pain reduction activity of Q8003IR at all dose levels. "Further analysis suggests that the 12mg to 8mg dose delivers the best analgesic effect and tolerability profile," Dr Holaday said.

He said the data confirmed that the patented dual opioid combination of morphine and oxycodone provided "synergistic effects on pain relief" and was able to achieve equal or better analgesia at materially lower doses than the active opioid comparator while reducing incidence levels of specific side effects.

The goal of the double-blind, placebo-controlled phase III study was to compare four different doses of Q8003IR in patients with moderate to severe post-surgery pain (bunionectomy) and establish the preferred dose parameters.

Secondary endpoints included efficacy relating to the time to onset of analgesia and the duration of effect from a single oral dose and safety as measured by the incidence and intensity of opioid-related adverse events.

QRX said that of the patients receiving 12mg morphine and 8mg oxycodone dose, 58 percent reported good to excellent global improvement as compared to 13 percent for placebo and demonstrated the greatest dose-response effect ($p < 0.0003$) in terms of reducing pain intensity scores as well as other measures of analgesic effect.

Post-surgery and prior to the first 12mg-8mg dose of Q8003IR, the baseline patient pain intensity scores averaged 6.6 out of 10 with 10 being the most severe pain.

Analgesic effects as reflected in the maximum pain improvement for the 12mg-8mg dose of Q8003IR yielded a two unit reduction of pain (decreasing patient scores to 4.6) compared to a 0.14 unit increase for placebo-treated patients.

Placebo patients were treated with ibuprofen, a non-opioid analgesic.

The mean time to confirmed perceptible pain relief for Q8003IR was 42 minutes compared to 4.4 hours for placebo. The duration of analgesic effect was 6.6 hours for Q8003IR versus 2.8 hours for placebo.

The 12mg-8mg dose data demonstrated that Q8003IR was well tolerated, with a low rate of patient withdrawal (8% discontinuing use due to adverse events and 6% discontinuing use due to efficacy failure) compared to placebo (with 2% discontinuing use due to adverse events and 25% discontinuing use for efficacy failure).

The company said two percent of 12mg-8mg Q8003IR treated patients experienced somnolence with no incidences of euphoria were reported. The low level of somnolence and absence of euphoria reported were unexpected outcomes compared to what is typically seen with morphine or oxycodone. The significance of these observations will need to be confirmed in future studies that provide a direct data comparison.

All patients had acceptable respiratory rates with reduction in blood oxygen levels occurring in less than two percent of those on the preferred dose of Q8003IR.

Nausea and vomiting were the most common adverse events. Of patients receiving the 12mg-8mg dose, 56 percent experienced mild to moderate nausea that diminished over the first few hours of treatment; no incidences of severe nausea were reported; 32% of patients reported vomiting with initial dosing (18% mild to moderate and 14% severe); 20% of patients experienced mild to moderate dizziness; no incidences of severe dizziness were reported.

Final phase III will be initiated to complete the required data package for new drug application submission to the US Food and Drug Administration in 2009 as planned.

QRX was down four cents or 4.71 percent to 81 cents.

[EASTLAND MEDICAL](#)

Eastland Medical Systems has increased its stake in the African drug development company, Star Medical (Botswana) to 78 percent.

Eastland said it had acquired the interests from an African shareholder for about \$604,000.

The company acquired 55 percent of Star though its interests in Fee-Zone in November 2007 for 3,506,180 Eastland shares issued as fully paid at a deemed issue price of 30 cents a share.

Star holds the exclusive rights to the intellectual property for the patented sub lingual delivered anti-malaria treatment Artimist for Africa.

Eastland chief executive officer Dermot Patterson said it was “an important step in our continuing organizational restructuring, as we have always recognized that Star would be an integral element of our overall strategy to expand our market penetration within Africa for Artimist”.

“It is important to us to continue to strengthen our position in Africa ahead of the market introduction of Artimist, our sub lingual delivered anti malaria treatment, which is currently preparing for phase III field trials in Africa,” Mr Patterson said.

Eastland was unchanged at 13 cents.

[BIOPROSPECT, SOLAGRAN](#)

The ANZ has reduced its substantial holding in Bioprospect from 97,491,926 shares (20.2%) to 86,291,926 shares (17.72%).

The shares were acquired following the collapse of Opes Prime Stockbroking.

The ANZ has disposed of most of the biotechnology shares acquired from Opes Prime, but the most recent substantial shareholder notice (May 15, 2008) said the bank still held 55,822,662 ordinary Solagran shares (42.4%) and 9,828,258 partly paid shares (20.4%).

Bioprospect climbed 0.1 cents or five percent to 2.1 cents.

Solagran fell 3.5 cents or 8.05 percent to 40 cents with 1.2 million shares traded.

[BIODIEM](#)

Biodiem has appointed Dr Andrew O’Brien as chief executive officer.

Dr O’Brien was appointed interim chief executive officer on September 7, 2007.

Biodiem fell 0.1 cents or 5.13 percent to 18.5 cents.