Biotech Daily

Friday July 18, 2014

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: BIOTRON UP 10%, LIVING CELL DOWN 20%**

*** PRANA SUB-ANALYSIS 'UNDERSTANDS' ALZHEIMER'S PLACEBO EFFECT**

*** REMINDER: BIO-MELBOURNE FIBROTECH $3m TO $81m+ BRIEFING**

MARKET REPORT

The Australian stock market was up 0.17 percent on Friday July 18, 2014 with the S&P ASX 200 up 9.3 points to 5,531.7 points.

Thirteen of the Biotech Daily Top 40 stocks were up, 16 fell, eight traded unchanged and three were untraded.

Biotron was the best, up one cent or 10 percent to 11 cents with 36,668 shares traded.

Clinuvel climbed 7.7 percent; Atcor, Compumedics and Oncosil were up more than six percent; Avita and Prana rose four percent or more; Ellex was up 2.8 percent; Alchemia, Phosphagenics and Viralytics were up more than one percent; with Benitec, Cochlear and Sirtex up by less than one percent.

Living Cell led the falls, down 1.4 cents or 20 percent, to 5.6 cents with 58,472 shares traded, followed by Uscom down 15.4 percent to 22 cents with 40,000 shares traded.

Bionomics lost 6.6 percent; Anteo fell 5.6 percent; Prima was down 4.55 percent; both Cellmid and Patrys fell 3.45 percent; Analytica, Nanosonics and Starpharma shed more than two percent; GI Dynamics, IDT, Mesoblast, Pharmaxis and Tissue Therapies were down more than one percent; with Acrux, CSL and Resmed down by less than one percent.

PRANA BIOTECHNOLOGY

Prana says that a sub-analysis has helped understand the placebo group response in its 42-patient phase II trial of PBT2 for Alzheimer's disease.

In April, Prana's imaging trial of PBT2 for Alzheimer's disease failed to meet its primary endpoint of reducing amyloid beta plaques and despite a reduction in the overall levels of plaques in Alzheimer's patients treated with PBT2, "the results were confounded by an atypical reduction of levels ... in the placebo group as well" (BD: Apr 1, 2014).

In April, Prana said that the 'Imagine' 12-month, phase II, imaging trial of PBT2 for Alzheimer's disease showed the drug did not meet its primary endpoint of a statistically significant reduction in the levels of beta-amyloid plaques in the brains of prodromal or mild Alzheimer's disease patients, as measured using Pittsburgh compound B (PiB) positron emission tomography (PET) standardized uptake value ratio (SUVR).

The company said at that time that no improvement was observed on the secondary endpoints of brain metabolic activity, cognition and function, but there was a trend towards preserving hippocampal brain volume in the PBT2 group.

Yesterday, Prana said that Florey Institute of Neuroscience's Prof Colin Masters included data from the trial and the 78-patient 2008 phase IIa Euro trial in a presentation entitled 'How to change and monitor the rates of [amyloid beta] amyloid accumulation and cognitive decline in Alzheimer's disease' at the Alzheimer's Association International Conference in Copenhagen, Denmark (BD: Feb 26, 2008; Jul 10, 2009).

Prana said that the primary objective of the Imagine trial was to explore whether amyloid burden, as measured by PiB-PET would decrease in participants treated with PBT2 relative to placebo, but in contrast to published literature, the average amyloid burden in the placebo group fell during the trial.

The company said it conducted a sub-analysis to better understand the behavior of the placebo group and what could be learned about the utility of exploratory biomarkers.

Prana said that Prof Masters' presentation noted that the baseline amyloid burden level in the PBT2-treated group had an important bearing on the decrease of amyloid over time ($p=0.035$), whereas there was no such correlation in the placebo group.

The company said that Prof Masters showed that in the subgroup of PBT2-treated patients with a baseline of SUVR above 2.5, there was a significant decrease in amyloid burden not seen in patients on placebo nor PBT2 participants with a SUVR less than 2.5.

Prana said the utility of PiB in small trials might be questioned, but the impact of baseline SUVR amyloid burden level on the response of a cohort was important for future trials.

The company said the data analysis confirmed the finding that there was a trend towards the preservation of brain volume in PBT2-treated patients compared to placebo.

Prana said that PBT2 prevented formation and toxicity of pathological amyloid beta species, primarily soluble oligomers, and promoted their clearance and Prof Masters proposed that the observed effect on amyloid burden was due to increased clearance by PBT2 of pools of PIB-detectable non-fibrillar soluble and membrane bound amyloid beta.

The company said that the trend towards reduced hippocampal atrophy seen in the PBT2 treatment group mirrored preclinical observations and reinforced a similar trend observed in the Reach2HD Huntington's disease study (BD: Feb 18, 19, 2014).

"Understanding the limitations of a small trial, the atypical placebo group response, previous clinical findings ... the company remains enthusiastic about the prospects of a large trial statistically powered to demonstrate cognitive benefit," Prof Masters said.

Prana said that 33 patients joined the open label extension trial with 21 identified as being randomized to the PBT2 treatment arm in the IMAGINE study and all 21 completing 14 months of PBT2 administration, 20 completing 18 months and nine completing 21 months.

Prana was up one cent or four percent to 26 cents.

BIO-MELBOURNE NETWORK

The Bio-Melbourne Network's July 31, 2014 Bio-Briefing will examine how Fibrotech achieved "such a stunning return" from $3 million in Federal Government funding.

In May, Fibrotech, funded with about $3 million in Federal Government backed-Innovation Investment Fund loans through the Medical Research Commercialization Fund and Uniseed, was acquired by Shire Plc for $US75 million ($A80.9 million) as an upfront fee to acquire the company, primarily for its FT011 oral anti-fibrotic drug (BD: May 2, 2014).

Biotech Daily believes the total value of the deal to be about $600 million and has already returned $24 million to the Federal Government, which axed the Innovation Investment Fund program in the May Budget (BD: May 14, 2014)

The Medical Research Commercialization Fund is managed by Brandon Capital.

Uniseed is a venture fund operating at the University of Melbourne, the University of Queensland and the University of New South Wales with capital provided by the universities and Australian Super.

Fibrotech said in May that Shire would also make payments for development and regulatory milestones and undertake the further development of FT011, which had completed a phase Ia study in healthy volunteers and was currently in a phase Ib study in patients with diabetic nephropathy (BD: Mar 4, 2014).

The Bio-Melbourne Network said the deal highlighted the success of the Medical Research Commercialisation Fund of which Fibrotech was its first investment.

The Network said that Fibrotech chief executive officer Prof Darren Kelly would discuss attracting the interest of pharmaceutical companies and striking such the deal.

The Network said that MCRF principal executive and Brandon Capital Partners managing director Dr Chris Nave would address the role that investors could play in guiding successful, early-stage biotechnology companies and what the industry could do to attract other investors to the sector.

The Briefing will be held at Nexia Australia, Level 18, 530 Collins Street, Melbourne on July 31, 2014 at 3:45pm for a 4pm start.

The Briefing until 5pm will be followed by networking drinks.

For more information and to book go to: http://www.biomelbourne.org/events/view/324.