

Biotech Daily

Thursday June 20, 2013

Daily news on ASX-listed biotechnology companies

- * ASX, BIOTECH DOWN: OPTISCAN UP 8%, IMPEDIMED DOWN 13%
- * PRANA'S PBT434 MODIFIES PARKINSON'S DISEASE IN MICE
- * PHARMAXIS STARTS EUROPEAN PAEDIATRIC BRONCHITOL CF TRIAL
- * CSIRO SPONSORS DEADLY AWARD FOR INDIGENOUS SCIENTISTS
- * AVEXA SIGNS DEAL WITH LINK FOR APRICITABINE
- * ALLAN GRAY TAKES 12.4% OF STARPHARMA
- * MCRAE TECHNOLOGY REDUCES BELOW 5% IN ALLIED HEALTH

MARKET REPORT

The Australian stock market followed Wall Street down 2.12 percent on Thursday June 20, 2013 with the S&P ASX 200 down 103.0 points to 4,758.4 points.

Six of the Biotech Daily Top 40 stocks were up, 21 fell, 10 traded unchanged and three were untraded. All three Big Caps defied the market and were up.

Optiscan was the best, up 0.6 cents or 7.9 percent to 8.2 cents with 70,000 shares traded, followed by Atcor up 7.1 percent to 7.5 cents with 186,467 shares traded.

Benitec climbed 6.25 percent; Benitec was up 5.7 percent; Alchemia and Psivida were up more than three percent; both Cochlear and Resmed rose one percent; with CSL up 0.9 percent.

Impedimed led the falls, down 1.5 cents or 13.0 percent to 10 cents with 161,000 shares traded.

Allied, Patrys and Sirtex lost more than seven percent; Pharmaxis fell 6.25 percent; Phylogica and Reva were down more than five percent; Ellex, Mesoblast and QRX fell more than four percent; Anteo, Avita, Clinuvel, Phosphagenics and Viralytics were down more than three percent; Living Cell shed 2.3 percent; Acrux, Prima and Universal Biosensors were down more than one percent; with Heartware and Starpharma down by less than one percent.

PRANA BIOTECHNOLOGY

Prana says PBT434 shows significant disease-modifying capability in mouse models of Parkinson's disease, with potential utility in a range of movement disorders.

Prana said the findings were presented in a poster entitled 'PBT434, a novel 8-hydroxyquinazolinone, preserves nigro-striatal circuitry, improves motor performance and inhibits alpha synuclein accumulation inanimal models of Parkinson's disease by modulation of iron homeostasis' at the Congress of Parkinson's Disease and Movement Disorders in Sydney by Victoria Mental Health Research Institute director Prof Colin Masters and the Florey Institute Parkinson's disease head Prof David Finkelstein. The company said that Parkinson's disease was caused by the death of specialized neurons in the region of the brain called the substantia nigra, the only part of the brain

neurons in the region of the brain called the substantia nigra, the only part of the brain where iron, the neurotransmitter dopamine and the alpha synuclein protein were all present at high concentrations.

Prana said that in Parkinson's disease, iron bound to dopamine, preventing it from functioning normally and creating toxic free radicals as well as iron also binding to alpha synuclein, causing it to aggregate, which was a well-established pathological feature of Parkinson's disease and a target for new disease-modifying therapies.

Prana said that PBT434 prevented alpha synuclein from aggregating and also prevented the toxic consequences of iron combining with dopamine.

The poster presentation concluded that iron was a component of the etiopathological cascade in Parkinson's disease and "PBT434 buffers iron to effectively reduce insoluble [alpha synuclein] formation in vivo and prevent [alpha synuclein] fibril formation in vitro". The poster said that compounds designed to target iron dyshomeostasis could preserve substantia nigra pars compacta neurons and striatal connectivity.

The poster concluded that iron chelation, that is depletion, was not required for therapeutic benefit and that neuronal survival was dose-dependent and correlated closely with improvement in motor function.

"PBT434 represents a plausible addition to current [Parkinson's disease] therapies," the poster concluded.

Prana said that the dose-dependent therapeutic benefit was "a further sign of the potential of PBT434 as an effective treatment" and increasing increments of the drug resulted in increased preservation of neurons and increased improvement in motor function. Prana executive chairman Geoffrey Kempler said the data was "highly positive and support the advancement of PBT434 as a first-in-class drug that could change the course of Parkinson's disease and related movement disorders".

"This would be a major step forward in therapy as existing treatments are focused on symptomatic relief and offer little in the way of halting neurodegenerative decline once it has begun," Mr Kempler said.

"The drug is progressing through the development process, with the aim of first clinical trials in 2015," Mr Kempler said.

"What we have known for some time is that dopamine and iron, together in the brain, form a combustible mix and this drives alpha synuclein aggregation and toxicity," Prof Finkelstein said.

"What we've seen with PBT434 is two beneficial modes of action," Prof Finkelstein said. "It prevents cell death by inhibiting the interaction between dopamine and iron and it also stops this accumulation of alpha synuclein," Prof Finkelstein said.

"This is the first molecule designed to inhibit the neurotoxic build-up of alpha synuclein in the brain and PBT434 could support the next generation for [Parkinson's disease] therapies," Prof Finkelstein said.

Prana was unchanged at 23 cents with 2.3 million shares traded.

PHARMAXIS

Pharmaxis says it has begun its 160-patient, phase II European paediatric clinical trial of Bronchitol for cystic fibrosis in patients aged six to 17 years.

Pharmaxis said it had enrolled the first subject and the trial, being conducted in Europe and Canada, and if positive, would form part of an application to extend European approval to children and adolescents.

The company said the 27-week, randomized, double-blind, crossover study of Bronchitol, administered twice daily, would assess improvements in lung function, treatment-induced sputum weight and safety and was expected to take 18 months to complete enrolment. Although the trial is pivotal for paediatric approval, Pharmaxis chief financial officer David McGarvey told Biotech Daily the study was correctly described as phase II because it was "a small scale study as requested by the regulator and does not have a long safety tail". Pharmaxis chief executive officer Gary Phillips said that six to 17 year old patients made up about "one-third of patients in the EU who could potentially benefit from Bronchitol". "It utilizes a number of different design features to overcome some of the issues seen in this age group in the earlier phase III studies," Mr Phillips said. "We expect it will provide important additional evidence on the performance of Bronchitol in the paediatric and adolescent population."

The company said that Bronchitol was approved for patients aged more than six years in Australia and for patients aged 18 years and over throughout the European Union. Pharmaxis fell one cent or 6.25 percent to 15 cents with 2.4 million shares traded.

THE COMMONWEALTH SCIENTIFIC AND INDUSTRIAL RESEARCH ORGANISATION

The Commonwealth Scientific and Industrial Research Organisation will sponsor the first Deadly Award for Scientist or Science Project of the Year.

The annual Deadly Awards are hosted by the indigenous-owned Sydney-based Gavin Jones Communications which owns the Deadly Vibe magazine.

Known as 'The Deadlys' the awards acknowledge Aboriginal and Torres Strait Islanders primarily involved in the arts, community affairs and sport with past winners including Gary Foley, Cathy Freeman, Kylie Belling, Deborah Mailman, Evonne Goolagong Cawley, Archie Roach, Geoffrey Gurrumul Yunupingu, Dan Sultan, Michael Long, Nathan Lovett-Murray and Michael O'Loughlin.

This year, the CSIRO has sponsored an award to recognize the contribution made by Aboriginal and Torres Strait Islander people working in science roles or science projects. CSIRO chief executive Dr Megan Clark said the awards aimed to showcase outstanding individuals and projects and encourage others to take on science careers.

"If we look here, just at CSIRO, we've got Aboriginal and Torres Strait Islander people working across a range of areas, including marine science, plant ecology, social sciences, ecosystems science, fire management and geography, and we know there are many more high achievers out there in the community," Dr Clark said. "We want people to tell us about the outstanding indigenous scientists and science projects in their communities so they can be recognized at these national awards."

"Our sponsorship of the Deadlys is one more step we're taking to help close the gap between indigenous and non-indigenous Australians and we're hoping to inspire all Australians about the benefits of science at the same time," Dr Clark said.

Nominations for the Scientist or Science Project of the Year can be made on the Deadlys website http://www.deadlys.com.au/nominate and close on June 30, 2013.

Five finalists will then be selected by the Deadlys Academy, with the winner announced at the Sydney Opera House on September 10, 2103.

AVEXA

Avexa says it has signed a binding deal with the Sydney-based Link Healthcare Pte Ltd to develop and commercialize apricitabine (ATC) for HIV.

Avexa did not disclose the value of the deal.

The company said that the Link collaboration covered the development, registration and commercialization of ATC worldwide, including North America and Europe but excluding certain territories for which regional partners were previously announced, but did not specify Link's financial commitment.

Avexa chairman Iain Kirkwood said that "in parallel with completing the final clinical development, the company has initiated the requisite steps to commence the manufacture of ATC for both the remaining clinical development and for potential early clinical requests for treatment doses"

"Link has a proven track record of marketing specialist products in niche disease areas and growing substantial sales for these products in markets around the world" Mr Kirkwood said.

"Link is particularly strong through their South African, Australian, Asian and Japanese subsidiaries," Mr Kirkwood said.

Link executive chairman John Bacon said that ATC had "a potentially important role in the treatment of a well-identified subset of HIV patients".

"The combination of our core focus on specialist medicines and an existing competence in supply of anti-retrovirals in Southern Africa puts us in a good position to work with Avexa to see ATC through the final stages to commercialization".

Avexa was up 0.1 cents or 6.7 percent to 1.6 cents with 1.6 million shares traded.

STARPHARMA

Allan Gray Australia (formerly Orbis Investment Management) has increased its holding in Starpharma from 32,269,032 shares (11.38%) to 35,194,434 shares (12.41%).

Allan Gray said that it acquired 2,925,402 shares between May 24 and June 17, 2013 for \$2,474,798, or an average price of 84.6 cents a share.

Las month Allan Gray increased its Starpharma holding from 23,151,172 shares (9.45%) to 32,269,032 shares (11.38%), with the largest transaction the acquisition of 3,997,366 shares for \$4,609,047 or an average price of \$1.153 a share (BD: May 22, 2013). Starpharma fell 0.5 cents or 0.6 percent to 78.5 cents.

ALLIED HEALTHCARE GROUP

The Western Australia-based McRae Technology said it had reduced its holding in Allied health from 63,104,149 shares (6.1%) to 51,264,889 shares (4.96%).

McRae said that between June 4 and 18, 2103 it sold 11,839,260 shares for \$606,849 or an average price of 5.1 cents a share.

Allied Health fell 0.4 cents or 7.7 percent to 4.8 cents with 12.7 million shares traded.