

Biotech Daily

Friday May 3, 2013

Daily news on ASX-listed biotechnology companies

* ASX, BIOTECH EVEN: PSIVIDA UP 21%, COMPUMEDICS DOWN 20%

* MELBOURNE UNI IMPLANT STUDY PREDICTS EPILEPSY SEIZURES

- * GENETIC TECHNOLOGIES SIGNS CALIFORNIA PROVIDER NETWORK
- * LLOYDS & CASSANOVE TAKES 18% OF CYCLOPHARM
- * PERPETUAL TAKES 9% OF SIRTEX
- * CLINUVEL TAKES CAPITAL RAISING TRADING HALT TO SUSPENSION
- * BIO-MELBOURNE PATENT STRATEGY BRIEFING

MARKET REPORT

The Australian stock market was flat on Friday May 3, 2013, with the S&P ASX 200 down half a point or 0.01 percent to 5,129.5 points.

Eleven of the Biotech Daily Top 40 stocks were up, 11 fell, 12 traded unchanged and six were untraded. All three Big Caps were up.

Psivida was the best, up 42 cents or 20.7 percent to \$2.45, with 16,074 shares traded, followed by Genetic Technologies up 14.3 percent to eight cents with 448,934 shares traded and QRX up 14.0 percent to \$1.22 with 90,138 shares traded.

Medical Developments climbed 5.5 percent; Cellmid was up 4.2 percent; Atcor, Pharmaxis and Tissue Therapies were up more than three percent; Heartware rose 2.6 percent; Anteo, CSL, Mesoblast and Resmed were up more than one percent; with Cochlear up 0.6 percent.

Compumedics led the falls, down one cent or 20 percent to four cents with 6,400 shares traded.

Benitec lost 7.1 percent; Alchemia fell four percent; Living Cell, Optiscan, Osprey, Prana and Prima shed more than two percent; Acrux was down one percent; with Sirtex and Starpharma down by less than one percent.

UNIVERSITY OF MELBOURNE, ST VINCENT'S HOSPITAL

The journal Lancet Neurology says that Melbourne researchers working with Neurovista have shown that a brain implanted device can accurately predict epileptic seizures. A Lancet media release said that the 15-patient, proof-of-concept study by the University of Melbourne's Prof Mark Cook at St Vincent's Hospital in collaboration with the Seattle, Washington-based Neurovista had shown for the first time shown that an implanted device predicted seizures in some adults who had epilepsy that did not respond to drugs. The article, entitled 'Prediction of seizure likelihood with a long-term, implanted seizure advisory system in patients with drug-resistant epilepsy: a first-in-man study' was published in the Lancet Neurology and the article is available at:

http://www.thelancet.com/journals/laneur/article/PIIS1474-4422%2813%2970075-9/fulltext Prof Cook told Biotech Daily that his team was working with the Centre for Neural

Engineering, part of the University of Melbourne's Faculty of Engineering. "We are assisting in the analysis of the trial data and developing a more accurate algorithm for better prediction of seizures," Prof Cook said.

Prof Cook said that the device consisted of an electrode implanted beneath the skull and over the surface of the cortex with a lead to a wireless transmitter below the clavicle. "Knowing when a seizure might happen could dramatically improve the quality of life and independence of people with epilepsy and potentially allow them to avoid dangerous situations such as driving or swimming, or to take drugs to stop seizures before they start, rather than continuously as at present," Prof Cook said in the Lancet media release. The Lancet said that the Neurovista technology was designed to detect abnormal electrical activity that preceded a seizure and colored lights warned patients of the high (red), moderate (white), or low (blue) risk of an impending seizure.

The Lancet said the study, of 15 people with focal epilepsy aged 20 to 62 years who had between two and 12 seizures a month and had not had their seizures controlled despite use of at least two anti-epileptic drugs, correctly predicted seizures with a high warning sensitivity greater than 65 percent and worked to a level better than chance in 11 of the 15 adults.

The Lancet said the technology appeared to be relatively safe, with a similar safety profile to other implanted devices, with three patients experiencing serious device-related adverse events and two requiring the device be removed.

The study also showed substantial disparities between reported and detected events, with most participants greatly underestimating the number of their seizures and one patient reported 11 seizures a month who actually had 102 seizures.

A Lancet Neurology editorial said the research was "a major milestone in epileptology, showing for the first time (to our knowledge) that prospective seizure prediction is possible" and that with the exception of a few articles, published studies either neglected or failed to show that a prediction technique was significantly better than chance.

The editorial said that the article contained the second interesting finding that seizure diaries - currently the gold standard for assessment of any type of therapeutic intervention in epilepsy - were unreliable.

When comparing documentation of seizures by intracranial EEG against documentation by patients during several months, the patients' records substantially underestimated the frequency of seizure occurrence and the authors reported that "reported and actual events varied unpredictably within patients from month to month", the editorial said.

For the first time, the unreliability of seizure counting in patients with epilepsy has been shown objectively during several months, the editorial said.

More than 60 million people worldwide have epilepsy with up to 40 percent unable to control their seizures with existing treatments, the Lancet said.

GENETIC TECHNOLOGIES

Genetic Technologies says it has executed an agreement with the Chula Vista, Californiabased Three Rivers Provider Network for its Brevagen breast cancer tests. Genetic Technologies said that Three Rivers claimed to be the largest supplemental preferred provider organizations network foundation in the US, providing healthcare benefits to more than 10 million members, at more than one million locations. The company said that Brevagen patients covered by insurers that were part of the Three Rivers Provider Network would have their claims adjudicated as 'in-network', expediting the claim processing at an agreed discount. Genetic Technologies said the agreement with Three Rivers was the fifth such credentialing agreement and increased the total number of covered lives, for which its Brevagen test could be adjudicated as in-network, to more than 23 million people.

The company said that the impact of the credentialing had been demonstrated in reviewing reimbursement claims for the Brevagen test since its launch.

Genetic Technologies said that in its March 2013 Appendix 4C Quarterly Activities Report, the average reimbursement received in respect of claims adjudicated as innetwork was more than 25 peercent higher than the amounts received for claims that were adjudicated as out of network, with the time taken to collect the funds materially shorter. The company said that once Brevagen sample volumes reached a significant level and it had gathered any necessary clinical utility data, it would approach insurers directly. Genetic Technologies said that a preferred provider organization was a managed care organization of medical doctors, hospitals and other health care providers who had agreed with an insurer or a third-party administrator to provide health care at reduced rates to the insurer's or administrator's clients and contracts with preferred provider organizations were fundamental to having claims adjudicated in-network.

Genetic Technologies was up one cent or 14.3 percent to eight cents.

CYCLOPHARM

Lloyds & Cassanove Investment Partners has increased its substantial shareholding in Cyclopharm from 9,717,600 shares (16.7%) to 10,186,974 shares (17.7%). The London-based Lloyds & Cassanove said that between February 18 and April 30, 2013 it acquired 469,374 shares for \$72,406 or an average price of 15.4 cents a share. Lloyds & Cassanove held 10.5 percent of Cyclopharm in February 2012, increasing to 13.5 percent in September and 16.7 percent in December 2102 (BD: Sep 20, 2102). Cyclopharm was untraded at 18 cents.

SIRTEX MEDICAL

Perpetual and its subsidiaries have increased their substantial shareholding in Sirtex from 4,376,914 shares (7.85%) to 5,095,042 shares (9.14%).

Perpetual said that the 718,128 shares were bought on May 1, 2013 at \$9.60 a share. Sirtex fell one cent or 0.1 percent to \$9.85.

CLINUVEL PHARMACEUTICALS

Clinuvel has requested a voluntary suspension to follow the trading halt requested on May 1 "regarding a proposed capital raising" (BD: May 1, 2013). Clinuvel last traded at \$1.85.

BIO-MELBOURNE NETWORK

The Bio-Melbourne Network will analyze the recent changes to patent law at their 'Rethinking your patent strategy' Bio-Briefing on May 9, 2013.

Bio-Melbourne chief executive officer Michelle Gallaher said that in March "the US made dramatic changes to its patent law which will have profound effects upon patent owners ... followed by the Raising the Bar Act in Australia that came into force on April 15".

"There is also ongoing debate regarding the patent eligibility of genetic and other biological materials, with litigation cases in Australia and the US relating to Myriad's breast cancer diagnostics and the follow-on effects of the US decision in Mayo v Prometheus – all of which stand to have major implications for Australia life science companies protecting their [intellectual property]," Ms Gallaher said.

The Network said that Davies Collison Cave partners Michael Caine, Dr Bill Pickering and Dr Tania Obranovich would highlight the most important aspects of these major changes including an update on the current Pharmaceutical Patent Review Panel draft report. The Network said that the panel would provide recommendations as to how patent protection and enforcement strategies need to be modified to meet the challenges of this rapidly changing landscape.

The Bio-Briefing will be held at Davies Collison Cave, 1 Nicholson St, Melbourne on May 9, 2013 with registration from 3:45pm for a 4pm - 5:30pm presentation.

For more information and to book go to: <u>http://www.biomelbourne.org/events/view/275</u>.