



Biotech Daily

Friday September 5, 2014

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH DOWN: PRANA UP 35%, ACRUX DOWN 16%**
- * **FEDERAL COURT BACKS MYRIAD, GENETIC TECHNOLOGIES BRCA CASE**
- * **FDA ORPHAN STATUS FOR PRANA PBT2 FOR HUNTINGTON'S DISEASE**
- * **CORRECTION: REPRODUCTIVE HEALTH**
- * **BIONOMICS RECEIVES \$7.5m FEDERAL R&D TAX REFUND**
- * **WESTPAC, ASSOCIATES TAKE 6% OF MAYNE PHARMA**

MARKET REPORT

The Australian stock market fell 0.58 percent on Friday September 5, 2014 with the S&P ASX 200 down 32.6 points to 5,598.7 points.

Ten of the Biotech Daily Top 40 stocks were up, 15 fell, nine traded unchanged and six were untraded. All three Big Caps fell.

Prana was the best, up as much as 11.4 cents or 47.3 percent to 35.5 cents before closing up 8.5 cents or 34.7 percent to 33 cents with 9.1 million shares traded.

Patrys climbed 9.5 percent; Genetic Technologies was up 8.7 percent; Clinuvel and Universal Biosensors rose more than five percent; Biotron was up 4.35 percent; Cellmid was up 3.1 percent; Analytica and Nanosonics climbed two percent or more; with Bionomics up 0.8 percent.

Acrux led the falls following its removal from the Dow-Jones S&P ASX All Australian 200 Index, down 30 cents or 15.7 percent to \$1.61 with 5.1 million shares traded, followed by Tissue Therapies down 10.1 percent to 40 cents with 781,652 shares traded.

Admedus and Impedimed lost more than six percent; Circadian fell 5.3 percent; Mesoblast fell 4.9 percent; Antisense and Benitec were down more than three percent; Alchemia, Atcor and Prima shed more than two percent; with Cochlear, CSL, GI Dynamics, Pharmaxis, Resmed, Sirtex and Viralytics down by more than one percent.

GENETIC TECHNOLOGIES

The Full Bench of the Federal Court has dismissed an appeal against last year's decision supporting Myriad Genetics right to patent biological materials.

In 2013 in the Federal Court in Sydney, Judge John Nicholas dismissed the application brought by Yvonne D'Arcy, Cancer Voices Australia and others against Myriad, Genetic Technologies and others, alleging that the BRCA1 patent held by Myriad and Genetic Technologies, known as Patent 686,004, was invalid, with Justice Nichols saying that isolating DNA and RNA was a manner of manufacture (BD: Feb 21, 2012; Feb 15, 2013). The then Genetic Technologies chief executive officer Dr Paul MacLeman told Biotech Daily in 2012 that although his company was a party to the proceedings it had "no economic interest in the outcome".

Justice Nichols dismissed the case and Ms D'Arcy appealed to the Full Bench of the Federal Court.

Today the Full Bench of the Federal Court dismissed the appeal.

The detailed decision is at: <http://bit.ly/1rbSwEC>.

Genetic Technologies chief executive officer Alison Mew told Biotech Daily today that the BRCA patents protected the intellectual property in Australia until December 2015, but her company had amended the Myriad licence to a distribution agreement.

Genetic Technologies was up 0.2 cents or 8.7 percent to 2.5 cents.

PRANA BIOTECHNOLOGY

Prana says that the US Food and Drug Administration has granted orphan drug designation to PBT2 for the treatment of Huntington's disease.

Prana said that orphan drug designation was granted by the FDA to promote the development of drugs for diseases affecting fewer than 200,000 people in the US and entitled the company to seven years of market exclusivity for the use of PBT2 in the treatment of Huntington's disease, protocol assistance by the FDA to optimize drug development in the preparation of a dossier that will meet regulatory requirements, and reduced fees associated with applying for market approval.

The company said it would apply for orphan designation in Europe and other jurisdictions.

Prana said that Huntington's disease was a neurodegenerative genetic disorder that affected muscle coordination and led to cognitive decline and behavioral symptoms.

The company said that more than 30,000 people in the US had Huntington's disease and there were no treatments for the cognition or executive function symptoms of the disease.

Prana said that in February 2014 that its lead metal protein attenuating compound PBT2 had met its primary end point of safety and tolerability, with improved measures of cognitive performance in its phase II trial of PBT2 in 109 people with Huntington's disease (BD: Feb 18, 19, 2014).

Prana executive chairman Geoffrey Kempler said that the FDA orphan drug designation was "a reflection of the high unmet need for neurological drugs that can slow, halt or improve the decline of cognition and allow sufferers to have a better quality of life".

"We are very pleased to have received orphan drug designation from the FDA, which is a highly important input to determining the commercialization pathway for PBT2 for the treatment of Huntington's disease, and to bring to market as quickly as possible an improved treatment for people suffering from Huntington's disease," Mr Kempler said.

Prana said it was preparing its post-phase II trial dossier for submission to the FDA to begin discussions on the next development steps for PBT2.

Prana climbed as much as 11.4 cents or 47.3 percent to 35.5 cents before closing up 8.5 cents or 34.7 percent to 33 cents with 9.1 million shares traded.

REPRODUCTIVE HEALTH SCIENCE

Yesterday's report on Reproductive Health's Melbourne presentation included several small but important errors of fact.

The company expects to be profitable in 2017, not by 2017, as reported.

Reproductive Health chief executive officer Dr Michelle Fraser has told Biotech Daily that the Embryocollect system was intended to be cheaper, easier to use and simpler to read than competitor products and that was being assessed by the clinics.

Dr Fraser said that the kits cost \$3,600 each, rather than providing 20 embryo tests at \$180 per embryo, as reported, and that the list price of the lead competitor Illumina's 24Sure was \$360 per embryo, which provided more detailed data information from its micro-array, not gene sequencing, as reported.

Dr Fraser said the company did not have ethics approvals from the 10 clinics referred to in the article, but was in discussions with those clinics, and emphasized that her company hoped to take 10 percent of the in-vitro fertilization testing market, which was expected to grow to 20 percent of the in-vitro fertilization market which, in turn, was expected to grow to \$21.6 billion by 2020.

The mistakes were made by the former Thursday sub-editor and Biotech Daily apologizes unreservedly.

Reproductive Health fell one cent or five percent to 19 cents.

BIONOMICS

Bionomics says it has received \$7.5 million from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Bionomics said the rebate related to research and development expenditure for the year to June 30, 2014.

Bionomics chief executive officer Dr Deborah Rathjen said that the Australian R&D Tax Incentive was "an important factor contributing to the success of Bionomics' partnering strategy".

"The cash refund enables Bionomics to undertake additional [research and development] than would otherwise be possible," Dr Rathjen said.

Bionomics was up half a cent or 0.8 percent to 60.5 cents.

MAYNE PHARMA

Westpac Banking Corp and associates have increased their substantial holding in Mayne Pharma from 29,924,517 shares (5.10%) to 36,723,857 shares (6.26%).

Westpac said shares were bought by Advance Asset Management, Asgard Capital Management, BT Funds Management, BT Investment Management ANZ Bank, the National Australian Custodial Services, National Nominees and National Australia Bank.

Westpac said that BT Investment Management bought the largest number of shares for the National Australia Bank between February 19 and April 8, 2014, acquiring 11,782,894 shares for \$8,477,255 or an average price of 71.95 cents a share

Mayne fell half a cent or 0.7 percent to 74 cents with 1.6 million shares traded.