



# Biotech Daily

Wednesday October 30, 2013

*Daily news on ASX-listed biotechnology companies*

- \* **ASX UP, BIOTECH DOWN: PHARMAXIS UP 8%, ALCHEMIA DOWN 10%**
- \* **AUSBIOTECH BRISBANE CONFERENCE OPENS**
- \* **FDA ORPHAN STATUS FOR NEUREN NNZ-2566 FRAGILE X TRIAL**
- \* **WEHI'S PROF TERRY SPEED WINS \$300k PM'S SCIENCE PRIZE**
- \* **REGENEUS HIQCELL ARTHRITIS TREATMENT IN MELBOURNE**
- \* **PHARMAXIS OPTS FOR NOVAQUEST'S \$42m**
- \* **IMPEDIMED APPOINTS INVESTIGATORS FOR PIVOTAL TRIAL**
- \* **DSM TO MANUFACTURE CIRCADIAN, OPTHEA OPT-302 (VGX-300)**
- \* **IMMURON AGM FOR 18m DIRECTOR, CFO SHARES, 55m OPTIONS**
- \* **PROCTOR & GAMBLE PROMOTES ISONEA AIRSONEA TO WOMEN**
- \* **CELLMID TO RELEASE 10m ADVANGEN ESCROW SHARES**
- \* **NOVOGEN APPOINTS LIONEL MATEO JOINT CO SEC**
- \* **BIODIEM HAS ONE QUARTER CASH, DELISTING**

## MARKET REPORT

The Australian stock market was up 0.28 percent on Wednesday October 30, 2013 with the S&P ASX 200 up 15.4 points to 5,430.9 points. Ten of the Biotech Daily Top 40 stocks were up, 14 fell, 15 traded unchanged and one was untraded.

Pharmaxis was the best, up one cent or 8.3 percent to 13 cents with 6.4 million shares traded. Universal Biosensors climbed 5.1 percent; Genetic Technologies, Patrys and Phylogica were up four percent or more; Atcor, Ellex and Mesoblast were up more than three percent; Resmed rose 2.45 percent; Acrux was up 1.5 percent; with CSL and Osprey up by less than one percent.

Alchemia led the falls, down six cents or 10 percent to 54 cents with 527,092 shares traded. Both Benitec and Phosphagenics lost 6.9 percent; Medical Developments and Prima fell more than five percent; Avita lost 4.35 percent; Bionomics shed 2.1 percent; Clinuvel, Nanosonics, QRX, Reva and Viralytics were down more than one percent; with Cochlear and Sirtex down by less than one percent.

## AUSBIOTECH

Ausbiotech says that its Brisbane national conference opened today at the Brisbane Convention and Exhibition Centre, returning to Queensland for the first time since 2007. An Ausbiotech spokesperson told Biotech Daily that about 1,000 delegates were participating in the conference.

In an Ausbiotech media release, Queensland Minister for Science and Innovation Ian Walker said his Government welcomed the opportunity for the state to host the event. "This is a great opportunity for Queensland researchers and life sciences companies to network with other industry leaders," Mr Walker said.

"Our scientists are working on everything from therapeutics, diagnostics and vaccine development, to adult stem cell technology, ag-biotech, and tropical health - so the sector has vast potential for increased revenue and job creation for the future," Mr Walker said. Ausbiotech said that Queensland's life sciences industry had 252 companies, 86 core biotechnology companies and 47 biotechnology-related research institutes, generating about \$4.36 billion in 2011.

Mr Walker said Queensland had welcomed an integrated approach to medical research, with new clinically focused models including the Translational Research Institute, the Wesley Research Institute and the Queensland Institute of Medical Research Berghofer Medical Research Institute.

Ausbiotech chief executive officer Dr Anna Lavelle said Queensland was a leader in supporting robust biotechnological inventions through to commercialization.

"We are delighted to bring this year's conference to Brisbane, which is one of Australia's most active hubs for research and development, innovation and commercial development in the biotechnology sector," Dr Lavelle said.

Ausbiotech said that as part of the conference launch, delegates would tour the DSM Biologics facility which was the result of a collaboration between DSM Biologics and Biopharmaceuticals Australia, funded by the Queensland and Federal Government.

Ausbiotech said the conference would focus on changing international laws and regulations; the influence of social and digital media in developing biotechnology; the global economic landscape; techniques to successfully source capital and fund good ideas; and government policy supporting the development of the bio-economy.

The Ausbiotech conference continues until November 1, 2013.

## NEUREN PHARMACEUTICALS

Neuren says that the US Food and Drug Administration has granted orphan drug designation to NNZ-2566 for treatment of Fragile X syndrome.

Neuren said that orphan drug designation was granted to drugs to treat a rare disease or condition and qualified the sponsor of the drug for seven years of marketing exclusivity following approval as well as development incentives, including waiver of the prescription drug user fee for a marketing application.

The company said its Fragile X syndrome development program also had FDA fast track designation, which was designed to expedite the development and review of important new medicines.

Neuren said it would begin a phase II double-blind, placebo-controlled trial of NNZ-2566 in Fragile X syndrome in December 2013, with enrolment expected to be completed by the end of 2014 and top-line results by July 2015.

The company said that the study was designed to assess the safety, tolerability and efficacy of NNZ-2566 in treating symptoms of Fragile X syndrome.

Neuren was unchanged at 12 cents with 17.9 million shares traded.

## FEDERAL GOVERNMENT, WALTER AND ELIZA HALL INSTITUTE

The \$300,000 Prime Minister's Prize for Science will be awarded to the Walter and Eliza Hall Institute's Prof Terry Speed at Parliament House in Canberra tonight.

A media release from Science in Public on behalf of the Department of Industry said that Prof Speed had used mathematics and statistics to assist farmers, miners and criminologists and paved the way to modern biology and personalized medicine by interpreting the actions of thousands of genes.

The media release said that Prof Speed was using statistical analyses to evaluate which cancers were lethal and which did not require surgery.

The Department of Industry said that University of New South Wales' Prof Angela Moles would be awarded the \$50,000 Frank Fenner Prize for Life Scientist of the Year for work on plant defences, seed variation and ecosystems adaptation to a changing climate.

The media release said that the University of New South Wales Prof Andrea Morello won the \$50,000 Malcolm McIntosh Prize for Physical Scientist of the Year for work in quantum computing; Richard Johnson from Perth's Rostrata Primary School won the Prime Minister's Prize for Excellence in Science Teaching in Primary Schools for a model science laboratory and would share the \$50,000 prize with the school; and Townsville State High School Sarah Chapman won the Prime Minister's Prize for Excellence in Science Teaching in Secondary Schools, sharing the \$50,000 prize money with her school for creating science that students "can see and touch", studying the impact of the V8 Supercar races, held at the school and its environs, on nearby mangroves.

## REGENEUS

Regeneus says its Hiqcell fat-derived stem cell treatment for arthritic joints is available at Melbourne's Bounce Health Group.

The Eastern suburbs Bounce Health describes itself as a "sports physiotherapy clinic specializing in sports medicine, physiotherapy and other allied health and sports science". Regeneus said that Bounce sports and exercise physician Dr Philip Bloom would work in conjunction with Linley Clinic Private Hospital, where state-of-the-art cell-processing laboratory had been established.

The company said it had equipped and staffed the laboratory to enable registered medical specialists to treat patients with the Hiqcell stem cell therapy for musculoskeletal conditions.

Regeneus said that since 2011 the treatment had been used on more than 350 people and more than 800 arthritic joints.

The company said it had developed "a best in class procedure and manufacturing protocol for safe cell harvest, optimal cell yield in 60 minutes processing time and the option for storing patient's stem cells for future re-injections".

Regeneus said that the Hiqcell treatment involved harvesting a small amount of a patient's own stem cells from adipose, or fat, tissue and after separating and concentrating the regenerative cells they were re-injected in osteo-arthritic affected joints such as knees, hips and ankles.

The company said that the treatment "reduces inflammation and repairs damaged tissue" and was carried out under the supervision of the treating medical specialist.

Dr Bloom said that Hiqcell "provides a viable treatment option for mid-stage age or impact related [osteo-arthritis] patients who might otherwise face ongoing debilitating pain, loss of function, the inability to play sport and reduced quality of life".

Regeneus was up one cent or 4.1 percent to 25.5 cents.

## PHARMAXIS

Pharmaxis says it has elected for the full \$US40 million (\$A42 million) allowed under its agreement with Novaquest to fund its US approval of Bronchitol (BD: Jan 31, 2013). Pharmaxis said that the initial investment of \$US20 million was made by Novaquest in February 2013 and an additional \$US20 million investment was subject to Pharmaxis meeting certain commercial and regulatory performance criteria including randomization of the first patient into a US pivotal phase III clinical trial of Bronchitol for cystic fibrosis by October 17, 2014.

The company said it had until October 29, 2013 to advise Novaquest whether it wanted to reduce the additional \$US20 million investment and had elected for the full amount. Pharmaxis said it would receive the additional \$US20 million investment after the first patient was randomized into the US phase III trial required by the US Food and Drug Administration and it would be paid in four equal instalments of \$US5 million, each three months apart.

The company said that, in return, Novaquest received quarterly payments based on Bronchitol sales in the US and European Union, determined by reference to sales revenue tiers and corresponding annual payment percentages which varied between the US and EU and over the term of the agreement to reflect the expected growth in Bronchitol sales. Pharmaxis said that the agreement had a term of eight years in the EU and seven years from the launch of Bronchitol in the US.

Pharmaxis chief executive officer Gary Phillips said that the Novaquest agreement "was a prudent decision".

"We have accessed an innovative financing source and begun transitioning the Pharmaxis business model to the use of non-equity funding for the development of the company's assets," Mr Phillips said.

Pharmaxis was up one cent or 8.3 percent to 13 cents with 6.4 million shares traded.

## IMPEDIMED

Impedimed said it has appointed Prof Sheila Ridner and Dr Frank Vicini to lead a pivotal five-year, multi-center clinical trial studying lymphoedema patient outcomes.

Impedimed said that the Nashville Tennessee-based Vanderbilt University School of Nursing's Prof Ridner would be the principal investigator

The company said that Prof Ridner had been involved in lymphoedema research since 2000 and a member of the National Lymphedema Network since 2001 and chaired the subcommittee for the Lymphedema Measurement Guidelines National Accreditation Program for Breast Centers and Protocol Development (BD: Apr 28, 2011).

Impedimed said that radiation oncologist Dr Vicini would act as co-investigator.

The company said that Dr Vicini had held "multiple academic appointments, authored over 200 peer-reviewed articles and been involved in numerous clinical studies focusing on breast cancer" and was currently the principal investigator of several National Institutes of Health trials.

Impedimed chief executive officer Richard Carreon said the pivotal trial would help establish L-Dex as the standard of care for all cancer patients at risk of developing lymphoedema.

Mr Carreon told Biotech Daily that he expected to enrol the first patient in the trial in 2014.

Impedimed was unchanged at 17 cents.

## CIRCADIAN TECHNOLOGIES

Circadian says that wholly-owned subsidiary Opthea has contracted DSM Pharmaceutical Products to manufacture its lead compound for age-related macular degeneration. Circadian said that the contract covered process development and manufacture of Opthea's OPT-302, formerly known as VGX-300, a soluble form of human vascular endothelial growth factor-3 (VEGFR-3) for wet or neovascular age-related macular degeneration.

The company said the agreement was "a significant milestone" in the development of OPT-302 which was on-track for a phase I trial by early 2015.

Circadian said that OPT-302 was a soluble receptor that specifically and potently blocked the activity of VEGF-C and VEGF-D that were involved in the progression of both retinal and corneal diseases.

Circadian was unchanged at 24.5 cents.

## IMMURON

Immuron will vote to grant directors and the CFO Solution 18,229,167 shares and 55,000,000 options in lieu of fees and wages.

Immuron said it proposed to grant 8,750,000 shares at 0.4 cents each to Grandlodge Pty Ltd a company associated with director Stephen Anastasiou.

The company said it proposed to issue 10,000,000 options to Mr Anastasiou exercisable at 50 percent above the share price on the date of issue, within three years.

Immuron proposed to issue chairman Dr Roger Aston 2,604,167 shares at 0.6 cents each and 20,000,000 options exercisable at 50 percent above the share price on the date of issue, within three years.

The company said it proposed to issue director Daniel Pollock 1,875,000 shares and 10,000,000 options on the same terms.

The company's notice of meeting said it would also seek shareholder approval to issue the CFO Solution Partners 5,000,000 shares and 15,000,000 options on the same terms and re-elect directors Mr Anastasiou and Mr Pollock.

The meeting will be held at K&L Gates, Level 25, South Tower, 525 Collins Street, Melbourne on November 29, 2013 at 10am (AEDT).

Immuron was up 0.1 cents or 14.3 percent to 0.8 cents with 1.3 million shares traded.

## ISONEA

Isona says Procter & Gamble's Tremor division will promote Airsona to women with asthma and mothers of children with asthma.

Isona said that Tremor used research and community-based social marketing strategies "to engage volunteer advocates and create positive word-of-mouth for select brands of interest to their consumer social network".

Isona chief executive officer Michael Thomas said that working with Tremor to create awareness and experience with Airsona among women would play a significant role in the 2014 US launch of the wheeze monitoring device, once US Food and Drug Administration regulatory clearance was achieved.

"This presents a tremendous opportunity to develop positive word-of-mouth advocacy among women with asthma and mothers of children with asthma," Mr Thomas said.

Biotech Daily asked Isona who would market Airsona to men with asthma and fathers of children with asthma, but a reply was not received at the time of publication.

Isona fell five cents or 7.1 percent to 65 cents.

### CELLMID

Cellmid says that 10,217,822 shares will be released from voluntary escrow on November 20, 2013.

Cellmid said that the shares were issued on May 20, 2013 as part consideration for the acquisition Japan's Advangen (BD: May 28, 2013).

The company said that following the release of these shares from escrow and a further 38,019,802 shares continuing in escrow until April 2014, there would be 650,470,078 shares available for trading on the ASX.

Cellmid was unchanged at 4.1 cents with 2.2 million shares traded.

### NOVOGEN

Novogen says that Lionel Mateo was appointed joint company secretary, joining company secretary Andrew Bursill on October 8, 2013.

Novogen said that Mr Mateo holds a Bachelor and a Masters Degree in Law from France's Université Paul Cézanne Aix-en-Provence.

The company said that Mr Mateo previously was company secretary of RM Williams Agricultural Holdings.

Novogen fell 2.5 cents or 9.6 percent to 23.5 cents.

### BIODIEM

Biodiem says its net operating cash burn for the three months to September 30, 2013 was \$545,000 with cash at the end of the quarter of \$621,000.

Biodiem is expected to delist from the ASX on November 15 (BD: Oct 28, 2013).

Biodiem fell 0.1 cents or 2.4 percent to four cents.