



Biotech Daily

Wednesday September 4, 2013

Daily news on ASX-listed biotechnology companies

- * **ASX UP, BIOTECH DOWN: PRANA UP 8.5%, TISSUE THERAPIES DOWN 7%**
- * **ELLEX RECRUITS 50 PATIENTS, ADDS 2 SITES TO 2RT AMD TRIAL**
- * **PARKINSON'S UK GRANTS \$260k FOR PRANA PBT434 STUDY**
- * **MEXICO APPROVES ATCOR'S SPHYGMOCOR XCEL**
- * **NSW \$3.25m FOR CHRONIC DISEASE**
- * **ISONEA: AIRSONEA CE MARK DOCUMENTS FILED**
- * **CELLMID REVENUE UP 344% to \$761k, LOSS DOWN 22% TO \$1.5m**
- * **AUSBIOTECH BRISBANE CONFERENCE: 'BIO-ECONOMY IN TRANSITION'**
- * **AUSTRALIAN MUSEUM EUREKA PRIZES TONIGHT**

MARKET REPORT

The Australian stock market fell 0.67 percent on Wednesday September 4, 2013 with the S&P ASX 200 down 35.0 points to 5,161.6 points.

Eight of the Biotech Daily Top 40 stocks were up, 15 fell, 10 traded unchanged and seven were untraded.

Prana was the best, up five cents or 8.5 percent to 64 cents with 1.1 million shares traded, followed by Avita up 8.3 percent to 13 cents with 566,703 shares traded.

Neuren climbed 6.1 percent; Impedimed was up 5.9 percent; Compumedics, Ellex and Starpharma were up three percent or more; with Medical Developments up 0.3 percent.

Tissue Therapies led the falls, down 2.5 cents or 6.85 percent to 34 cents with 326,237 shares traded.

Clinuvel and Optiscan lost more than five percent; Allied Health fell 4.8 percent; Acrux, Osprey, Phosphagenics, Reva and Sirtex were down more than three percent; Cochlear, Heartware, Mesoblast, Nanosonics and Prima shed two percent or more; with Alchemia, Benitec, CSL, QRX and Resmed down more than one percent.

ELLEX MEDICAL LASERS

Ellex says it has recruited 50 of 300 patients and added two sites to its trial of retinal rejuvenation therapy (2RT) for early age-related macular degeneration.

Ellex said the 50 patients had been recruited at Melbourne's Centre for Eye Research Australia and Sydney's Marsden Eye Clinic with the new sites at Melbourne's Eye Surgery Associates and Perth's Lions Eye Institute.

The company said that its recent US Food and Drug Administration 510(k) pre-market approval for 2RT in the treatment of diabetic eye disease cleared the path to extend the 2RT clinical trial program to the US and the establishment of additional clinical sites was expected to further accelerate patient recruitment (BD: Jul 18, 2013).

Ellex said the 'Lead' trial was a multi-centre, double-blind, randomized, controlled clinical trial of about 300 patients with bilateral high-risk early age-related macular degeneration of more than 50 years of age.

The company said that patients in the treatment group would undergo the 2RT procedure in one eye, with treatment to be repeated at six-monthly intervals, as required under the protocol design.

Ellex said that patients in the control group would undergo a sham procedure, in which the laser makes its working sound but does not enter the eye.

The company said that the primary endpoint was progression to advanced age-related macular degeneration in the treated eye, as assessed by ocular examination, colour fundus photography, ocular coherence tomography and fluorescein angiography at 36 months post initial intervention.

Ellex said the secondary endpoint was progression to advanced age-related macular degeneration in the non-treated eye.

The company said there were no approved treatments for the early form of age-related macular degeneration, which was a considerable market opportunity.

Ellex said that the trial began in November 2012 to validate the clinical efficacy of 2RT in the treatment of the early stages of age-related macular degeneration (BD: Nov 23, 2013).

The company said that the trial was led by the Centre for Eye Research Australia's head of macular research Prof Robyn Guymer.

Prof Guymer said that the establishment of additional sites in Australia was "a significant milestone in our clinical development program for 2RT".

"We are also in discussion with several other potential sites, including two in the USA and three in Europe, with ethics and regulatory approval arrangements underway," Prof Guymer said.

Ellex said that the Lead trial followed a successful pilot study by the Centre in 2011, which completed two-year patient follow-up in December 2012, with results expected to be published "in the near future".

Ellex chief executive officer Tom Spurling said that patient recruitment was "a key focus for the clinical research teams over the coming year".

Mr Spurling said that commercially Conformité Européenne (CE) mark for 2RT for early age-related macular degeneration would be "a principal goal for our business".

Ellex said that the Centre was seeking trial participants in Melbourne, Sydney and Perth, aged between 50 and 95 years with good vision and with a diagnosis of high-risk, intermediate age-related macular degeneration.

The company said that the treatment was not suitable for people who had already developed either wet or dry age-related macular degeneration in its advanced stages.

Ellex said that individuals who thought that they might be suitable for inclusion in the trial should contact their eye care professional.

Ellex was up one cent or 3.6 percent to 29 cents.

PRANA BIOTECHNOLOGY

Prana says that Parkinson's UK has awarded £150,000 (\$A260,000) to the University of Leeds to study the mechanism of action of its PBT434.

Prana said that Leeds principal investigator Dr James Duce would collaborate with the Melbourne's Florey Institute of Neuroscience and Mental Health's Prof David Finkelstein and Prof Robert Cherny, who was also the company's head of research.

Prana said that Dr Duce had "published extensively on the role of iron in both the healthy and diseased brain".

The company said the funds would be spent over 18 months to study the mechanism of action of PBT434 in animal models of Parkinson's disease and Parkinsonian syndromes. Prana said the work would focus on the ability of PBT434 to reduce the elevated iron levels in the Parkinsonian brain, attenuate oxidative stress and alter the function or abundance of iron regulated proteins.

Parkinson's UK director of research and innovation Dr Kieran Breen said that Parkinson's research was "starting to identify drugs that will treat Parkinson's - possibly slowing down or halting its progression - rather than just treating the symptoms".

"This research has been funded by our innovative translational research program," Dr Breen said. "Research such as this could ultimately bring us closer to our ultimate goal, a cure for Parkinson's."

Prana said that PBT434 had completed the first stage of preclinical toxicology studies, with the support of the Michael J Fox Foundation and was completing further toxicology studies for phase I clinical trials at the end of 2014.

Prof Cherny said that PBT434 had proven effective in preventing neuronal loss and preserving motor function in three different animal models of Parkinson's disease.

"PBT434 also inhibits the accumulation of alpha synuclein, a hallmark of the disease, which is promoted by increasing iron levels in the brain," Prof Cherny said.

"Elevation of iron in the brain is a well-established pathological feature of Parkinson's disease," Prof Cherny said. "The evidence so far suggests that PBT434 targets the biochemical pathways that influence the trafficking and distribution of iron in the brain."

Prof Cherny said the grant would "allow us to gain more refined insights into PBT434's therapeutic activity and better understand the pathological events underlying the disease".

Prana climbed five cents or 8.5 percent to 64 cents with 1.1 million shares traded.

ATCOR MEDICAL

Atcor says that Mexico's Comisión Federal para la Protección contra Riesgos Sanitarios has approved its Sphygmocor XCel system.

Atcor said that its Mexico distributor BCR Internacional would be permitted to market and sell the Sphygmocor non-invasive measure of central aortic blood pressures and arterial stiffness to clinicians and researchers in Mexico.

The company said that Mexico, with a population of 113 million, was the second largest medical device market in Latin America, after Brazil, with an estimated annual market of \$US4 billion.

Atcor said that a 2010 study of 20,000 Mexican adults reported that hypertension affected almost 30 percent of adults and about 13 percent of adults had diabetes.

Atcor chief executive officer Duncan Ross said that Mexico was an important market and the Sphygmocor XCel system "provides an opportunity to incorporate measurement of central aortic blood pressure into patient management and to positively impact healthcare in the Mexican population".

Atcor was unchanged at 12.5 cents with 1.6 million shares traded.

NEW SOUTH WALES GOVERNMENT

New South Wales Health Minister Jillian Skinner says her Government has provided \$3.25 million over five years for the \$22.6 million Australian Prevention Partnership Centre.

A media release from Ms Skinner said the national centre would conduct "cutting-edge research to help arrest the rapid increase of chronic disease".

The media release said the centre was jointly funded by the New South Wales Government, the National Health and Medical Research Council, the Australian Capital Territory Health Department, the Australian National Preventive Health Agency, and the private health insurance company HCF and the HCF Research Foundation.

The media release said that the Australian Prevention Partnership Centre would be managed by the Sydney-based Sax Institute, which received funding from New South Wales Health.

"Chronic diseases like diabetes, asthma, angina and hypertension are now responsible for more than half of all potentially preventable hospitalizations," Ms Skinner said.

"To reverse this trend, it is vital that research not only focuses on how best to treat chronic disease but on how best to prevent it developing," Ms Skinner said.

"The Australian Prevention Partnership Centre will transform the way prevention research is conducted, with a particular focus on translating that research into better prevention policy, services and programs," Ms Skinner said.

"The centre is supported by a team of 28 investigators from across Australia who will work closely with leading prevention researchers, policy makers, clinicians and practitioners from 24 universities, policy agencies and organizations," Ms Skinner said.

"By working closely with health system investigators, the centre will identify the type of strategies and programs that will make a real difference to people's health," Ms Skinner said.

Ms Skinner said the Australian Prevention Partnership Centre would identify the most effective strategies to change behaviors, risk factors and environments and help people make the lifestyle changes that prevent chronic diseases.

ISONEA

Isona says that the testing and technical documentation has been completed for its Airsona wheeze monitor to receive Conformité Européenne or CE mark.

Isona said that the Standards Institute of Israel and the Electronics and Telematics Laboratory had certified that the Airsona device conformed to the International Organisation for Standardisation (ISO) standards for safety and performance, clearing the way for Airsona to be marketed in the 27 member states of the European Union, as well as in the four member states of the European Free Trade Association and in Turkey.

Isona said it had received ISO safety, performance, and electromagnetic compatibility certificates for Airsona.

Isona chief executive officer Michael Thomas said that "attainment of these standards of safety and performance allows the company to complete the technical file and issue a declaration of conformity with the CE".

"This is an important step in certifying the product's readiness for sale in key international markets," Mr Thomas said.

Isona said it planned to launch the Airsona wheeze monitor in Australia this month and was assessing market opportunities in the EU for possible entry, following an expected 2014 US launch.

Isona was up half a cent or 0.8 percent to 63.5 cents.

CELLMID

Cellmid says that revenue for the year to June 30, 2013, was up 344.5 percent to \$761,288 reducing net loss after tax 22.4 percent to \$1,528,041.

Cellmid chief executive officer Maria Halasz told Biotech Daily that apart from a Federal Government R&D Tax Incentive payment, the company's hair loss products had a 300 percent increase in sales to \$541,649 for the year to June 30, 2013.

The company said that net tangible assets per share was unchanged at 0.48 cents and diluted loss per share fell 41.3 percent to 0.27 cents at June 30, 2013.

Cellmid said it had cash and cash equivalents of \$1,754,994 at June 30, 2013, compared to \$1,050,593 at June 30, 2012.

Cellmid filed its preliminary final report shortly after the market closed on August 28, 2013, but the former sub-editor missed it and has been seconded to the Labor Star.

Cellmid was unchanged at 2.9 cents with 1.1 million shares traded.

AUSBIOTECH

Ausbiotech says that this year's conference in Brisbane from October 30, 2013 would focus on the "bio-economy in transition".

Ausbiotech said that the conference was expecting about 1,200 delegates for the plenary speaker sessions, professional development courses and the business matching program.

The industry organization said that topics to be addressed included changing international laws and regulations on a global scale including patent law; 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 that supported the development of the bio-economy.

Ausbiotech said that the program was available at: <http://ausbiotechnc.org/program>.

AUSTRALIAN MUSEUM EUREKA PRIZES

The Australian Museum says its 18 Eureka science prizes will be announced tonight at Sydney Town Hall.

A media release from the Museum said its website would be updated as each winner was announced: <http://australianmuseum.net.au/2013-winners-eureka>.

The media release said the prizes would be announced through the Twitter website and by following @eurekaprizes or at <https://twitter.com/eurekaprizes> with comments able to be made through the link: #Eureka13.