



Biotech Daily

Thursday March 2, 2017

Daily news on ASX-listed biotechnology companies

- * **ASX UP, BIOTECH EVEN: USCOM UP 15%, PRIMA DOWN 11%**
- * **VICTORIA: APPLICATIONS OPEN FOR \$100k, \$500k GRANTS**
- * **LEGAL ACTION DELAYS SIRTEX SHARE BUY-BACK**
- * **CYNATA, MONASH COLLABORATE ON STEM CELLS FOR ASTHMA**
- * **CELLMID PAPER DESCRIBES FGF5 INHIBITOR FOR HAIR LOSS**
- * **PLATINUM ROAD \$2m CELLMID R&D TAX INCENTIVE LOAN**
- * **PRIME CO-INVESTOR CRESCENDAS LENDS MEMPHASYS \$250k**
- * **NEUROTECH APPOINTS DENG G MEDIZINTECHNIK FOR AUSTRIA SALES**
- * **JCP REDUCES TO 5.8% OF NANOSONICS**
- * **CRAIG HADFIELD REPLACES VOLPARA CFO, CO SEC BRIAN LEIGHS**

MARKET REPORT

The Australian stock market climbed 1.26 percent on Thursday March 2, 2017 with the ASX200 up 71.8 points to 5,776.6 points. Sixteen of the Biotech Daily Top 40 stocks were up, 15 fell, seven traded unchanged and two were untraded. All three Big Caps rose for the second day in a row.

Yesterday's worst, Uscom, was today's best, up three cents or 15.4 percent to 22.5 cents with 46,747 shares traded.

Living Cell climbed 9.5 percent; Airxpanders rose 8.4 percent; Viralytics improved 7.9 percent; Opthea was up 6.4 percent; Medical Developments climbed 5.9 percent; Atcor and Starpharma were up more than four percent; Orthocell was up 3.45 percent; Benitec, Osprey and Sirtex rose more than two percent; Admedus, Bionomics, CSL, Nanosonics and Resmed were up more than one percent; with Clinuvel and Cochlear up by less than one percent.

Yesterday's best, Prima, was today's worst, down 0.4 cents or 11.1 percent to 3.2 cents with 4.5 million shares traded. Factor Therapeutics and Psivida lost more than five percent; both Ellex and Prana fell four percent; Cyclopharm, IDT and Oncosil shed more than two percent; Compumedics, Impedimed, Pharmaxis, Polynovo and Reva were down more than one percent; with Mesoblast and Pro Medicus down by less than one percent.

VICTORIA GOVERNMENT

The Victoria Government says that applications have opened for the inaugural Victorian Medical Research Acceleration Fund.

A media release from Health Minister Jill Hennessy said the fund was intended to “fast-track ... breakthroughs in health and medical research with grants of up to \$100,000 and \$500,000.

A Victoria Department of Health website said that funding for proposals up to \$100,000 would support early stage innovations including discovery research, clinical research and health practice, or an idea or innovation to attract peer review funding or investment by industry, while tier 2 funding for proposals up to \$500,000 supported “a small number of research proposals to fast-track translation into health and economic outcomes [and] matching funding [would] be required to demonstrate capacity to collaborate and undertake research that has a clear pathway to translation”.

Applications close on April 14, 2016, with more information at: <http://bit.ly/2lf8kiM>.

SIRTEX MEDICAL

Sirtex says that it has postponed a proposed up to \$30 million, 2,000,000 share buy-back following a threatened injunction from a shareholder.

Last month, Sirtex said it received a letter and draft statement of claim from Portfolio Law’s Anthony Zika on behalf of client Todd Hayward who acquired 340 Sirtex shares for \$9,449 on December 1, 2016 and held them when the company’s share price fell following a profit warning (BD: Dec 9, 2016; Feb 1, 13, 2017).

Sirtex said at that time the claim alleged breaches of its continuous disclosure obligations and alleged misleading and deceptive conduct, arising an August 24, 2016 statement regarding “double digit dose sales growth”, but the company “declined” an invitation to enter into settlement discussions with Mr Zita and Mr Hayward and said that if they began legal action, it would “vigorously defend the proceeding”.

Today, Sirtex said the new correspondence threatened an injunction to stop the share buyback, “on the basis he alleges that the implementation of the share buyback will materially prejudice Sirtex’s ability to satisfy any liability arising in respect of the claims”. The company said that it would delay the buy-back from March 9 to March 27, 2017, while it addressed the allegation.

Sirtex climbed 43 cents or 2.7 percent to \$16.27 with 508,843 shares traded.

CYNATA THERAPEUTICS

Cynata says it has an agreement with the Monash Lung Biology Network for a pre-clinical study of its Cymerus mesenchymal stem cells for asthma.

Cynata said that the Monash Lung Biology Network was a consortia of the Monash Biomedicine Discovery Institute and Monash University’s Department of Pharmacology.

Last year, Cynata said that a 48-mouse model of asthma provided “compelling data” for its Cymerus mesenchymal stem cells (BD: Oct 17, 2016).

Today, the company said that the initial results demonstrated that Cymerus mesenchymal stem cells had “a dramatic effect on improving airway hyper-responsiveness [and] consistently reduced markers of airway inflammation and airway remodelling”.

Cynata head of product development Dr Kilian Kelly said the final report of the initial study “strengthened our confidence that Cymerus [mesenchymal stem cells] could exert substantial disease-modifying effects, rather than just treating the symptoms, in asthma”.

Cynata was up 3.5 cents or seven percent to 53.5 cents.

CELLMID

Cellmid says that one formulation of its FGF5 inhibitory technology monoterpene family, MTP3, for hair loss has demonstrated significant efficacy over placebo.

Cellmid said that a research paper was published in the journal *Clinical, Cosmetic, and Investigational Dermatology* described the development and screening program for its FGF5 inhibitory technology.

The company said that the research paper, co-authored by Cellmid chief executive officer Maria Halasz and head of operations Dr Dominic Burg, was entitled 'Promotion of anagen, increased hair density and reduction of hair fall in a clinical setting following identification of FGF5 Inhibiting compounds via a novel two stage process', with an abstract available at: <http://bit.ly/2mw7l8J>.

The article concluded that "Isolates from the monoterpene family displayed efficacy in FGF5 inhibition in-vitro".

"A topical formulation containing a leading isolate significantly improved [anagen:telogen] ratio, reduced hair fall and increased apparent hair density in the tested population of men and women," the article concluded.

Cellmid said that the paper described the results of the blinded, placebo-controlled clinical study of topical formulations containing the lead inhibitor in men and women.

The company said that formulations of the FGF5 inhibitor underwent safety testing through a repeated insult patch test on 50 individuals and no adverse events or reactions were recorded.

Cellmid said that 32 healthy individuals with hair loss were randomized into three groups, comparing two concentrations of MTP3 and placebo and assessed over 16 weeks of treatment measuring hair fall, anagen:telogen ratio, or the ratio of hairs in growth phase compared to those in rest phase, expert visual grading, and a subset was examined by high resolution matched photography.

The company said that both formulations showed significant improvements over baseline and compared to placebo, with the better performing formulation able to increase the number of follicles in the growth phase ($p = 0.002$), reduce hair loss ($p = 0.007$), improve the appearance on visual grading ($p = 0.004$) and displayed a continued increase in hair density on digitally matched photography over the 16-week study period.

Cellmid said that the placebo group did not show any improvement and had a trend for worsening hair-fall over 16 weeks.

The company said that there were few effective treatments for hair loss and the current market had numerous products with unknown mechanisms of action, and/or cosmetic claims not verified by scientific data, whereas its Advangen subsidiary's technology was based on the inhibition of FGF5, an important molecule in the hair cycle that signals hair follicles to stop producing hair and rest.

Cellmid said that FGF5 had no other known function, with animals and humans carrying mutations in the FGF5 gene having long, thick hair, but were otherwise healthy.

The company said that the lead compound identified in the screening method, MTP3, had been shown to be almost seven times more effective in inhibiting FGF5 than previous extracts and was included in all Évolis branded products.

Cellmid said that the data generated through the compound screening was the subject of a patent application, currently under examination.

"The identification of single molecule inhibitors rather than whole botanical extracts represents a significant improvement in the precision of the company's Évolis hair loss treatments, and resulted from a substantial body of work by our dedicated Japanese research team," Dr Burg said.

Cellmid was unchanged at 3.2 cents.

CELLMID

Cellmid says it has refinanced a loan \$700,000 secured against its expected Federal Government Research and Development Tax Incentive.

Cellmid said that the loan agreement with the Richmond, Melbourne-based Platinum Road for \$700,000 had been repaid by a \$2,000,000 loan, with 4,565,218 shares issued at 2.3 cents each to the lenders in lieu of accumulated interest.

Last year, Cellmid said it repaid a \$1,000,000 loan from Platinum Road with interest, when it agreed to the \$700,000 loan.

Today, Cellmid said the \$2,000,000 loan was secured on improved terms to “propel Cellmid’s midkine ischemia program, through its wholly owned subsidiary Kinera, towards clinical development” to reach investigational new drug application stage.

The company said that the loan period increased from 12 months to 24 months to better match product development time lines and the funds were expected to cover the costs of research and development up to preparation of the application for midkine in the treatment of ischemic diseases, including pre-clinical validation in an ischemia related indication, toxicology and regulatory work.

Cellmid said that the loan interest rate would 12 percent a year compared to the previous 15 percent, with the lenders having the right to be issued shares in lieu of payment of the accrued interest at 3.5 cents a share, compared to the previous 2.3 cents a share, at both 12 and 24 months from commencement, with a maximum number of shares issued in lieu of interest set at 6,857,142 for each twelve-month period.

The company said that the principal might be converted by the lenders at 5.0 cents a share compared to 3.4 cents previously, with the lenders able to convert up to 50 percent of the total loan facility in the first 12 months and a maximum number of shares to be issued in the first 12 months of 20,000,000 shares.

Cellmid said the remaining 50 percent of the loan could be converted to shares at 5.0 cents by the lenders at any time in the second year.

The company said it expected its next R&D Tax Incentive in November.

MEMPHASYS

Memphasys says it has a loan of \$250,000 from Crescendas Projects Pte Ltd, which is related to a co-investor in legal adversary Prime Biologics.

Last week, Memphasys executive chairman Alison Coutts provided a \$300,000 loan and \$200,000 line-of-credit to her company (BD: Feb 23, 2017).

Today, Memphasys said that Crescendas was a private Singapore company, and the arms-length loan would have an interest rate of 9.0 percent a year payable quarterly in arrears.

The company said that Crescendas was part of the Crescendas Pte Ltd conglomerate, which was the major shareholder of JP Asia Prime Capital, which was the co-investor with Pulau Manukan Ventures Labuan Ltd in Prime Biologics Pte Ltd, with whom Memphasys was in a legal dispute.

Memphasys said that JP Asia Prime held a substantial number of A class voting shares in Prime.

The company said it was involved in legal disputes against both Prime and Manukan which were being heard by arbitration in Singapore and JP Capital was “assisting the parties in their negotiations to reach a commercial settlement”.

Memphasys said that negotiations were continuing in parallel with the Arbitration process.

Memphasys was untraded at 0.4 cents.

NEUROTECH INTERNATIONAL

The Malta-based Neurotech says it has appointed the Innsbruck-based Dengg Medizintechnik GmbH to distribute its Mente Autism product in Austria.

Last year, Neurotech listed on the ASX to commercialize the product which it said was a clinical-quality electroencephalogram (EEG) device using neuro-feedback to help children with autism spectrum disorder (BD: Nov 4, 2016).

Today, Neurotech said that Dengg would “oversee a test study of Mente Autism to be conducted at a local university hospital children’s department” expected to begin in March and run for six to eight weeks.

The company said that terms of the agreement were confidential, but it expected to ship the first batch of devices immediately following the test study.

Neurotech fell two cents or 6.7 percent to 28 cents.

NANOSONICS

JCP Investment Partners says it has reduced its substantial shareholding in Nanosonics from 24,829,090 shares (8.39%) to 17,391,567 shares (5.84%).

The Melbourne-based JCP substantial shareholder notice said that it bought and sold shares between July 23, 2016 and February 27, 2017 with the single largest purchase 905,000 shares for \$2,554,726 or \$2.82 a share and the single largest sale was 495,100 shares for \$1,339,138 or \$2.705 per share, with other significant purchases and sales above \$3.00 a share.

JCP previously reduced its holding in Nanosonics from 26,655,463 shares (9.40%) to 24,829,090 shares (8.39%) in July last year with the single largest sale 248,100 shares for \$676,009 or \$2.725 per share (BD: Jul 27, 2016).

In April, JCP increased its Nanosonics holding by 2,879,710 shares with the largest purchase 500,000 shares for \$1,042,002 or \$2.08 per share (BD: Apr 12, 2016).

Today, JCP said its shares were held by National Nominees, HSBC Custody Nominees, BNP Paribas Nominees, JP Morgan Nominees and UBS Nominees.

Nanosonics was up five cents or 1.7 percent to \$2.93 with 1.4 million shares traded.

VOLPARA HEALTH TECHNOLOGIES

Volpara says it has appointed Craig Hadfield as its chief financial officer and joint company secretary replacing Brian Leighs.

Volpara said that Mr Leighs had been its contract chief financial officer since 2009 and director John Diddams would continue as joint company secretary.

The company said that Mr Hadfield had more than eight years’ experience in auditing roles at accounting firms Ernst and Young and Deloitte.

Volpara said that Mr Hadfield held a Bachelor of Commerce from the Johannesburg, South Africa-based University of Witwatersrand.

Volpara was up three cents or 7.2 percent to 44.5 cents.