



Biotech Daily

Friday July 12, 2013

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH UP: IMPEDIMED UP 17%, GENETIC TECHNO DOWN 15%**
- * **MELBOURNE UNI THIN FILM COATINGS FOR DRUG DELIVERY**
- * **US PATENTS FOR NEUREN NNZ-2566, NNZ-2591**
- * **PSIVIDA INTERIM DATA BACKS MICRO-INSERT FOR UVEITIS**
- * **ECO QUEST MOVES TO TAKE 100% OF CYNATA FOR STEM CELLS**
- * **PHOSPHAGENICS READY FOR TPM-TRETINOIN ACNE TRIAL**
- * **HUNTER HALL LIGHTENS, AGAIN, TO 19% OF SIRTEX**
- * **PERPETUAL REDUCES TO 8% OF SIRTEX**
- * **GREENLIGHT TAKES 5% OF GI DYNAMICS**
- * **ONCOSIL PLEADS SCHULTZ, DR NEIL FRAZER TO ASX 67% QUERY**
- * **SCOTT WARD REPLACES IMPEDIMED DIRECTOR MARTIN KRIEWALDT**

MARKET REPORT

The Australian stock market was up 0.17 percent on Friday July 12, 2013 with the S&P ASX 200 up 8.2 points to 4,973.9 points. Eighteen of the Biotech Daily Top 40 stocks were up, 10 fell, six traded unchanged and six were untraded.

Impedimed was the best, up 1.5 cents or 16.7 percent to 10.5 cents with 119,470 shares traded, followed by Pharmaxis up 12.5 percent to 18 cents with 2.9 million shares traded, Circadian up 12 percent to 28 cents with 33,400 shares traded and Phosphagenics up 10 percent to 11 cents with 1.5 million shares traded. Antisense and Tissue Therapies climbed more than seven percent; Anteo, GI Dynamics and Phylogica were up more than five percent; Alchemia, Starpharma and Universal Biosensors were up more than four percent; Allied Health and Cellmid were up more than three percent; Mesoblast rose 2.3 percent; with Heartware, Neuren and Resmed up more than one percent.

Genetic Technologies led the falls, down 1.5 cents or 15 percent to 8.5 cents with 189,242 shares traded, followed by Prima down 12.4 percent to 9.2 cents with 13 million shares traded. Nanosonics fell 4.9 percent; Clinuvel and Psivida lost more than three percent; Atcor and QRX shed more than two percent; Acrux, Medical Developments and Prana were down more than one percent; with Cochlear and CSL down less than one percent.

UNIVERSITY OF MELBOURNE

The University of Melbourne says its researchers have developed a system to coat objects as small as bacteria cells with implications for advanced drug delivery.

A University of Melbourne media release said that the self-assembling thin film coatings “could have important implications for drug delivery as well as biomedical and environmental applications”.

The University said that the Department of Chemical and Biomolecular Engineering’s Prof Frank Caruso and his team developed the new strategy to coat microscopic materials, leading to a new-generation particle system with engineered properties, expected to underpin advances in the delivery of therapeutics for cancer, vaccines, cardiovascular disease and neural health.

The University said that the capsules could be engineered to degrade under different conditions, providing opportunities for the timed release of substances contained inside the capsules.

The team’s research, entitled ‘One-Step Assembly of Coordination Complexes for Versatile Film and Particle Engineering’ was published in the journal Science and an abstract is available at: <http://www.sciencemag.org/content/341/6142/154.abstract>.

“Nano-engineered capsules are attracting much attention as drug carriers, as they have the potential to improve the delivery and effectiveness of drugs while reducing their side effects,” Prof Caruso said

“Our engineered particle system can be assembled rapidly from naturally occurring materials, minerals and nutrients, with specific physical and chemical properties, making it a versatile platform for various applications,” Prof Caruso said.

The abstract said that group achieved “one-step coating of interfaces using coordination complexes of natural polyphenols and Fe(III) ions”.

The abstract said that film formation was initiated by the adsorption of the polyphenol and directed by pH-dependent, multivalent coordination bonding.

It said that aqueous deposition was performed on a range of planar as well as inorganic, organic and biological particle templates, demonstrating an extremely rapid technique for producing structurally diverse, thin films and capsules that could disassemble.

“The ease, low cost and scalability of the assembly process, combined with pH responsiveness and negligible cytotoxicity, makes these films potential candidates for biomedical and environmental applications,” the abstract said.

NEUREN PHARMACEUTICALS

Neuren says that the US Patent and Trademark Office has allowed patents covering oral formulations of NNZ-2566 and the use of NNZ-2591 for peripheral neuropathy.

Neuren said that the two patents would provide protection for additional methods of formulating NNZ-2566 for oral administration and for a new therapeutic use for NNZ - 2591.

The company said the NNZ-2566 patent expiry would be 2027 and the NNZ-2591 patent expiry was 2031 and both patents related to treatment of chronic conditions with oral forms of the molecules.

Neuren said that seven patents for composition, methods of use and formulation had been issued for NNZ-2566 and three patents for composition and methods of use had been issued for NNZ-2591.

Neuren was up 0.1 cents or 1.3 percent to 7.6 cents with three million shares traded.

PSIVIDA

Psivida says that interim data from an investigator-sponsored phase I/II study supports its injectable micro-insert in patients with posterior uveitis.

Psivida said that in the first 12 months of enrollment, none of the treated eyes had a recurrence of uveitis and inflammation had been reduced in all treated eyes.

The company said that untreated eyes showed either recurrence of uveitis or worsening or no improvement in inflammation.

Psivida said that at the last follow-up, best corrected visual acuity on the Early Treatment Diabetic Retinopathy Study eye chart had improved by an average of more than nine letters in treated eyes and had declined by an average of one letter in untreated eyes.

The company said that interim data showed that the micro-inserts were well-tolerated and the observed safety profile was consistent with the short-term safety profile reported in clinical studies of Iluvien in diabetic macular oedema subjects.

Psivida said that with one exception, intraocular pressure measurements of treated eyes had all remained in the normal range and one treated eye, which at baseline had a history of elevated pressure, required surgery to control pressure.

The company said that the same micro-insert was being marketed in the European Union by licensee Alimera Sciences as Iluvien for chronic diabetic macular odema that was insufficiently responsive to available therapies, but Psivida was independently developing the uveitis application.

Psivida chief executive officer Paul Ashton said the interim data was “consistent with our hypothesis that our micro-insert will treat chronic non-infectious uveitis affecting the back of the eye with an efficacy profile that is comparable to Retisert, a current FDA-approved implant for uveitis developed by Psivida, and a side effect profile that is superior to Retisert and comparable to Iluvien in [diabetic macular oedema]”.

Psivida said the three-year, investigator-sponsored phase I/II study would evaluate the safety and efficacy of the micro-insert in up to 12 patients with uveitis and the company had initiated the first of two phase III trials for the use of the micro-insert in the treatment of posterior uveitis.

Psivida fell 14 cents or 3.4 percent to \$3.96.

ECO QUEST, CYNATA

Eco Quest says it will acquire 100 percent of Cynata following an agreement for its stem cell technology with the Wisconsin Alumni Research Foundation.

Eco Quest said that the acquisition of Cynata would take place in two stages, with an investment of \$250,000 to increase its holding to 33 percent and an option to acquire the balance of Cynata shares within 18 months for 200,000,000 Eco Quest shares.

The company said that the option was conditional on Eco Quest shareholder approval.

Last year Eco Quest said it has paid \$250,000 for an 11 percent of Cynata, a California based company developing multipurpose stem cell technology for regenerative medicine (BD: Oct 5, 2012).

Cynata chief executive officer and former Genera chief executive officer Dr Allen Bollands told Biotech Daily at that time that the company was developing mesenchymal stem cells derived from cord blood that “grow clonally at a phenomenal rate, doubling in number in 25 to 33 hours.”

Dr Bolands said he was a founder of Cynata, with former Mayne Pharma chief executive officer Dr Roger Aston as the company’s chairman.

Cynata is a private company.

Eco Quest was up 0.1 cents or 9.1 percent to 1.2 cents.

PHOSPHAGENICS

Phosphagenics says it has ethics approval for its 45-patient phase II trial of tocopheryl phosphate mixture tretinoin study for acne, expected to start this year.

Phosphagenics said that tretinoin was also known as retinoic acid and was a form of vitamin A.

The company said that the study would compare tocopheryl phosphate mixture-tretinoin (TPM-tretinoin) formulation against the market leading product Retin-A, as well as a placebo TPM formulation at the Linear Clinic in Perth and Specialist Connect in Brisbane. Phosphagenics said that the phase II trial results would be used to power subsequent pivotal trials.

The company said that the acne trial was “the culmination of the announced strategic direction of the company into the dermatology space where clinical studies are relatively inexpensive, involve minimal risk, shortened time to market and hence a speedier commercial outcome”.

Phosphagenics said that previous human trials produced “excellent results with its formulation compared to Retin-A” (BD: Apr 30, 2009).

The company said that the results demonstrated improved and deeper delivery of the drug and a significant reduction in irritation.

In 2011, Phosphagenics said it had begun the second stage of a development agreement with an unnamed dermatology company to develop a transdermal prescription drug for acne (BD: Apr 4, 2011).

Phosphagenics chief executive officer Dr Esra Ogru told Biotech Daily in 2011 that the unnamed European-based major dermatology company would pay all development costs which included establishing its stability profile and final formulation before entering clinical trials and would probably take over all development work itself in three or four months time with the trial expected to be completed by the end of 2011.

Dr Ogru has been suspended from the company pending an investigation into “irregular transactions in relation to its invoicing and accounting records” that may be material and is currently underway (BD: Jul 1, 2013).

Today, Phosphagenics said that retinoic acid was most often prescribed by dermatologists for the topical treatment of acne and irritation was a common adverse side effect affecting about 90 percent of patients.

The company said its TPM formulations had been shown to reduce irritation and the product had the potential to capture a substantial share of the tretinoin market.

Phosphagenics said the TPM-tretinoin clinical program was being overseen by chief operating officer Sally Kinrade.

Phosphagenics was up one cent or 10 percent to 11 cents with 1.5 million shares traded.

SIRTEX MEDICAL

Hunter Hall Investment Management has again reduced its substantial holding in Sirtex, this time from 11,040,370 shares (19.80%) to 10,506,023 shares (18.73%).

The Sydney-based Hunter Hall said it sold 534,346 shares between June 26 and July 10, 2013 with the single largest sale 75,000 shares for \$919,112 or \$12.25 a share.

In May, Hunter Hall reduced its holding in Sirtex from 23.77 percent to 22.26 percent and in June further reduced to 19.80 percent (BD: May 29, Jun 28, 2013).

Hunter Hall has been a long term shareholder in Sirtex and in 2009 increased to 16,684,884 shares (29.92%) when the company was at \$2.35 a share (BD: Mar 5, 2009).

Sirtex was up seven cents or 0.6 percent to \$12.19 with 281,777 shares traded.

SIRTEX MEDICAL

Perpetual and its subsidiaries have reduced their substantial shareholding in Sirtex from 5,095,042 shares (9.14%) to 4,460,503 shares (7.96%).

Perpetual said the 634,539 shares were sold between May 2 and July 10 for prices ranging from \$9.70 to \$12.30 a share.

In May Perpetual increased the holding from 4,376,914 shares (7.85%) to 5,095,042 shares (9.14%) and the 718,128 shares were bought at \$9.60 a share (BD: May 3, 2013).

GI DYNAMICS

The New York-based Greenlight Capital has become a substantial shareholders in GI Dynamics with the acquisition of 19,414,494 shares or 5.40 percent of the company.

Greenlight said that Goldman Sachs was the registered holder of the securities acquired for \$10,289,683 or 53 cents a share in the recent placement (BD: Jul 3, 2013).

GI Dynamics was up three cents or 5.3 percent to 60 cents.

ONCOSIL MEDICAL (FORMERLY NEURODISCOVERY)

Oncosil has told the ASX that it is not aware of any information it has not announced which, if known, could explain recent trading in its securities.

The ASX said the company's share price rose 66.7 percent from 4.2 cents on July 3 to seven cents on July 11, 2013, and noted an increase in trading volume.

Oncosil said that on July 2, it announced the appointment of Dr Neil Frazer as its chief executive officer (BD: Jul 3, 2013)

Oncosil was up half a cent or 7.1 percent to 7.5 cents with 1.4 million shares traded.

IMPEDIMED

Impedimed says that Scott Ward has been appointed a director replacing Martin Kriewaldt.

Impedimed chair Dr Cherrell Hirts said that Mr Ward's "considerable experience in the medical device industry will be very important to us in the coming years".

"His expert knowledge in building and growing medical device companies will enhance our strategic thinking and strengthen our operations," Dr Hirst said.

Dr Hirst thanked Mr Kriewaldt for his "eight years of committed service" as a director.

Impedimed was up 1.5 cents or 16.7 percent to 10.5 cents with 119,470 shares traded.