



Biotech Daily

Tuesday September 2, 2014

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH UP: TISSUE THERAPIES UP 13%
- GENETIC TECHNOLOGIES DOWN 14%**
- * **HATCHTECH TRIALS PROVE ONE-SHOT HEAD LICE, EGG TREATMENT**
- * **ARC \$546k GRANT FOR PHYLOGICA, UQ PHYLOMER TUMOR PROJECT**
- * **NANOSONICS PLEADS REVENUE, MEETINGS TO ASX 11% QUERY**
- * **IMMURON REDUCES HADASIT ROYALTY**
- * **CEO HARRY ROSEN DILUTED TO 5% OF PHOSPHAGENICS**

MARKET REPORT

The Australian stock market climbed 0.51 percent on Tuesday September 2, 2014 with the S&P ASX 200 up 28.7 points to 5,658.5 points.

Fourteen of the Biotech Daily Top 40 stocks were up, 12 fell, 10 traded unchanged and four were untraded. All three Big Caps were up.

Tissue Therapies was the best, up five cents or 13.3 percent to 42.5 cents with 1.1 million shares traded.

Cellmid and Oncosil climbed more than nine percent; Impedimed was up 8.3 percent; Benitec rose 6.4 percent; Atcor and Mesoblast were up more than five percent; Admedus and Clinuvel were up more than three percent; Universal Biosensors rose 2.7 percent; Neuren and Sirtex climbed more than one percent; with Bionomics, Cochlear, CSL, Psivida and Resmed up by less than one percent.

Genetic Technologies led the falls, down 0.4 cents or 13.8 percent to 2.5 cents with 5,000 shares traded.

Uscom lost 7.4 percent; Medical Developments was down 6.1 percent; Living Cell fell 5.7 percent; Osprey and Pharmaxis were down more than three percent; Prana shed 2.1 percent; Nanosonics, Phosphagenics and Viralytics were down more than one percent; with Alchemia and Starpharma down by less than one percent.

HATCHTECH PTY LTD

Hatchtech says its two US pivotal phase III trials of Xeglyze Lotion has show that it kills lice and their eggs in single 10-minute treatment.

Hatchtech said that 704 subjects with active head lice infestation aged six months and older were enrolled at 14 study sites in the double-blind, randomized, multi-center, vehicle-controlled, parallel-group and treated subjects

The company said that the studies were designed to assess the efficacy, safety and tolerability of a single application of Xeglyze Lotion, formerly Deovo Lotion, compared to a vehicle lotion, when applied to the scalp and hair for 10 minutes at home.

Hatchtech said that the results were assessed in follow-up visits at one, seven and 14 days following application and both studies achieved the pre-defined primary and secondary endpoints, conducted according to a special protocol assessment agreement with the US Food and Drug Administration.

Hatchtech said that 81.5 percent of patients who received one application of Xeglyze and without nit-combing remained lice-free at all follow up visits through to the day 14 visit, which was the primary efficacy endpoint as agreed with the FDA.

The company said that the secondary efficacy endpoint was the proportion of subjects who were lice-free at the day-1 visit and the day-7 visit with 90 percent lice-free after one day following treatment with Xeglyze Lotion and 88 percent lice-free after seven days.

Hatchtech said there were no serious adverse events related to treatment and no subject discontinued either study due to an adverse event, while reported adverse events were predominantly mild or moderate in nature and the product was well tolerated.

Hatchtech chief executive officer Hugh Alsop told Biotech Daily that a 100 percent lice-free rate was very difficult to achieve in an at-home trial as children continued about their normal routines in contact with untreated children.

He said that Xeglyze Lotion was intended initially for the US prescription market and had a higher rate of success with a single treatment than existing products that required two treatments and nit-combing.

"This is an at home trial and the subjects go about their normal activities and re-infestation can and does occur," Mr Alsop said.

"There are comparator lice treatments in the US and work in different ways but they don't kill the eggs," Mr Alsop said.

Hatchtech said the Lotion was based on research at the University of Melbourne by the company's founder Dr Vern Bowles and the active ingredient, abametapir, was selected in 2005 as a lead compound, targeting key biological pathways of the lice life cycle, including the lice egg.

The company said that Xeglyze Lotion treated both eggs and the lice, meaning repeat applications and nit combing were not required, and the Lotion had a different mechanism of action with no known resistance.

The Los Angeles, California-based Axis Clinical Trials chief executive officer and trial principal investigator Dr Lydie Hazan said that eradication of head lice required treating the lice as well as the eggs.

"The results of these studies demonstrate that Xeglyze Lotion is effective at eliminating a head lice infestation in 81.5% of subjects, but most importantly with only one application and without nit combing," Dr Hazan said.

Mr Alsop said the trial results provided "clear evidence in support of the safety and efficacy of Xeglyze Lotion, as well as the superior commercial potential of the product".

"The company remains on track to file a new drug application with the US Food and Drug Administration in the first half of 2015," Mr Alsop said.

Hatchtech is a public unlisted company.

PHYLOGICA

Phylogica says the Australian Research Council has awarded a \$546,420 grant to it and partner the University of Queensland to identify Phylomers inhibiting tumor metastasis. Phylogica said the ARC Linkage Grant for a project entitled 'Targeting the undruggable: epitope mapping using Phylomers to modulate the activity of transcription factors' to the University of Queensland's Institute for Molecular Bioscience would be administered by University of Queensland with Phylogica as a commercial partner.

Phylogica chief executive officer Dr Richard Hopkins said the grant "strongly supports [the] strategic focus to develop Phylomer-based therapies against high-value cancer targets".

"The outcomes of this collaboration will enable us to accelerate our oncology programs, which are aimed at delivering potent Phylomer drugs inside cells," Dr Hopkins said.

Phylogica said that with the Institute it would "exploit the unique structural diversity of Phylogica's Phylomer libraries for screening against a critical protein complex involved in cancer metastasis ... centred on a key intracellular master-switch protein known as SOX18" which was involved in the spread of cancer through the body, or metastasis, through the control of blood and lymphatic vessel outgrowth.

The company said the transcription factor SOX18 was a promising anti-metastatic target, acting as a molecular switch triggering the development of the lymphatic vasculature.

Phylogica said that in solid tumors such as melanoma, SOX18 was re-expressed in lymphatic endothelial cells, helping the cancer to spread through the lymphatic system.

The company said that genetic disruption of SOX18 function in this context had been shown to protect from tumor metastasis and tumor growth, so blocking its function with Phylomers was expected to reduce the potential for metastasis.

Phylogica said that with the Institute it aimed to develop a new platform to validate networks of protein interactions using Phylomer peptides as probes to inhibit specific interactions and to identify therapeutically relevant epitopes on target proteins.

The company said that using the endothelial specific transcription factor SOX18 as a target, the collaboration would apply the concept to the family of proteins, which had so far largely eluded pharmacological intervention.

The Institute's chief investigator Dr Yann Gambin said that his organization was "looking forward to working with Phylogica to explore the enormous diversity of Phylomer libraries and dissect the components of a protein machine used by cancer cells to spread".

"Phylogica's expertise in drug development, particularly intracellular delivery, makes it an ideal partner for this exciting medical research project," Dr Gambin said.

Phylogica chief scientific officer Dr Paul Watt said the partnership would "allow us to accelerate the search for safer drugs with fewer side effects and considerably expand the landscape of therapeutic targets".

Phylogica was up 0.3 cents or 20 percent to 1.8 cents with 3.3 million shares traded.

NANOSONICS

Nanosonics 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 climbed from 94 cents to \$1.04, a 10.6 percent increase, on September 1, 2014 but did not note an increase in trading volumes.

Nanosonics said that it released its full year results on August 21 and held investor meetings in Melbourne and Sydney between August 25 and 27, 2014.

In its results Nanosonics said revenue for the year to June 30, 2014, was up 46 percent to \$25,606,000 reducing net loss after tax by 55 percent to \$2,605,000 (BD: Aug 21, 2014).

Nanosonics fell two cents or 1.96 percent to \$1.00.

IMMURON

Immuron says it has amended its agreement for reduced royalty payment obligations to Hadasit Medical Research Services & Development.

Immuron said that Hadasit was the technology transfer company of the Hadassah Medical Organization in Jerusalem and the company's principal research and development collaborator.

Immuron chief executive officer Amos Meltzer told Biotech Daily that the company had licenced intellectual property from Hadassah expanding the indications for its bovine hyper-immune colostrum based technology.

The company said that the royalties would be derived from net income received, rather than from revenues received by an Immuron licensee.

Immuron said that the changed "provides further certainty" in the commercialization of its non-alcoholic steato-hepatitis product and any other prescription product developed with the intellectual property assigned by Hadasit to Immuron.

The company said that it had also reduced the royalty payable on all its over-the-counter products.

Mr Meltzer said the licence agreement was renegotiated "to reflect the significant investment Immuron and its shareholders are making in the upcoming phase II trial and we have been able to attain a result that gives the company and its shareholders a more robust financial structure and a stronger business model".

"Hadasit has been a strong partner over the past five years and continues to be so," Mr Meltzer said.

Immuron was unchanged at 0.7 cents with 22.1 million shares traded.

PHOSPHAGENICS

Phosphagenics chief executive officer Harry Rosen says his indirect holding of 64,226,436 shares has been diluted from 6.31 percent to 5.09 percent in the recent capital raising.

Phosphagenics issued 51,000,000 shares as part of its \$19.3 million capital raising (BD: Jul 11, 2014).

Mr Rosen said the shares were held by Paroha Nominees Pty Ltd and Paroha Nominees Pty Ltd (Superannuation Fund A/c of Toorak Victoria and of which he was a director and beneficiary, respectively).

Phosphagenics fell 0.1 cents or one percent to 9.7 cents.