



Biotech Daily

Monday April 13, 2015

Daily news on ASX-listed biotechnology companies

- * **ASX DOWN, BIOTECH UP: MESOBLAST UP 24%, COMPUMEDICS DOWN 18%**
- * **CELGENE TAKES 4.5% OF MESOBLAST, OPTION ON GVHD, INDICATIONS**
- * **EDITORIAL: REPORTING GOLDMAN SACHS SUBSTANTIALS**
- * **IDT MANUFACTURES 1st OF 23 US GENERICS, FDA CONFIRMS TRANSFER**
- * **UNIVERSAL BIOSENSORS J&J SERVICE FEES UP 142%**
- * **BLUECHIIP REQUESTS 'CAPITAL RAISING' TRADING HALT**
- * **EUROPEAN PATENT FOR ACTINOGEN'S XANAMEM**
- * **PHARMAUST APPROVED FOR 7-DAY DOG PPL-1 CANCER TREATMENT**
- * **NUSEP'S ALISON COUTTS TEMPORARY RESIGNATION FROM PRIME**
- * **PHOSPHAGENICS: DR MURDOCH, DR COLLIER, MR LANKAU DIRECTORS**

MARKET REPORT

The Australian stock market slipped 0.14 percent on Monday April 13, 2015 with the S&P ASX 200 down 8.1 points to 5,960.3 points. Nineteen of the Biotech Daily Top 40 stocks were up, 13 fell, six traded unchanged and two were untraded. All three Big Caps climbed.

Mesoblast was the best, up 78 cents or 24.3 percent to \$3.99 with 1.8 million shares traded, followed by Patrys up 18.2 percent to 1.3 cents with five million shares traded and GI Dynamics up 17.9 percent to 16.5 cents with 119,917 shares traded.

IDT and Universal Biosensors climbed more than 14 percent; Antisense was up 12.5 percent; Actinogen was up 10.7 percent; Atcor rose 8.3 percent; Sirtex and Tissue Therapies were up five percent or more; Cellmid and Osprey were up more than four percent; Prana was up 3.6 percent; Oncosil, Psivida and Resmed rose more than two percent; Admedus, Avita, Impedimed and Viralytics were up more than one percent, with CSL and Cochlear up by less than one percent.

Friday's best, Compumedics, led the falls, down four cents or 18.2 percent to 18 cents with 640,860 shares traded. Circadian lost 6.25 percent; Analytica fell five percent; Benitec, Ellex, Nanosonics, Optiscan and Prima were down three percent or more; Anteo shed 2.1 percent; Clinuvel, Medical Developments and Starpharma were down more than one percent; with Acrux down 0.6 percent.

MESOBLAST

Mesoblast says Celgene will acquire 4.5 percent of the company and has taken an option on its mesenchymal stem cells for graft versus host disease and other diseases.

Mesoblast said that the New Jersey-based Celgene would acquire 15.3 million Mesoblast shares for \$58.5 million or \$3.82 per share.

Mesoblast's most recent Appendix 3B statement said it had 324,441,029 shares on offer meaning that the new shares would represent 4.5 percent of the company.

According to Nasdaq data, Celgene had a market capitalization of \$US93.725 billion (\$A122.175 billion).

Mesoblast said that the agreement gave Celgene a six month option for graft versus host disease as well as "certain oncologic diseases, inflammatory bowel diseases, and organ transplant rejection".

In a teleconference, Mesoblast executive director Prof Silviu Itescu said that Celgene was interested in the mesenchymal stem cell program across a range of indication including rheumatoid arthritis and diabetic nephropathy.

Prof Itescu said that its relationship with Teva was focused on cardio-vascular and neurological diseases, and would be in parallel with the Celgene agreement focused on inflammatory disease.

Prof Itescu said that Celgene would be looking at the named specific indications but could be interested in a range of inflammatory diseases and would "focus more broadly on the areas Mesoblast has investigated".

Prof Itescu said that the most recent data on its MSC-100-IV mesenchymal stem cells for graft versus host disease was published in February and Celgene had not access to any further unpublished data (BD: Feb 16, 2015).

In 2013, Mesoblast acquired the stem cell assets from the Columbia, Maryland-based Osiris, for \$US100 million, with its lead product, Prochymal, already available in the US under an extended access program for graft versus host disease, a complication arising primarily from bone marrow transplants from leukemia (BD: Oct 11, 2013).

Prof Itescu said that Celgene was a leader in cancer, inflammatory disease and regenerative medicine.

Celgene president and chief operating officer Mark Alles said the agreement "provides an opportunity for Celgene to add to its leading cellular and regenerative medicine pipeline". Mesoblast climbed 78 cents or 24.3 percent to \$3.99 with 1.8 million shares traded.

EDITORIAL: GOLDMAN SACHS

In the past month, Goldman Sachs has filed three becoming substantial shareholder notices and two ceasing substantial shareholder notices in Nanosonics.

The Goldman Sachs notices, filed on behalf of subsidiaries, said the shares were subject to master lending agreements and cite the purchase, sale, borrowing and return of shares. Biotech Daily has previously expressed concern with other institutional investors, in particular UBS AG, and understands the holdings are being borrowed and returned as part of short-selling arrangements in which traders 'borrow' shares for a fee and sell them in the hope or expectation that the price will fall and they can be bought back at a lower price and returned for a profit. (BD: Nov 21, 2013)

While there is nothing illegal about the activity, Biotech Daily is concerned that the public does not know the true identity of the ultimate share traders in defiance of the spirit, but not the letter, of the Corporations Act, as well as the frequency and meaninglessness of the notices, which say little other than acknowledging that person or persons unknown are playing with Australian biotechnology companies for their own purposes.

IDT AUSTRALIA

IDT says it has manufactured 1mg and 8mg doxazosin mesylate tablets at its Boronia facility, the first of the 23 generic drugs acquired last year (BD: Nov 3, Dec 18, 2014). IDT said that batch manufacture involved matching the formulation and manufacturing process contained within the original drug registration dossier and it was “an important milestone for IDT to show regulators that it can make these drug products according to the original FDA approved registration”.

The company said that the US Food and Drug Administration had confirmed receipt of the change of ownership letters formally transferring ownership of the 23 generic drug products to IDT, but IDT has not disclosed the name of the vendor of the generic drugs.

IDT chief executive officer Dr Paul MacLeman told Biotech Daily that doxazosin was indicated for benign prostatic hyperplasia and hypertension, or high blood pressure.

In a media release IDT said that it would manufacture exhibit batches of drug product to be placed in stability studies and the data from the exhibit batch manufacture and stability work would form the basis of a submission to the FDA to re-activate the marketing approval of the products.

Dr MacLeman said that “the successful manufacture of doxazosin in IDT’s Boronia solid oral dosage form facility is a turning point for the company in that we have now shown that IDT has the personnel, equipment and resources required to manufacture these newly acquired products in-house”.

“We are focused on getting these drug products back on the market as quickly as possible using established and strong distribution partners,” Dr MacLeman said.

IDT was up 3.5 cents or 14.9 percent to 27 cents with one million shares traded.

UNIVERSAL BIOSENSORS

Universal Biosensors says quarterly service fees were up 141.55 percent to \$2,930,420 for the three months to March 31, 2015 compared to the previous corresponding period.

Universal Biosensors said that sales by Johnson & Johnson Lifescan of the Onetouch Verio blood glucose test strips provided an increase of 28.2 percent compared to three months to December 31, 2014 and comprised most of the \$4,122,828 in revenue reported to March 31, 2015.

Universal Biosensors chief financial officer Saleshe Balak told Biotech Daily that most of the remaining revenue was receipt of \$US1,000,000 (\$A1,290,000) milestone payment from Siemens.

The company said that net cash consumed during the three months was \$1.5 million, a reduction of \$2.8 million or 64 percent compared to the three months to March 31, 2014.

Universal Biosensors said it had \$14.8 million in cash at March 31, 2015 with about \$8 million expected to be received from the Federal Government R&D Tax Incentive by October 2015.

Universal Biosensors was up 3.5 cents or 14.9 percent to 27.5 cents with 587,104 shares traded.

BLUECHIIP

Bluechiip has requested a trading halt “pending an announcement to the market in connection with a proposed capital raising”.

Trading will resume on April 15, 2015 or on an earlier announcement.

Bluechiip last traded at 5.5 cents.

ACTINOGEN MEDICAL

Actinogen says the European Union Patent Office has granted a patent relating to Xanamem for Alzheimer's and related diseases to 2031.

Actinogen said the patent, entitled '3,3-disubstituted-(8-aza-bicyclo[3.2.1]oct-8-yl)- [5-(1h-pyrazol-4-yl)-thiophen-3-yl]-methanone and related compounds and their use' protected Xanamem for use in Alzheimer's dementia and other related diseases associated with the inhibition of 11-beta-hydroxysteroid dehydrogenase type 1 (11 beta-HSD1).

The company said that the patent related to pharmaceutical compositions of 11 beta-HSD1 inhibitors and the use of these compounds to inhibit 11 beta-HSD1 in order to treat disorders that ameliorated by the inhibition of the enzyme.

Actinogen said that the claims covered method-to-treat for various diseases beyond Alzheimer's dementia including the metabolic syndrome, which included disorders such as type 2 diabetes and obesity and associated disorders including insulin resistance, hypertension, lipid disorders, cardiovascular disorders such as ischaemic heart disease and central nervous system disorders such as mild cognitive impairment and early dementia, including Alzheimer's disease, post-traumatic stress disorder, depression and schizophrenia.

Actinogen was up 0.9 cents or 10.7 percent to 9.3 cents with 1.2 million shares traded.

PHARMAUST

Pharmaust says the New South Wales Department of Primary Industries has approved an amended dog cancer trial protocol for seven days of treatment rather than 28 days.

Pharmaust said the approval included the soft-gel capsule form of PPL-1.

The company said that dog owners had found the 28 days treatment period "challenging, particularly as the dogs often had late stage cancers".

Pharmaust said it would look for the tumor marker p70S6K in dogs as it was "rapidly and meaningfully reduced in blood cells of human patients following treatment with PPL-1 after three days".

Principal investigator Dr Angela Frimberger said the revision would allow the trial "to fast-track development of this promising drug".

The company said that four dogs with untreatable progressive cancers, one melanoma, two soft tissue sarcomas and one chemo-resistant lymphoma, had received PPL-1 either as liquid or soft-gel formulation on a compassionate use basis without adverse events or toxicities.

Pharmaust executive chairman Dr Roger Aston said that PPL-1 was approved for veterinary use by the company's unnamed animal health partner and if the trial was successful PPL-1 would "be able to be approved quickly for the treatment of dog cancers following a further pivotal study".

Pharmaust fell 0.1 cents or 7.7 percent to 1.2 cents with six million shares traded.

NUSEP HOLDINGS

Nusep says that executive chairman Alison Coutts was temporarily stepping down from her position as Nusep's representative on the Prime Biologics board.

Nusep said the temporary resignation was "to ensure no possibility of conflict of interest whilst Nusep explores a potential transaction relating to Nusep's shareholding in Prime".

Nusep fell half a cent or 12.5 percent to 3.5 cents.

PHOSPHAGENICS

Phosphagenics has appointed chief executive officer Dr Ross Murdoch, Dr Greg Collier and Peter Lankau as directors.

Phosphagenics said that Dr Greg Collier was currently the chief executive officer of Invion, was formerly the chief executive officer of Chemgenex and had more than 20 years experience spanning operational, clinical and scientific aspects of pharmaceutical research, development and commercialization.

The company said that Dr Collier had published more than 150 peer-reviewed articles, as well as having senior authorship on 33 patents.

Phosphagenics said that Peter Lankau was formerly the chief executive officer of Endo Pharmaceuticals which was "one of the largest companies commercializing drugs in the pain industry" including Lidoderm or lidocaine, Percodan or oxycodone with aspirin, Opana or oxymorphone and Voltaren gel or diclofenac.

Phosphagenics has been developing its tocopheryl phosphate mixture or TPM technology for the transdermal delivery of a range of opiates, opioids and diclofenac, among other compounds.

The company said Dr Murdoch had more than 25 years experience in the pharmaceutical and biotechnology industries, held senior executive positions with Glaxosmithkline, Astra Zeneca and Shire Pharmaceuticals, was formerly the chief operating officer at Prana and was appointed chief executive officer earlier this year (BD: Jan 18, 2015).

Dr Murdoch told Biotech Daily that the existing board of Harry Rosen, Lawrence Gozlan, Nathan Drona and Dr Geert Cauwenbergh continued.

Phosphagenics fell 0.3 cents or 8.8 percent to 3.1 cents with 5.5 million shares traded.