

Biotech Daily

Friday August 23, 2013

Daily news on ASX-listed biotechnology companies

* ASX, BIOTECH UP: OSPREY UP 35%, CLINUVEL DOWN 5%

- * FDA APPROVES OSPREY AVERT CARDIAC DYE REDUCTION SYSTEM
- * NANOSONICS, TOSHIBA SELL 6 TROPHONS TO UK HOSPITAL
- * US PATENT EXPANDS BIODIEM BDM-I ANTI-MICROBIAL CLAIMS
- * MEDICAL DEVELOPMENTS REVENUE UP 4% TO \$12m, PROFIT DOWN 15%
- * NUSEP EXPECTS \$1.6m R&D TAX REFUND
- * LA JOLLA COVE DEAL SENDS BONE INTO SUSPENSION
- * NICHOLAS FALZON REPLACES ONCOSIL CO SEC JILLIAN MCGREGOR

MARKET REPORT

The Australian stock market climbed 0.94 percent on Friday August 23, 2013 with the S&P ASX 200 up 47.7 points to 5,123.4 points.

Nineteen of the Biotech Daily Top 40 were up, six fell, 11 traded unchanged and four were untraded.

Osprey was the best, up 18 cents or 34.6 percent to 70 cents with 370,029 shares traded, followed by Genetic Technologies up 15 percent to 9.2 cents with 2.9 million shares traded and Impedimed up 14.3 percent to 16 cents with 312,126 shares traded.

Prana climbed 9.9 percent; Medical Developments was up 8.4 percent; Ellex, Patrys and Phosphagenics rose five percent or more; Avita, GI Dynamics, Living Cell and Nanosonics were up four percent or more; Sirtex was up three percent; Alchemia, Anteo, CSL and Viralytics rose more than one percent; with Acrux, QRX, Resmed and Reva up by less than one percent.

Clinuvel led the falls, down nine cents or five percent to \$1.70 with 1,028 shares traded.

Benitec, Heartware, Mesoblast, Psivida and Starpharma fell more than one percent; with Cochlear down 0.8 percent.

OSPREY MEDICAL

Osprey says it has received US Food and Drug Administration 510(k) pre-market clearance for its Avert system for reducing cardiac imaging dye injected into patients. Osprey said that a pilot clinical study showed that the Avert system reduced the amount of dye by up to 40 percent without compromising image quality (BD: Oct 31, 2012).

The company said that there were more than four million angiogram procedures performed each year in Western Europe and the US and using its Avert system would significantly reduce the amount of dye used in these procedures.

Osprey chief executive officer Mike McCormick said that approval was an "important milestone".

"Avert was not yet part of our plans when we undertook our [initial public offer] in May 2012," Mr McCormick said.

"Developing the Avert system and obtaining FDA clearance in such a short period of time is testament to the capabilities of our team at Osprey and potentially opens up further exciting opportunities for the company," Mr McCormick said.

"We will shortly begin to commercialize Avert in a controlled manner to demonstrate awareness and adoption patterns among select key opinion leading physicians," Mr McCormick said.

Osprey said it was building product inventory, developing product labels to meet FDA requirements and finalizing its US sales plans.

The company said it would begin a US commercialization expected to begin in Texas, by the end of the year.

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NANOSONICS

Nanosonics says that UK distribution partner, Toshiba Medical Systems, has installed six Trophon EPR units at King's Mill Hospital in Sutton-in-Ashfield, Nottinghamshire. Nanosonics said that since signing the distribution agreement in April, Toshiba had initiated numerous trials of the Trophon EPR ultrasound probe sterilization systems. The company said that the 600-bed King's Mill Hospital had "one of the UK's most highly regarded ultrasound departments and following a trial of the Trophon EPR … [had] purchased six units".

The company has previously said the units sell for between \$10,000 and \$15,000. King's Mill Hospital clinical lead sonographer Ann Allen said the Trophon EPR was "extremely easy to use and [we] take reassurance from the fact that our trans-vaginal probes are now being deep-cleaned in-line with international best practice".

"The automated procedure fits in well with our workflow and has not caused any extension in examination times, which is crucial in a busy ultrasound department," Ms Allen said. "We like this disinfection process because it removes user subjectivity, which means our sonographers and helpers no longer have to worry if they have disinfected each probe." Nanosonics chief executive officer Dr Ron Weinberger said the UK was a major market opportunity for the Trophon EPR and the Toshiba partnership, together with the introduction of a new validation kit was helping to build momentum.

Nanosonics said that UK decontamination guidelines required each Trophon EPR to undergo an independent validation process and the company had developed a dedicated validation kit to meet regulatory requirements in England, Scotland and Wales.

The company said that the validation service, which was required to ensure compliance with UK guidelines, would lead to an additional source of revenue.

Nanosonics was up 3.5 cents or four percent to 91.5 cents.

BIODIEM

Biodiem says the US Patent and Trademark Office has allowed a US divisional patent entitled 'Antimicrobial and Radioactive Compounds', expanding the BDM-I portfolio. Biodiem said the new claims covered use of BDM-I as a treatment of skin and wound infections caused by fungi and bacteria, until June 2022.

Biodiem chief executive officer Julie Phillips said that a US patent for BDM-I use in skin and soft tissue infections was "a major milestone".

"While we already have development work underway for BDM-I use in other bacterial and fungal diseases, we are keen to pursue treatment of super-bug wound infections," Ms Phillips said.

"This is where the medical need is high and the market size is growing," Ms Phillips said. "We already have in-vitro activity against some of these bugs such as [methicillin-resistant Staphylococcus aureus] and will look for a partner or licencee to accelerate this development," Ms Phillips said.

Biodiem said that BDM-I was a synthetic compound being developed as a treatment for serious infections and patents had been granted in the US, Europe, Japan, Canada, Australia, Singapore and South Africa.

The company said it was pursuing its development of BDM-I through partnerships with the US National Institutes of Health, the US Army Medical Research Institute of Infectious Diseases and the Queensland Institute of Medical Research.

Biodiem said that it would seek licencees to complete the development and commercialize the BDM-I antimicrobial.

Biodiem fell half a cent or 7.7 percent to six cents.

MEDICAL DEVELOPMENTS INTERNATIONAL

Medical Developments says that revenue for the 12 months to June 30, 2013 was up 3.7 percent to \$11,733,000 with net profit after tax down 14.6 percent to \$2,309,000. Medical Developments said that sales and margins were up and the company had invested \$4.9 million in a range of clinical trials, research and development and product development and had paid two three cent fully-franked dividends in the year ending 30 June 2013.

The company said it would pay a final fully franked dividend of two cents a share for the year to June 30, 2013.

Medical Developments said that net tangible asset backing per share was down 68.75 percent to 2.5 cents and diluted earnings per share was down 19.6 percent to 4.1 cents for the year to June 30, 2013 compared to 5.1 cents for the previous corresponding period.

The company said it had \$768,000 in cash and cash equivalents at June 30, 2013, compared to \$3,483,000 at the end of the previous financial year.

Medical Developments was up 13 cents or 8.4 percent to \$1.68.

NUSEP

Nusep says it expects to receive \$1.6 million from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program. Nusep said it expected to receive the funds relating to research and development expenditure for the year to June 30, 2013 "in the coming weeks". Nusep was untraded at 4.3 cents.

BONE MEDICAL

Bone says La Jolla Cove's delayed payments has led to it being suspended from trading for failing to pay its ASX listing fee.

Earlier this week, Bone said that La Jolla Cove Investors had delayed its monthly payments under the draw down equity facility agreement (BD: Aug 19, 2013).

The company said it had not paid its ASX listing fee for the year ended June 30, 2014 which was due on August 22, 2013, and the ASX had imposed a suspension.

Bone said it was seeking "new, alternative sources of funds to supplement or replace the La Jolla funding, but until this effort is successful remains dependent on La Jolla for funding to meet its operating obligations in the meantime, including the immediate obligation of the ASX listing fee".

Bone last traded at 0.1 cents.

ONCOSIL MEDICAL

Oncosil says Nicholas Falzon has been appointed joint company secretary and financial controller replacing joint secretary and legal counsel Jillian McGregor.

Oncosil deputy chairman Martin Rogers told Biotech Daily that the other joint company secretary was Rob Hodby.

Oncosil said that Mr Falzon was a partner at Lawler Partners working with listed and unlisted companies advising on financial management.

The company said that Mr Falzon specialized on research and development tax concessions and had been successful in identifying substantial potential savings for the company in its planned clinical trial of its silicon brachytherapy for pancreatic cancer. Oncosil said that Mr Falzon had business management, corporate finance and compliance related experience.

Oncosil was unchanged at 12.5 cents.