



Biotech Daily

Thursday September 3, 2015

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH DOWN: OPTISCAN UP 14%, USCOM DOWN 13%**
- * **NHMRC GRANTS \$5.8m TO 11 EU, CALIFORNIA COLLABORATIONS**
- * **INDEPENDENT ROCHE REGISTRY DATA BACKS SIRTEX SIR-SPHERES**
- * **ADMEDUS RELEASES SMALLER CARDIOCEL SCAFFOLD**
- * **CORTENDO PROSPECTUS CITES ANTISENSE ATL1103 MILESTONES**
- * **RESAPP APPOINTS EXPERIEN, BLUE CURVE FOR FDA APPLICATIONS**
- * **AUCKLAND TRUST, LANG WALKER TAKE 13% OF BIOTECH CAPITAL**
- * **UNILIFE HIRES MORGAN STANLEY FOR STRATEGIC REVIEW**
- * **PRIMA PLEADS SCHULTZ TO ASX 28% QUERY**
- * **CRYOSITE LOSES JANUARY CEO JOSEPH SAAD**
- * **AMPLIPHI APPOINTS DR ALEXANDER GAIDAMAKA CHEMISTRY HEAD**

MARKET REPORT

The Australian stock market fell 1.4 percent on Thursday September 3, 2015 with the ASX200 down 73.7 points to 5,027.8 points. Eleven of the Biotech Daily Top 40 stocks were up, 15 fell, 11 traded unchanged and three were untraded.

Optiscan was the best, up 0.6 cents or 13.6 percent to five cents with 753,555 shares traded, followed by Compumedics up 10.2 percent to 27 cents with 183,214 shares traded. Prana climbed 7.7 percent; Bionomics was up 6.1 percent; IDT and Medical Developments were up more than three percent; Atcor, Starpharma and Universal Biosensors rose more than two percent; with Admedus, Neuren and Resmed up more than one percent.

Uscom led the falls, down two cents or 13.3 percent to 13 cents with 35,822 shares traded, followed by Prima down 13.0 percent to six cents with 19.5 million shares traded. Antisense and Avita lost more than six percent; Sirtex fell 4.1 percent; Oncosil, Orthocell and Osprey were down three percent or more; Mesoblast and Nanosonics shed more than two percent; Benitec, Cochlear, CSL, Ellex, Reva and Viralytics were down more than one percent; with Clinuvel down 0.4 percent.

THE NATIONAL HEALTH AND MEDICAL RESEARCH COUNCIL

The National Health and Medical Research Council says that 5.8 million has been granted to 11 projects to support international collaborative research.

The NHMRC said that nine grants were awarded under its European Union Collaborative Research Grant scheme, with two awarded under its Californian Institute of Regenerative Medicine (CIRM) Collaborative Research Grant scheme.

The NHMRC said the EU collaborative grants included \$450,721 to the Melbourne-based Baker IDI Heart and Diabetes Institute's Prof Karlheinz Peter to study the proteins, genes, and biological pathways behind the rupture of atherosclerotic deposits in blood vessels.

The Council said the Berghofer Queensland Institute of Medical Research Institute's Prof Georgia Chenevix-Trench would receive \$472,984 to develop ways of predicting which women were at risk of particular types of breast cancer, and the likely outcome.

The NHMRC said that Monash University's Prof Colin Pouton would receive a \$902,949 CIRM collaborative research grant to develop new tools and approaches to create microglia from human stem cells, with potential use in neurological disorders.

The Council said that Melbourne's Murdoch Childrens Research Institute's Prof Andrew Elefanty would receive \$881,221 to study how pluripotent stem cells develop into haematopoietic stem cells, which would allow them to more precisely engineer cells for clinical use, with application for leukaemia and other blood diseases.

The NHMRC said that a detailed list of grant recipients was available on-line at:

<https://www.nhmrc.gov.au/grants-funding/outcomes-funding-rounds>.

SIRTEX MEDICAL

Sirtex says that data from a Roche-sponsored registry supports the findings of its 530-patient Sirflox trial data (BD: Mar 17, Jul 1, 2015).

Sirtex chief medical officer Dr David Cade told Biotech Daily that like the Sirflox study, the registry data showed a non-significant difference on progression free survival for patients treated with chemotherapy and SIR-Spheres compared to chemotherapy alone, but did show significance for overall survival.

Sirtex said the independent research, entitled 'Current utilisation of Selective Internal Radiation Therapy (SIRT) in metastatic colorectal cancer (mCRC) in Australia' was presented by the Royal Melbourne Hospital's Prof Peter Gibbs at the Australasian Gastro-Intestinal Trials Group meeting in Sydney, today, reporting outcomes for patients treated with SIR-Spheres in first-line metastatic colorectal cancer taken from a large, prospective multi-site Australian registry of patients enrolled from January 2009.

Sirtex said that 30 patients with liver-only disease who were non-resectable and treated with palliative intent, received SIR-Spheres with first-line chemotherapy, with 188 patients receiving chemotherapy only, with the SIR-Spheres treated patients having a median overall progression-free survival of 10.6 months compared to 9.9 months ($p = 0.18$).

But Sirtex said median overall survival was 24.3 months for the SIR-Spheres treated patients, compared to 19.3 months for chemotherapy alone ($p = 0.038$).

Dr Cade said that the Sirflox data showed "a clinically significant 7.9 month delay in tumor progression in the liver for patients treated with SIR-Spheres microspheres, even though there was no difference in overall [progression free survival] at any site in the body".

Dr Cade said that the registry findings were "consistent with our view that delaying tumor progression in the liver is a worthwhile treatment objective, if that could translate to an overall survival benefit in patients treated with SIR-Spheres microspheres under a prospective clinical study design".

Sirtex fell \$1.37 or 4.1 percent to \$32.25 with 224,664 shares traded.

ADMEDUS

Admedus says it has released a new 2cm by 2cm Cardiocel bio-scaffold following surgeon feedback that a smaller scaffold could be useful in heart repair.

Admedus said that surgeons had reported that the smaller scaffold could be valuable across the spectrum of congenital heart disease repair and reconstruction procedures.

The company said that the Cardiocel Adapt-treated bovine cardiac scaffold was also available in 4cm by 4cm, 5cm by 8cm and 2cm by 8cm sizes.

Admedus chief executive officer Lee Rodne said the company was “excited to make the new size available to our key surgeons, as we work closely with them to advance the management of congenital heart defects internationally and offer patients the clinical benefits of the Adapt tissue engineering process”.

“With Cardiocel now used in over 95 centres across the US, Canada, Asia, Australia and Europe, we will continue to investigate the development of additional regenerative tissue products across a range of surgical applications,” Mr Rodne said.

Admedus was up 0.1 cents or 1.5 percent to 6.7 cents with 2.4 million shares traded.

ANTISENSE THERAPEUTICS

Antisense says that ATL1103 licencing partner Cortendo’s prospectus for its Nasdaq initial public offering details the agreements milestone payments (BD: Sep 1, 2015).

According to Exhibit 10.4 of the prospectus, the milestones include the start of the first phase III trial for ATL1103/COR-004 for the first acromegaly indication in any jurisdiction outside Australia & New Zealand, the filing of new drug application to the US Food and Drug Administration for ATL1103/COR-004 for the first acromegaly indication and the filing of a marketing approval application in the European Union for ATL1103/COR-004 for the first acromegaly indication;

The Cortendo prospectus cites as milestones US, EU and Japanese approvals, with additional commercial milestones based on sales performance.

The value of the milestone payments was not disclosed.

Antisense fell 0.6 cents or 6.7 percent to 8.3 cents.

RESAPP HEALTH (FORMERLY NARHEX LIFE SCIENCES)

Resapp says it has appointed the Sunnyvale, California-based Experien Group and Melbourne’s Blue Curve Pty Ltd as regulatory consultants.

Resapp said it would work with Experien to prepare and submit a pre-submission package to the US Food and Drug Administration, with the aim of conducting a pre-submission meeting by the end of this year.

The company said that Blue Curve had extensive FDA software quality system requirements experience.

Resapp was unchanged at 1.8 cents with 1.8 million shares traded .

BIOTECH CAPITAL

Auckland Trust and Lang Walker have become substantial shareholders in Biotech Capital with 12,860,583 shares or 13.04 percent.

The substantial shareholder notice said that Auckland Trust Co as trustee for the Second Pacific Master Superannuation and Langley Alexander Walker acquired the shares in a placement at eight cents a share (BD: Sep 1, 2015).

Biotech Capital was up 1.5 cents or 12.5 percent to 13.5 cents.

UNILIFE CORPORATION

Unilife says that “in response to third-party initiated expressions of interest” it has engaged Morgan Stanley & Co to conduct a strategic review.

Unilife said that potential strategic alternatives included a possible sale of the company, a strategic partnership with one or more parties or the licencing of some of the company’s proprietary technologies.

Unilife was up 2.5 cents or 8.5 percent to 32 cents with 1.2 million shares traded.

PRIMA BIOMED

Prima 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 1.5 cents or 28.3 percent from 5.3 cents on September 1 to 6.8 cents on September 2 and noted an increase in trading volume.

Yesterday, after the ASX query was lodged, Prima closed up 1.6 cents or 30.2 percent to 6.9 cents with 39.1 million shares traded (BD: Sep 2, 2015).

Today, Prima fell 0.9 cents or 13.0 percent to six cents with 19.5 million shares traded.

CRYOSITE

Cryosite says that Joseph Saad, who was appointed its chief executive officer on January 27 has resigned “for personal reasons” (BD: Jan 20, 2015).

Cryosite said that executive director Graeme Moore would take on the role of interim chief executive officer and the company planned to undertake a search for a permanent chief executive officer.

Cryosite fell 4.5 cents or 15.8 percent to 24 cents.

AMPLIPHI BIOSCIENCES CORP

The Richmond Virginia-based Ampliphi says it has appointed Dr Alexander Gaidamaka as its head of chemistry, manufacturing and control.

Ampliphi has said it was developing bacteriophage-based antibacterial therapies to treat drug resistant infections, with a facility in Sydney

Ampliphi said that Dr Gaidamaka had more than 25 years experience in the life sciences sector and previously was the chief executive officer and chief scientific officer at Personalized Oncotherapeutics Inc and held executive research and development, product development and quality control roles at Pharma Green, Merial, Sanofi Pasteur, Bioniche Life Sciences and Biopharm JSC.

The company said that Dr Gaidamaka was previously head of the Ukraine-based All-Union Research Institute of Drug Chemistry and Technology’s Department of Immunopharmacology and Allergology.

Ampliphi said that Dr Gaidamaka held a Doctorate of Veterinary Medicine and Doctorate of Philosophy from the Ukrain’s Kharkov State Veterinary Academy.

Last night on the Nasdaq, Ampliphi fell five US cents or 0.72 percent to \$US6.89 (\$A9.81) with 5,979 shares traded.