



# Biotech Daily

Friday June 13, 2014

*Daily news on ASX-listed biotechnology companies*

- \* **ASX, BIOTECH DOWN: ONCOSIL UP 4.55%, LIVING CELL DOWN 14%**
- \* **ASUREQUALITY IN-VITRO DIAGNOSTICS ISO APPROVAL**
- \* **SUDA APPOINTS TORREYA FOR ARTIMIST DEAL**
- \* **ACTINOGEN: 'ACTINOMYCETES ISOLATES STOP CANCER STEM CELLS'**
- \* **CRYOSITE PROFIT WARNING**
- \* **HEALTHLINX RAISES \$200k FOR VIDEO-GAMING**
- \* **ROBERT THOMAS REPLACES STARPHARMA CHAIR PETER BARTLES**
- \* **MEDICINES AUSTRALIA'S DR BRENDAN SHAW OFF TO GENEVA**

## MARKET REPORT

The Australian stock market fell 0.44 percent on Friday June 13, 2014 with the S&P ASX 200 down 23.7 points to 5,405.1 points.

Six of the Biotech Daily Top 40 stocks were up, 20 fell, 12 traded unchanged and two were untraded.

Oncosil was the best, up half a cent or 4.55 percent to 11.5 cents with one million shares traded, followed by Benitec up 4.1 percent to \$1.14 with 134,786 shares traded.

Acrux climbed 3.6 percent; Nanosonics rose 2.6 percent; Tissue Therapies was up 1.7 percent; with Medical Developments and Resmed up by less than one percent.

Living Cell led the falls, down 0.8 cents or 13.8 percent to five cents with 404,000 shares traded, followed by Genetic Technologies down 10 percent to 3.6 cents with 67,457 shares traded.

Atcor lost 9.1 percent; Antisense was down 6.9 percent; Analytica, Avita, Biotron, Osprey, Prana and Prima fell more than four percent; Bionomics and Compumedics were down more than three percent; Neuren and Sirtex shed more than two percent; Alchemia, Starpharma and Viralytics were down one percent or more; with Cochlear, CSL, GI Dynamics, Mesoblast and Psivida down by less than one percent.

## ASUREQUALITY

Melbourne'sASUREquality says that ISO 13485:2012 certification is global approval for its contract manufacturing of in-vitro diagnostic medical devices.

ASUREquality business manager Dr Michael Zalunardo told Biotech Daily that the approval meant the company was approved to produce immunoassay kit production, automated microplate processing and the production of associated biologicals.

"Yesterday's announcement of ISO 13485 certification will be attractive to companies seeking a contract manufacturer who can provide Australian and international market access, and meet the regulatory requirements for medical devices," Dr Zalunardo said.

Dr Zalunardo said the ASUREquality Melbourne facility was built in 2006 for the contract manufacture of products for the Swiss biotechnology company Prionics AG.

Dr Zalunardo said the products included the Bovigam interferon gamma test first developed at the Commonwealth Scientific and Industrial Research Organisation and manufactured by CSL in the early 1990s.

"ASUREquality acquired the technical staff and production equipment originally with CSL," Dr Zalunardo said.

Dr Zalunardo said the company had manufactured Cellmid's midkine enzyme-linked immunosorbent assay (Elisa) for cancer (BD: Nov 3, 2010; Oct 12, Dec 1, 2011).

ASUREquality said that the European notified body TÜV Rheinland awarded it the internationally recognized standards ISO 13485:2012 and ISO 9001:2008.

"This achievement is a significant milestone for ASUREquality and represents a major commitment to quality," Dr Zalunardo said.

"Our local and international customer base is continuously expanding, including companies marketing highly regulated in-vitro diagnostic medical devices," Dr Zalunardo said.

"So it is important to us to ensure the quality systems of our [good manufacturing practice] facility continue to meet and exceed our customers' expectations," Dr Zalunardo said.

"Our accreditation to this quality standard will demonstrate to the international community that we are passionate about being the best at what we do," Dr Zalunardo said.

ASUREquality said that its diagnostic production facility in Melbourne had contract manufacturing services for immuno-diagnostic kits and diagnostic reagents, microplate coating, bulk solutions of biological buffers, custom formulated liquid cell culture media, aseptic dispensing of liquids, and freeze-drying of reagents.

ASUREquality is a public unlisted company owned by the Government of New Zealand.

## SUDA

Suda says it has appointed the New York and London-based Torrey Partners to lead the negotiations to out-licence or sell its Artimist paediatric sublingual malaria treatment.

Suda said there were no benchmark examples of pharmaceutical deals for novel late-stage development anti-malarial products.

The company said it had entered discussions with several companies with an interest in potentially licencing or acquiring the rights to Artimist including major pharmaceutical companies that had extensive business units for the treatment of neglected diseases; together with mid-sized pharmaceutical companies that had a commercial presence in sub-Saharan Africa and were seeking to expand their anti-malarial portfolio.

Suda said that with Torrey Partners it aimed to conduct a bidding process to secure a deal on optimal terms.

Suda was up 0.2 cents or 4.3 percent to 4.9 cents.

## ACTINOGEN

Actinogen says initial results from its cancer stem cell project at Curtin University shows that its actinomycetes isolates inhibit cancer stem cell proliferation.

Actinogen said that 11 isolates from its library were tested to demonstrate anti-tumorigenic effects by affecting the viability of cancer stem cells in selected glioblastoma cell lines.

The company said that glioblastoma was the most aggressive type of brain cancer.

Actinogen said the cell lines tested included U87, U138, A172 and U373 and researchers analyzed the viability of cells post-treatment using assay, cell morphology and gene expression profiling.

The company said the proliferation of cancer stem cells from U87 was inhibited by isolate samples ac4935, ac5049, ac5084 and ac5092, while the proliferation of cancer stem cells from U373 was inhibited by isolate samples ac4904, ac4935, ac5059 and ac5086.

The company said that in both A172 and U138, the isolates ac5049, ac5073 and ac5099 were observed to cause significant reduction of 10 to 25 percent and 25 to 30 percent, respectively, in the proliferation of cancer stem cell populations.

Actinogen said variation between cell lines could be explained by their different origins.

The company said that the proliferation of the cancer cell populations from A172 and U138 was significantly inhibited by isolates ac5059 and ac5086, reducing cell populations by about 80 percent.

Actinogen said the data was consistent with previous internal results and supported the strong anti-cancer activity of some of the actinomycetes isolates.

The company said that sphere formation, a characteristic phenotype of cancer stem cells, was examined following treatment with isolates and a reduction in sphere size, together with restoration of anchorage and differentiation were indicators of the inhibition of cancer stem cell activity and when examined after the treatment with isolates it was observed that there was sphere disruption, cell anchorage and cell death with respective isolates for the cancer stem cells from four cell lines.

Actinogen said that overall, the data was concurrent with cell viability assay and cell morphology characterization and favored further investigation into the mechanism of action of actinomycetes isolates on cancer stem cells viability.

Actinogen executive chairman said Dr Brendan de Kauwe the company was "very excited to see the data on anti-tumor activity of our actinomycetes isolates that has elements consistent with our previous findings".

Actinogen was developing actinomycetes for antibiotics and anti-fungals, then turned to bio-fuels before returning to its antibiotic project (BD: Nov 9, 2011; Feb 13, 2014).

Actinogen was unchanged at 2.1 cents.

## CRYOSITE

Cryosite says it expects that profit from continuing operations before tax for the year to June 30, 2014 will be in the range of \$500,000 to \$600,000.

Cryosite said that the previous guidance was between \$800,000 and \$1.0 million.

In 2013, Cryosite reported revenue for the year to June 30, 2013 up 9.3 percent to \$8,764,000 with net profit after tax up 22.3 percent to \$1,250,000, but later warned profit would be down for the year to June 30, 2014 (BD: Aug 29, 2013; Jan 19, 2014).

Cryosite said that its financial performance for the six months to June 30, 2014 "suffered from the company's decision to implement a long term business growth strategy by investing in a number of new development activities in both the biological services and warehousing and distribution segments".

Cryosite fell two cents or 4.9 percent to 39 cents.

## HEALTHLINX

Healthlinx says it is pursuing a transaction which would change its activities from biotechnology to "a mobile video gaming" business.

Healthlinx said the transaction would be subject to relevant regulatory and shareholder approvals.

Healthlinx said the precise form and structure of a transaction was to be finalized and was subject to various conditions.

The company said that the transaction would require a substantial capital raising.

Healthlinx said that to assist with the transaction and to provide ongoing working capital it had completed a private placement of ordinary shares at 7.9 cents per share to sophisticated investors raising \$200,000.

Healthlinx failed to commercialize its Ovplex test for ovarian cancer and last year went into administration emerging from administration this year (BD: May 7, 2013; Jan 31, 2014).

Healthlinx was untraded at 50 cents.

## STARPHARMA HOLDINGS

Starpharma says Robert Thomas has been appointed chairman replacing Peter Bartels as previously announced (BD: Nov 11, 2013).

Starpharma said Mr Thomas was appointed as a director in December 2013 and had a strong background in financial services and continued as a director on a number of listed companies in Australia and the US.

The company said that Mr Thomas had more than 35 years experience at Potter Partners (now UBS), County Natwest and Citigroup and was currently chairman of TAL Limited (formerly Tower Australia), Gragher Capital Securities and the New South Wales State Library.

Starpharma said that Mr Thomas was the immediate past chairman of Heartware and remained a non-executive director of Heartware as well as Reva, Virgin Australia and Biotron.

The company said that Mr Thomas held a Bachelor of Economics from Monash University.

Starpharma fell one cent or 1.6 percent to 60 cents.

## MEDICINES AUSTRALIA

Medicines Australia says chief executive Dr Brendan Shaw has been appointed to the International Federation of Pharmaceutical Manufacturers and Associations.

Medicines Australia said that Dr Shaw would take up the position of assistant director-general in Geneva, Switzerland in December 2014 and finish his tenure at Medicines Australia on September 12.

The industry organization said that Dr Shaw would have overview of global health policy for the Federation, reporting to the director-general and work on a range of issues including reimbursement, health technology assessment, access to medicines, vaccines and communications.

Medicines Australia chairman Dr Martin Cross said the organization had begun a search process for a new chief executive.