



# Biotech Daily

Monday November 12, 2012

*Daily news on ASX-listed biotechnology companies*

- \* **ASX DOWN, BIOTECH EVEN:  
- ALCHEMIA UP 13%, IMPEDIMED, VIRALYTICS DOWN 14%**
- \* **NSW \$20m FOR CHILDREN'S MEDICAL RESEARCH**
- \* **VICTORIA'S 1<sup>st</sup> VOUCHER APPLICATIONS CLOSE NOVEMBER 28**
- \* **VIRALYTICS PHASE I CAVATAK SAFE, ANTI-TUMOR ACTIVITY**
- \* **TGA ACCREDITATION FOR NUSEP MANUFACTURING**
- \* **ALCHEMIA'S AUDEO FILES ESTIMATED US SHARE PRICE**
- \* **BIOTA OPENS DOWN 7% ON NASDAQ**
- \* **NOVOGEN TO ACQUIRE TRIAXIAL PHARMACEUTICALS**
- \* **AUSTRALIAN ETHICAL INCREASES TO 13.5% IN AVITA**
- \* **BIONICHE 48% AGM DISSENT ON EMPLOYEE SHARE, OPTION PLANS**
- \* **GENESIS 'LACK OF FUNDS' TRADING HALT**

## MARKET REPORT

The Australian stock market fell 0.31 percent on Monday November 12, 2012 with the S&P ASX 200 down 14.0 points to 4,448.0 points. Fourteen of the Biotech Daily Top 40 stocks were up, 14 fell, nine traded unchanged and three were untraded.

Alchemia was the best, up seven cents or 13.2 percent to 60 cents with 2.4 million shares traded. Prima climbed 7.7 percent; Avita was up 4.2 percent; Universal Biosensors and Uscom were up three percent or more; Circadian, Clinuvel, Ellex and QRX rose more than two percent; Bionomics, GI Dynamics, Heartware and Sirtex were up more than one percent; with Cochlear and Starpharma up by less than one percent.

Impedimed and Viralytics led the falls, both down 14.3 percent to 12 cents and 36 cents, respectively, with 122,078 and 140,886 shares traded, respectively, followed by Optiscan down 10 percent to nine cents with 103,160 shares traded. Both Antisense and Benitec lost 7.1 percent; Neuren and Sunshine Heart fell more than five percent; Mesoblast, Prana and Tissue Therapies shed more than two percent; Acrux, Anteo, Nanosonics and Reva were down more than one percent; with CSL and Resmed down by less than one percent.

### NEW SOUTH WALES GOVERNMENT, CHILDREN'S MEDICAL RESEARCH INSTITUTE

New South Wales Health Minister Jillian Skinner launched construction of a seven-storey tower at the Children's Medical Research Institute.

A New South Wales Government media release said that the redevelopment at the Westmead Children's Hospital would see the number of researchers increase from 100 to 200 staff.

"This Government promised to boost medical research in NSW and we have delivered," Ms Skinner said.

"I am proud to see the commitments we've made realized so that we can continue to improve health outcomes for children and their families," Ms Skinner said.

The media release said that the Children's Medical Research Institute was Australia's first paediatric institute when it was founded in Camperdown in 1958 and its achievements included increasing survival rates for premature babies and helping introduce rubella vaccinations.

"CMRI conducts fundamental research to understand the genes involved in human health and development and the underlying causes of disease," Ms Skinner said.

"It is at the forefront of international research in the areas of embryonic development and birth defects, cancer, nerve cell signalling and gene therapy," Ms Skinner said.

"It is also a member of the Kids Cancer Alliance, which is committed to speeding up development of new cancer therapies for children and bringing those therapies to clinics in both urban and rural areas," Ms Skinner said.

Children's Medical Research Institute director Prof Roger Reddel said the redevelopment would further enhance Western Sydney's place at the forefront of medical research.

"Given that one in 20 children is born with a congenital abnormality or genetic disease, this expansion is welcome news," Prof Reddel said.

### VICTORIA GOVERNMENT, SMALL TECHNOLOGIES CLUSTER

The Small Technologies Cluster says Victoria's Minister for Technology Gordon Rich Phillips has opened the first round of Technology Implementation Vouchers.

The Small Technologies Cluster general manager Dr Buzz Palmer told Biotech Daily that the Cluster was an independent Victoria-based technology hub administering the Technology Voucher Program (TVP).

Dr Palmer said the program offered TVP Development vouchers worth up to \$50,000 to adopt existing technologies, with vouchers able to be exchanged for goods, services and advice by other companies or publicly funded research organizations.

Dr Palmer said that the \$250,000 TVP Implementation vouchers were administered by the Department of Business and Industry and were available to develop or manufacture a prototype or prototypes to demonstrate commercial feasibility, open up markets and/or improve current products or processes, test different applications of the technology within new markets, undertake pilot scale trials to demonstrate the benefits from incorporating technology into products or production processes and carry out applied development and testing of technologies that can improve productivity and/or profitability.

"TVP replaces and expands the highly successful Small Technologies Industry Uptake Program which provided similar services, but expands into information and communications technology and industrial biotechnology," Dr Palmer said.

More information on the vouchers and how to apply is at the Technology Voucher Program website: <http://business.vic.gov.au/tvp> as well as the Small Technologies Cluster website: <http://lnkd.in/evvVSC>.

Applications close on November 28, 2012.

## VIRALYTICS

Viralytics says phase I data shows that Cavatak indicates “good patient tolerance ... with some evidence of transient anti-tumor activity in late stage cancer patients.

Viralytics said that a paper on its phase I clinical trial entitle ‘Phase I, Open-Label, Cohort Study of Cavatak (Coxsackievirus A21) Given Intravenously to Stage IV Patients Bearing ICAM-1 Expressing Solid Tumours’ was presented at a symposium on Molecular Targets and Cancer Therapeutics in Dublin, Ireland on November 9, 2012.

The poster concluded that preliminary data analysis “in general indicated good patient tolerance to IV delivery of CVA21, together with some evidence of transient anti-tumor activity and disease stabilization”.

“Such observations provide a solid foundation for phase II investigations employing a multi-dose administration schedule to study the efficacy and safety of CVA21 in patients with late stage ICAM-1 expressing advanced solid cancers,” the poster concluded.

The company said the poster was presented by Sydney’s St George Hospital’ Dr Winston Liauw.

Viralytics said the phase I dose escalation study administered intravenous Cavatak to 10 patients of which eight were evaluable for assessment as per the protocol.

The company said the primary objective was patient tolerance to intravenous infusion of Cavatak.

“The Cavatak phase I study met key endpoints required to justify moving the product into phase II trials,” Dr Liauw said.

“Cavatak was well tolerated for single-dose intravenous administration, demonstrated replication and presence inside some target cancers and some evidence for tumor stabilization despite receiving only a single dose of oncolytic virus,” Dr Liauw said.

“The strongest signals came in melanoma patients and this would be an attractive target population in phase II studies,” Dr Liauw said.

Viralytics said it had since advanced to a 63-patient, phase II, melanoma study using intra-tumorally injected Cavatak under an investigational new drug application allowed by the US Food and Drug Administration (BD: Oct 20, 2011).

The company said that 13 subjects had been dosed in the trial, with three demonstrating immune-related progression-free survival at six months.

Viralytics fell six cents or 14.3 percent to 36 cents.

## NUSEP

Nusep says the Australia Therapeutic Goods Administration has provided accreditation for the manufacture of in-vitro diagnostics medical devices used in coagulation.

Nusep said it was one of the first in-vitro diagnostics manufacturers in Australia to have accreditation under the recently introduced requirement for ISO 13485 compliance.

Nusep managing director Prakash Patel said the TGA accreditation would allow the company to expand its in-vitro diagnostics product range allow it to capture the \$5 million diagnostic market.

Nusep said it would registration of its in-vitro diagnostics products with the European Union, which was expected to be completed in early 2013.

The company said it was in discussions with European distributors for the sale of its coagulation products.

Nusep said it was preparing the membrane manufacturing process to supply Prime Biologics with cartridges to manufacture therapeutic plasma products and Spermgen with in-vitro fertilization cartridges.

Nusep was up 0.1 cents or 1.2 percent to 8.8 cents.

## ALCHEMIA

Alchemia's Audeo Oncology will offer 3,250,000 shares of common stock at between \$US14.00 (\$A13.47) and \$US16.00 (\$A15.40) a share in its Nasdaq initial public offer. Audeo Oncology filed a further amendment to the US Securities and Exchange Commission providing the price guidance which equates to an average of \$14.435 and with Alchemia shareholders receiving one share in Audeo for every 37 shares they hold in Alchemia, prices Audeo at about 39.0 Australian cents per share.

Alchemia chief financial officer Charles Walker was able to confirm the mathematical equation but said he could not comment on any value of the Audeo assets in the current Alchemia market share price of 58 cents.

Mr Walker said that the Audeo revenue for the three months to June 30, 2012 was \$125,000 and the drug was in profit with further revenue expected for the three months to September 30, 2012, to be reported imminently.

In its US SEC filing Audeo said it had applied to list the common stock on the Nasdaq Global Market under the symbol AURX.

The company said that the amended S-1 filing made with the SEC on November 9, 2012 was in response to comments received from the SEC and was a standard part of the formal listing process in the US.

Audeo said that the filing included important information and was available at the SEC website [www.sec.gov](http://www.sec.gov) by searching for the company name.

Alchemia was up seven cents or 13.2 percent to 60 cents with 2.4 million shares traded.

## BIOTA PHARMACEUTICALS

Biota closed its first day of trading on the Nasdaq on November 9, 2012, down 33 US cents or 7.4 percent to \$US4.12 (\$A3.96).

At a share exchange rate of one Australian Biota share for 0.125 of a US Biota share the price equates to 49.5 Australian cents.

Prior to the Nabi merger announcement, Biota was trading at about \$1.00 a share and last traded on the ASX on October 30, 2012 at 57 cents (BD: Apr 23, 2012).

Biota trades under the Nasdaq code 'BOTA'.

## NOVOGEN

Novogen says it a term sheet to acquire Triaxial Pharmaceuticals for \$1.88 million in scrip and debt, based on clinical milestones.

Novogen said that Triaxial was a private company established in 2009 "to develop a technology platform addressing the problem of certain families of small molecular drugs where there is an inherent inflexibility in their chemical structure".

The company said that Triaxial's platform was not limited to specific compounds, but was initially using its technology to create a family of molecules known as 'super benzopyrans'.

Novogen said that super benzopyrans targeted a range of key signal transduction pathways at the heart of multi-drug resistance in cancer cells.

The company said the proposed transaction was conditional on completion of its previously announced capital reduction and remained subject to the execution of mutually satisfactory legal documentation.

In September, Novogen said an attempt to acquire Kai Medical failed (BD: Sep 25, 2012).

Novogen owns 67 percent of the US based MEI Pharma (formerly Marshal Edwards) which has licenced Novogen's Isoflavone anti-cancer compounds (BD: May 10, 2011).

Novogen was unchanged at 16.5 cents.

### AVITA MEDICAL

Australian Ethical Smaller Companies Trust has increased its share-holding and has been diluted in Avita from 30,815,558 shares (12.94%) to 43,700,257 shares (13.45%).

Australian Ethical said that it bought shares and participated in a capital raising at 12 cents a share.

Avita was up half a cent or 4.2 percent to 12.5 cents.

### BIONICHE

All Bioniche annual general meeting resolutions were passed but two providing stock were opposed by up to 48.2 percent of votes cast.

Bioniche said that a resolution to re-approve the amended and re-stated stock option plan was passed with 20,267,611 votes ((51.8%) in favor with 18,892,066 votes (48.2%) against.

A resolution, to increase the maximum number of shares to be issued under the group retirement savings and employee savings plans to 10,000,000 common shares, was passed by a similarly narrow margin.

The company's most recent Appendix 3B said that Bioniche had 103,738,712 shares on issue meaning that the votes against the two stock resolutions amounted to 18.2 percent of the company.

A resolution to increase the maximum number of shares for "outside directors" to 1,400,000 shares was passed with 22.6 million votes in favor and 12.1 million votes against, while a resolution to approve the shareholders rights plan was passed with 35 million votes in favor and 4.2 million against.

Bioniche was untraded at 40 cents.

### GENESIS RESEARCH AND DEVELOPMENT

Genesis has requested a trading halt pending an announcement "about the future of the company due to the lack of funds for ongoing costs"

Last month, the New Zealand-based Genesis reported a cash burn of \$NZ32,000 (\$A25,000) for the three months to September 30, 2012 with \$NZ17,000 in cash at the end of the quarter, but with loan facilities of \$NZ250,000.

Separately, Genesis told the ASX that it was "reasonable to conclude that Genesis may not have sufficient cash to continue operations if it does not receive any further cash inflow".

The company said that it was "evaluating the possibility of selling some assets, and is considering proposals for new funding through a loan or the issue of new shares, which would require shareholder approval ...[and] operating cash flows are likely to be similar to the last quarter, so Genesis is urgently pursuing the matters noted above".

"At this stage the negotiations are confidential and not sufficiently complete or definite to be disclosed to the market," Genesis told the ASX.

Trading will resume on November 14, 2012 or on an earlier announcement.

Genesis last traded at 1.9 cents.