

Biotech Daily

Wednesday October 8, 2014

Daily news on ASX-listed biotechnology companies

- * ASX, BIOTECH DOWN: ANTEO UP 7%, ACRUX DOWN 9%
- * CSL \$210m BROADMEADOWS EXPANSION FOR \$683m PA OUTPUT
- * LIVING CELL PLACEMENT RAISES \$3m, SHARE PLAN
- * ACUVAX COMPLETES ACTIVISTIC ACQUISITION
- * US PATENT FOR IMUGENE'S HER-VAXX
- * CLARIFICATION: REGENEUS
- * NUSEP BANKS \$1.2m ANDREW GOODALL NOTE, LOAN, PRIME DEBT
- * RHINOMED APPOINTS TWO SOUTH-EAST ASIA DISTRIBUTORS
- * BENITEC APPOINTS GEORGINA KILFOIL FOR TT-034 HEP C ENROLMENT

MARKET REPORT

The Australian stock market fell 0.81 percent on Wednesday October 8, 2014 with the S&P ASX 200 down 42.9 points to 5,241.3 points.

Seven of the Biotech Daily Top 40 stocks were up, 24 fell, seven traded unchanged and two were untraded. All three Big Caps fell.

Anteo was the best, up one cent or 6.9 percent to 15.5 cents with 6.9 million shares traded. Universal Biosensors climbed 6.7 percent; Avita and Patrys were up more than five percent; Analytica and Cellmid rose more than three percent; with Medical Developments up 1.9 percent.

Acrux led the falls, down 13.5 cents or 8.9 percent to \$1.375 with 2.1 million shares traded

Antisense lost 8.7 percent; Phosphagenics fell 7.1 percent; Admedus and Bionomics were down more than six percent; Benitec, GI Dynamics, Nanosonics and Prima shed five percent or more; IDT and Oncosil fell more than four percent; Compumedics, Starpharma, Tissue Therapies and Viralytics were down more than three percent; Atcor and Impedimed shed more than two percent; Clinuvel, Ellex, Mesoblast, Neuren, Osprey, Resmed and Sirtex were down one percent or more; with Psivida, Cochlear and CSL down by less than one percent. <u>CSL</u>

CSL says that a \$210 million expansion of its manufacturing site in the Melbourne suburb of Broadmeadows will help meet growing demand for albumin.

In a media release not posted to the ASX, CSL said that the investment would fund a new manufacturing facility, creating 200 jobs during construction and a further 190 highly skilled manufacturing jobs once the plant is fully operational.

The company said that in 2012 it integrated the Broadmeadows site with the CSL Behring global network, recently opened a biotechnology facility for novel product development and would soon open an adjacent plant to manufacture CSL's global immune disorder therapy for export markets.

CSL said the facilities were an investment of more than \$250 million and were supported by grants from the Victoria and Federal governments.

The company said that the new facility would have two manufacturing modules, with the first module to begin building in the next several weeks and would take about four years to complete.

CSL said that at full capacity, the annual commercial value of the albumin to be exported from the facility could be about \$US600 million (\$A683 million).

The company said that albumin was the most abundant protein in human plasma and was used to restore blood volume in people following trauma or major surgery and to support patients with extensive burns or serious infections.

CSL said that its global albumin product was manufactured by CSL Behring's US, German and Swiss facilities using plasma collected by CSL Plasma's collection centres.

The company said that the new facility would become an integral part of the global supply chain and would have the capacity to make a significant contribution to CSL's total global albumin output.

CSL said that following a review of CSL Behring sites, Broadmeadows was chosen for the albumin expansion and "a strategic contribution from the Victorian Government was instrumental to the success of the Broadmeadows bid".

CSL chief executive officer Paul Perreault said that the company was "proud to partner with the Victorian Government in undertaking this next important phase of expansion".

"The investment will generate significant economic returns for Victoria and further strengthen the role of the Broadmeadows site in our global manufacturing network," Mr Perreault said.

CSL said that the Broadmeadows site employed 650 highly skilled workers, was home to Australia's only plasma manufacturing facility and was contracted by the Federal Government to supply a range of plasma products for patients in Australia.

CSL fell 20 cents or 0.3 percent to \$73.08 with one million shares traded.

LIVING CELL TECHNOLOGIES

Living Cell says it has raised \$3 million through a placement at 6.08 cents a share and hopes to raise more funds through a share purchase plan.

Living Cell said the proceeds would be used for working capital to continue clinical trials of lead product NTCell in Parkinson's disease and further develop it for other indications. The company said the record date for the share plan was October 7 the plan would open on October 15 and close on October 31, 2014.

Living Cell said that shareholders would each be entitled to parcels of shares in \$1,000 increments up to \$15,000.

Living Cell was unchanged at seven cents.

<u>ACUVAX</u>

Acuvax says it has executed a securities sale agreement to acquire Activistic Pty Ltd for its funds collection system for mobile telephones.

Acuvax said it would continue to focus on its bio-health products, as well as undertake the development of the Activistic micro payments platform through the development of its existing charities program in the UK, roll-out the platform in the US within the next four months and establish the necessary infrastructure to develop the use of the platform in Australasia from mid-2015.

The company said that Activistic had developed a cost-efficient collection system through a technology that enabled regular payments or contributions using a mobile phone network.

Acuvax said that contributions were forwarded to the intended donor organization with minimal handling expense, maximizing the value of the contribution to the intended target organization.

The company said that Activistic had negotiated exclusive billing with global aggregators, including the UK and the US and secured the support of mobile telephone providers in those markets.

In 2013, Perth's GBU Capital tried to back-door list Biolife Science and its Her-Vaxx technology into Acuvax, returning Dr Roger Aston and Paul Hopper to their cancer company but failed to raise the minimum \$4 million, with Biolife later acquired by Imugene (BD: Dec 20, 2012; Jul 4, Oct 23, 2013).

In 2005, Australian Cancer Technology became Avantogen and was later renamed Acuvax, when major shareholder Dr Richard Opara was appointed chairman and in 2006 Dr William Ardrey was appointed chief executive officer (BD: Dec 20, 2012).

By 2010, Dr Opara had been reduced from as much as 87 percent to below substantial and a board spill was engineered to remove Dr Opara, followed in 2011 by a complete change of ownership, board and management including the departure of Dr Ardrey, who is on bail pending the hearing of unrelated fraud charges.

Acuvax was unchanged at 0.1 cents.

IMUGENE

Imugene says the US Patent and Trademark Office has granted a patent protecting its HER-Vaxx cancer immunotherapy in development for gastric cancer.

Imugene said that the patent, entitled 'Multiepitope Vaccine for HER2/Neu-associated Cancers' protected the method of composition and method of use of Imugene's HER-Vaxx for the generation of a therapeutic antibody response against HER-2/neu and was valid through to 2030.

The company said that HER-Vaxx was a proprietary therapeutic cancer immunotherapy that stimulated a polyclonal antibody response to HER-2/neu, the same biomarker targeted by the \$US6.9 billion a year drug Herceptin.

Imugene said that HER-Vaxx had completed a phase I study in breast cancer and the next stage of development would be a phase Ib/II study in gastric cancer.

The company said that gastric, or stomach, cancer was the second most common cause of cancer-related death in the world and the fourth most commonly diagnosed cancer, with more than 1,000,000 new cases diagnosed each year.

Imugene fell 0.1 cents or 7.7 percent to 1.2 cents with 3.7 million shares traded.

REGENEUS

Last night's edition quoted an ABC-TV 7.30 Report transcript saying that a complaint to the ASX related to a Regeneus announcement "in August last year".

The Regeneus announcement regarding Australian Football League approval for the case-by-case use of its fat-derived Hiqcell treatment was lodged to the ASX and reported in this publication on August 27, 2014.

No sub-editors were hurt in making this clarification.

Regeneus remained in a trading halt pending the release of a response to the television program and was last traded at 14 cents.

NUSEP

Nusep says it has received \$1,248,794.80 through the issue of a convertible note with face value of NZ\$1,400,000 to non-executive director Andrew Goodall.

Nusep said that the conversion of the note to shares would be subject to shareholder approval at the annual general meeting.

The company said that note carried an Australia-New Zealand exchange rate of \$A0.90 to \$NZ1.00 for all conversions to shares throughout the term of the note to October 2, 2017; with an interest rate of 14 percent per annum to be converted to shares at the conversion price of 6.45 cents a share.

Nusep said that Mr Goodall and/or his nominee would receive a fee of \$40,950 to be paid in shares at the conversion price together with 3.5 million unlisted options exercisable at 11.2 cents, with 2.0 million expiring on November 1, 2016 and 1.5 million options expiring on November 1, 2017.

The company said that should shareholders not vote in favor of granting the options, Mr Goodall could negotiate shares to be allocated to him to the same value as the options and Nusep would reimburse Mr Goodall for legal fees and other costs incurred in arranging the finance on receiving the funds.

Nusep said that the funds would be used to pay down debts and to further development of its intellectual property, in particular to progress the Spermsep project.

The company said that the terms of a loan from Chang Seow Ying Alison, also known as Alison Chang, have been amended.

Nusep said that the principal amount of the loan was SGD350,000 (\$A312,038) beginning on July 22 2013 and expiring on July 31, 2015, with a one-off fee of \$20,000 payable with the issue of 1,000,000 options exercisable at 11.2 cents by January 20, 2015, subject to shareholder approval, with an interest rate of 14 percent per year.

The company said that Ms Chang was a related party at the time of providing the loan, as the spouse of Clifford Eu who resigned as a director on November 29, 2013.

Nusep said that Mr Goodall had decided not to guarantee the debt of about \$4 million owed for its 74 percent ownership of the Prime Biologics Singapore plasma processing facility which was due to be repaid from March 2016.

The company said that final documentation had been delayed due to the first completion of the Prime Biologics investment transaction and there had been further delays but the board believed that there was sufficient time for Nusep to determine its strategy in meeting this funding requirement for the facility and it did not require the guarantee at present. In June, Nusep said it had completed the \$S6.55 million (\$A5.6 million) first tranche investment in Prime with Malaysia's Xeraya Capital Labuan through affiliate, Pulau Manukan Ventures Labuan and Singapore's JP Asia Prime Capital Pte Ltd as the primary investors (BD: May 12, Jun 19, 2014).

Nusep was unchanged at eight cents.

RHINOMED

Rhinomed says it has appointed Gadget Sports as its Breatheassist Turbine distributor for Thailand and PT Indovelo Mitra Abadi for Singapore, Indonesia and Malaysia.

Rhinomed said that Gadget would distribute the Turbine range to the Thai cycling and triathlon retail sector and would be the wholesale distributor for the Thai sporting goods and retail cycling market.

The company said that the Indonesia-based PT Indovelo would be the wholesale distributor for the Singaporean, Indonesian and Malaysian sporting goods and retail cycling market.

Rhinomed said that PT Indovelo Mitra Abadi owned and operated the largest cycling retail website in Indonesia.

Rhinomed was unchanged at three cents.

BENITEC BIOPHARMA

Benitec says it has appointed Georgina Kilfoil as senior drug development director to expedite enrolment in its phase I/IIa trial of TT-034 for hepatitis C.

Benitec said that the San Francisco, California-based Ms Kilfoil had more than 25 years experience in managing clinical trials and clinical development.

The company said that to increase the rate of recruitment for the trial Ms Kilfoil would liaise with the current trial sites to increase recruitment, advance negotiations with an additional five clinical trial sites in the US and appoint specialized patient recruitment vendors across all trial sites.

Benitec chief executive officer Dr Peter French said that appointing Ms Kilfoil "was an important step".

"She will work with the company and our clinical investigators to accelerate patient recruitment across all sites, and to ensure the trial progresses as rapidly as the guidelines allow," Dr French said.

Benitec said that the first patient dosed with TT-034, continued to be monitored and he laboratory data indicated that the drug was well tolerated and safe at the dose administered.

The company said that a second patient had been identified for dosing, and provided the patient continued to stay within the clinical parameters required by the trial protocol during the 28-day screening process, would be dosed as soon as possible following the completion of screening.

Benitec said it had two trial sites actively recruiting patients, Duke Clinical Research Centre and University of California San Diego.

The company said that Ms Kilfoil was previously Anthera Pharmaceuticals drug development senior vice-president and prior to that was a senior executive at Peninsular Pharmaceuticals.

Benitec said that Ms Kilfoil held a Bachelor of Science from the University of Bristol and a Masters of Business Administration for the Australian School of Management. Benitec fell 5.5 cents or six percent to 86.5 cents.