Biotech Daily

Friday December 6, 2013

Daily news on ASX-listed biotechnology companies

* **ASX DOWN, BIOTECH UP: REVA UP 8%, ANTEO DOWN 6%**

*** FDA APPROVES TISSUE THERAPIES VITROGRO TRIAL**

*** BIOTA DOSES BARDA PHASE II NORTHERN HEMISPHERE 'FLU PATIENTS**

*** VICTORIA ISRAEL $500k FOR COLLABORATION GRANTS**

*** VICTORIA, STC $100k for 5 MEDICAL TECHNOLOGY COMPANIES**

*** GENETIC TECHNOLOGIES BREVAGEN 'COST-EFFECTIVE'**

*** NOVOGEN CO SEC ANDREW BURSILL RESIGNS**

MARKET REPORT

The Australian stock market fell 0.23 percent on Friday December 6, 2013 with the S&P ASX 200 down 12.0 points to 5,186.0 points.

Fifteen of the Biotech Daily Top 40 stocks were up, 12 fell, nine traded unchanged and four were untraded. All three Big Caps were down.

Reva was the best, up 3.5 cents or 7.8 percent to 48.5 cents, with 108,270 shares traded.

Avita and Patrys climbed six percent or more; Phylogica was up 5.9 percent; Phosphagenics and Tissue Therapies were up more than four percent; Admedus and QRX were up more than three percent; Benitec, Compumedics, Ellex, Prana and Viralytics rose more than two percent; Psivida was up one percent; with Bionomics up 0.6 percent.

Anteo the falls, down one cent or 5.7 percent to 16.5 cents with 3.3 million shares traded.

Neuren, Optiscan, Pharmaxis and Prima fell more than four percent; Nanosonics shed 2.9 percent; Genetic Technologies, GI Dynamics, Mesoblast, Osprey and Sirtex were down more than one percent; with Cochlear, CSL, Medical Developments and Resmed down by less than one percent.

TISSUE THERAPIES

Tissue Therapies says that the US Food and Drug Administration has approved a 250 patient clinical trial of Vitrogro extra-cellular matrix (ECM) for venous ulcers.
Tissue Therapies chief executive officer Dr Steven Mercer told Biotech Daily that the trial would be a prospective, randomized, double-blinded, controlled study and Vitrogro ECM had been classified by the FDA as a combination product of a biologics and a medical device.
Dr Mercer said that the primary endpoint was time to wound closure.
Dr Mercer said the company would need to raise funds for the trial.
Tissue Therapies has had its European marketing application delayed with regulatory bodies changing Vitrogro ECM's classification (BD: Oct 30, 2012; Jul 29, 2013).
Today, Tissue Therapies said that the only request from the FDA for final approval to be granted was a plan acceptable to the FDA for an additional quality control test for manufacturing and stability test of Vitrogro ECM.
The company said that the scientific and clinical results demonstrated that Vitrogro ECM was stable and effective.
Tissue Therapies said that the additional test requested by the FDA was to detect a theoretically possible change in stability that the company has not observed with extensive testing to date.
The company said that it was not a requirement for this new testing to be complete to obtain approval for the venous ulcer clinical trial to proceed.
Tissue Therapies said that a contractor was actioning the plan for submission to the FDA.
The company said that the FDA had no other issues for approval of the Vitrogro ECM trial.
Tissue Therapies said that its immediate focus was the start of sales in the UK and Europe but it was "valuable to know that the US venous ulcer clinical trial will be able to proceed as soon as funding is available".
The company said that the final Conformité Européenne (CE) mark review required by the European Medicines Authority was progressing as expected and should allow the start of sales of Vitrogro ECM in the UK and Europe by July 2014.
Tissue Therapies was up one cent or 4.55 percent to 23 cents.

BIOTA PHARMACEUTICALS

Biota says it has begun dosing patients in the Northern Hemisphere part of its phase II, clinical trial of laninamivir octanoate.
Biota said that the 636-subject randomized, double blind, placebo controlled, parallel arm 'Igloo' trial, would compare the safety and efficacy of 40mg and 80mg of its long acting neuraminidase inhibitor laninamivir octanoate with placebo, delivered by its Twincaps inhaler in adults with presumed influenza A or B infection.
Biota began the phase II trial in the Southern Hemisphere in July (BD: Jul 17, 2013).
Today, the company said its goal was to complete enrollment in the trial by the end of the influenza season in the Northern Hemisphere and have top-line data available in mid-2014.
Biota said that the trial was being conducted in connection with its contract with the US Office of Biomedical Advanced Research and Development Authority (BARDA).
Last night on the Nasdaq, Biota was up two US cents or 0.49 percent to $US4.13 ($A4.56, equivalent to 57 cents pre-merger) with 33,470 shares traded.

VICTORIA GOVERNMENT

The Victoria Government says that collaboration grants of up to $50,000 are available under the Victoria Israel Feasibility and Proof of Concept program.

Victoria Minister for Innovation, Services and Small Business Louise Asher said the grants provided an opportunity for Victorian businesses and research institutions to collaborate with organizations in Israel to demonstrate new applications of technology.

“Victoria and Israel are both internationally recognized for the quality of their research and innovation,” Ms Asher said. “Through the Victoria Israel Feasibility and Proof of Concept grants our two countries can now collaborate on new projects that can lead to benefits in both Victoria and Israel.”

A Victoria Government media release said that the grants were open to Victoria-based companies and research institutions who had secured a collaborating partner in Israel.

The Government said it was working with Victorian organizations and Israel’s Office of the Chief Scientist to assist with partner matching to support both the Feasibility and Proof of Concept grants and the Vistech program that would be opened in 2014 with some Feasibility and Proof of Concept projects expected to progress to the Vistech program.

The Victoria-Israel Science and Technology Research and Development Fund (Vistech) was launched on December 7, 2005 by Victoria’s then Treasurer and Minister for Innovation John Brumby with Victoria and Israel’s Office of the Chief Scientist each providing half of the $US6 million fund to provide grants of up to $US500,000 to approved projects (BD: Dec 7, 2005).

Successful applicants included Immuron and the then Karmelsonix, now Isonea.

The Victoria Government said that applications for the $50,000 Victoria Israel Feasibility and Proof of Concept grants would remain open until the funding was fully committed.

For more information go to: www.business.vic.gov.au/visits.

VICTORIA GOVERNMENT, SMALL TECHNOLOGIES CLUSTER

The Small Technologies Cluster says that five companies have won $20,000 each in its inaugural ‘Medtech’s Got Talent’ pitch competition.

The STC said that its ‘Medtech’s Got Talent’ program was supported by Victoria’s Department of State Development, Business and Innovation as an initiative of the Enabling Technologies Skills Strategy for Small Technologies and that the five finalists would each receive $20,000 to support participation in the second stage of ‘Medtech’s Got Talent’ to support prototype development, consultants to assist with strategy development, or other costs to and prepare an investor due diligence package over the course of an intense two-month accelerator program.

The STC said each team would receive mentorship to become seed investment ready, develop a viable business case along with clinical insights.

The Cluster said the finalists were Danielle Bartolini and Frank Bartolini, mentored by Intellimedical’s Geoff Rogers for ‘Lighting the Way to New Bandage Application’; Paul Savage mentored by Capstone Partners’ Alexander Gosling for ‘Cardiovascular Imaging in a New Light’; Marita Cheng and Charles Korn, mentored by Design and Industry’s Luke Martin for ‘Robotic Arms for People in Wheelchairs’; Thomas Oxley mentored by Hydrix‘s Peter Lewis for ‘Minimally Invasive Brain Machine Interface for Bionic Limbs’; and Alen Keirnan and Adrian Lim, mentored by STC general manger Dr Buzz Palmer and chief operating officer Laura Faulconer for ‘The New Rule for Anaphylaxis, Save a Life, Not a Thumb’.

Ms Faulconer said STC ”suspected there was a need for this type of support … but we have been totally overwhelmed with the quantity of brilliant ideas”.

GENETIC TECHNOLOGIES

Genetic Technologies says its Brevagen genetic breast cancer risk prediction test was most cost-effective when given to “intermediate lifetime risk of breast cancer” patients

The article, entitled ‘Cost-effectiveness of a Genetic Test for Breast Cancer Risk’ was co-written by Genetic Technologies’ scientific director Dr Richard Allman and published in the journal Cancer Prevention Research with an abstract available at: http://cancerpreventionresearch.aacrjournals.org/content/6/12/1328.abstract.

Genetic Technologies said the study evaluated the cost-effectiveness of the Brevagen test against direct magnetic resonance imaging screening for breast cancer risk and was a collaborative project with the San Francisco, California-based healthcare modeling and analytics organization Archimedes Inc.

The company said that a simulation model of breast cancer and healthcare processes was used to represent women in a virtual trial comparing the use of the Brevagen test to the traditional Gail risk test alone, categorizing patients as either low or high risk.

Genetic Technologies said that low risk patients received an annual mammogram, while high risk patients received an annual magnetic resonance imaging (MRI).

Cancer incidence was based upon surveillance, epidemiology and end results (Seer) scores and validated to the Cancer Prevention Study II Nutrition Cohort data set, with risk factors drawn from the National Health and Nutrition Examination Survey and Prostate, Lung, Colorectal, and Ovarian Cancer Screening Trial data sets.

The company said that based on the study, the Brevagen test was most cost-effective when given to patients classified as having an intermediate lifetime risk of breast cancer.

Genetic Technologies said that for patients with a risk of 16 percent to 28 percent, the test resulted in savings of 0.023 quality-adjusted life years (Qaly) per patient at a cost of $US163,264 ($A180,418) per Qaly.

The company said that the results were sensitive to the age at which the test was given, the discount rate and the costs of the genetic test and MRI.

Genetic Technologies said the cost-effectiveness of the Brevagen test for patients with an intermediate Gail risk score was similar to other recommended strategies, including annual MRI for patients with a lifetime risk of greater than 20 percent or BRCA 1 or 2 mutations.

The company said the model showed that the Brevagen test gave a 2.7 percent reduction in cancer deaths relative to the Gail score alone for patients with a lifetime risk of at least 10 percent.

Genetic Technologies acting chief executive officer Tom Howitt said the company was “pleased to see a predicted reduction in cancer deaths based on the use of Brevagen, in addition to the identification of a group of women at intermediate risk of developing breast cancer for which it is optimally cost-effective”.

Genetic Technologies said that Brevagen was available for sale through the US.

Genetic Technologies fell 0.1 cents or 1.6 percent to six cents.

NOVOGEN

Novogen says that Andrew Bursill has resigned as joint company secretary, effective from today.

Novogen said that Lionel Mateo continues as company secretary.

Novogen was unchanged at 22 cents.