Biotech Daily

Friday December 20, 2013

Daily news on ASX-listed biotechnology companies

* **ASX, BIOTECH UP: PHOSPHAGENICS UP 9.5%; PHYLOGICA DOWN 12%**

* **RESONANCE JUMPS 183% ON FDA HEPAFAT-SCAN APPROVAL**

* **NOVOGEN, CORNELL COLLABORATE ON GLIOBLASTOMA MULTIFORME**

* **ELLEX RAISES $3m FOR US GLAUCOMA BUSINESS**

* **ATHYRIUM LENDS UNIVERSAL BIOSENSORS UP TO $28m**

* **ACTINOGEN ACQUIRES LABORATORY SPACE AT MURDOCH UNIVERSITY**

* **FDA REQUESTS HALTS INVION SMOKING CESSATION TRIAL**

* **IMUGENE BACKS BIOLIFE; CHAIR CHANGE, WEBINVEST 6%**

* **ANTISENSE REQUESTS XMAS EVE ATL1103 RESULTS TRADING HALT**

* **GENETIC TECHNOLOGIES DR MERVYN JACOBSON DOWN TO 19%**

* **IM MEDICAL DROPS BIOTECH FOR WHITE DATA**

* **NUSEP'S DR STEPHEN VAN DER MYE APPOINTED INTERIM CO SEC**

MARKET REPORT

The Australian stock market climbed 1.21 percent on Friday December 20, 2013 with the S&P ASX 200 up 63.0 points to 5,265.2 points. Fourteen of the Biotech Daily Top 40 stocks were up, 12 fell, 10 traded unchanged and four were untraded.

Phosphagenics was the best, up one cent or 9.5 percent to 11.5 cents with 352,922 shares traded. Benitec climbed 8.2 percent; IDT and Starpharma were up more than four percent; Atcor and Avita were up more than three percent; GI Dynamics, Mesoblast and Tissue Therapies rose more than two percent; Acrux, CSL, Neuren and QRX were up more than one percent; with Alchemia, Cochlear and Sirtex up by less than one percent.

Phylogica led the falls, down 0.2 cents or 11.8 percent to 1.5 cents with 489,086 shares traded. Admedus fell 9.7 percent; Anteo, Prana and Psivida lost more than six percent; Universal Biosensors fell 5.1 percent; Patrys and Prima fell more than four percent; Cellmid and Genetic Technologies were down more than three percent; Viralytics was down 1.6 percent; with Clinuvel and Resmed down by less than one percent.

RESONANCE HEALTH

Resonance jumped 183 percent on US Food and Drug Administration 510(k) market clearance for its Hepafat-Scan medical device to measure liver fat.
Resonance said that the approval was “a significant milestone”.
The company said that more than two-thirds of the US population was either overweight or obese, with obesity and ‘metabolic syndrome’ the most common risk factors for the development of non-alcoholic fatty liver disease, with about 30 percent of the US population having non-alcoholic fatty liver disease .
Resonance said that data from adult transplant centers suggested that liver transplantation due to fatty liver related disorders was increasing dramatically.
The company said that screening for fatty liver was a significant challenge, with liver biopsy the gold standard but not well suited for screening or monitoring because of its invasive nature, cost and complications.
Resonance said that using magnetic resonance imaging Hepafat-Scan was a safe non-invasive diagnostic tool.
Resonance was up 5.3 cents or 182.8 percent to 8.2 cents with 94.5 million shares traded.

NOVOGEN

Novogen says it has a research agreement with Cornell University’s Weill Cornell Medical College to study glioblastoma multiforme in Europe, US, Asia and Australia.
Novogen said glioblastoma multiforme was the main primary brain cancer and the collaboration would focus on the super-benzopyran drug, Trilexium.
The company said the program paralleled its Cantx ovarian cancer program with Yale University, which identified a Trilexium derivative Trx-1 as having equipotent killing ability of both ovarian cancer stem cells and ovarian cancer somatic cells, raising the prospect of being able to use one agent to kill all cells in an ovarian cancer.
Novogen said Cantx would take Trx-1 to the clinic “in the near-term as a generic treatment for late-stage ovarian cancer, but then to use the Trx pharmacophore to create a panel of drugs capable of killing ovarian cancer cells with specific genotypes”.
The company said the brain cancer program had the same objectives, intending to take Trilexium to the clinic as a generic treatment for glioblastoma multiforme that had failed to respond to Temozolomide, the only drug approved for the disease.
Novogen said the longer-term goal was to identify a panel of drugs capable of providing a personalized approach to glioblastoma multiforme chemotherapy, based on the potency of Trilexium against glioblastoma multiforme cells, with both stem cells and somatic cells being killed at equivalent dosages.
The company said glioblastoma multiforme progression after radio and chemotherapy was believed to result from the regrowth of chemo-resistant cancer stem cells.
Novogen said that recurrent tumor cells, like parent glioblastoma multiforme stem cells, were highly drug-resistant and with increased aggression, accounting for the poor prognosis associated with glioblastoma multiforme.
Novogen chief scientific officer Dr David Brown said the collaboration had focused on bringing Trilexium to the clinic for glioblastoma multiforme, expected in early 2015.
“The expansion of the collaboration to include Cornell takes the program to the next level, which is to achieve personalized chemotherapy for patients with glioblastoma multiforme,” Dr Brown said. “The objective is to identify a panel of Trx analogs that target individual … mutations within the genotype spectrum that characterizes [glioblastoma multiforme] malignancies … to match the best drug candidate to an individual tumor genotype.”
Novogen was up one cent or 5.1 percent to 20.5 cents.

ELLEX MEDICAL LASERS

Ellex says it has raised $3 million through the issue of 10,000,000 shares at 30 cents a share for a “North American glaucoma consumable device business”.
Ellex said it would pay the unnamed company $US1.5 million for the consumable device “used for the treatment of mild to moderate glaucoma” which represented a patient population of about 1.3 million people in the US.
The company said that the acquisition included an earn-out over several years based on a percentage of future revenues.
Ellex said that the device had both US Food and Drug Administration approval and Conformité Européenne (CE) mark, along with a current procedural terminology (CPT) code I coverage for reimbursement and was supported by major insurers.
The company said that the business had annual sales of about $4.0 million.
Ellex was unchanged at 32 cents.

UNIVERSAL BIOSENSORS

Universal Biosensors says it has an up to $US25 million ($A28.2 million) with funds managed by the New York City-based investment adviser Athyrium Capital Management.
Universal Biosensors said the facility leveraged its future quarterly service fees and was expected to fund the company to positive cash generation and profitability.
Universal Biosensors chief executive officer Paul Wright told Biotech Daily that the company had $14.7 million in cash at September 30, 2013.
The company said that funds provided “the financial strength and flexibility to pursue its expansion into the [point-of-care] coagulation testing market”.
Universal Biosensors said it would draw down $US15 million, with further tranches of $US5 million available if certain conditions were achieved prior to January 30, 2015.
Universal Biosensors said the loan interest was 10.5 percent a year with non-refundable fees, secured by “substantially all of the assets of the group” and Athyrium had a warrant for 4.5 million shares at an exercise price of $1.00 a share for seven years.
Universal Biosensors fell 2.5 cents or 5.1 percent to 46.5 cents.

ACTINOGEN

Actinogen says it has new laboratory premises at Murdoch University’s State Agricultural Biotechnology Centre in Perth, Western Australia.
Actinogen said that along with its own equipment, its team would have access to the Centre’s state-of-the-art on-site equipment and facilities.
The company said that the Centre had “the most comprehensive set of equipment and facilities … in Western Australia, with full facilities for; cell and molecular biology, high throughput agricultural genetic analyses and diagnostics, structural, comparative and functional genomics, microarray technologies, proteomics and mass spectroscopy and bioinformatics support” and expected new premises to be operational this year.
Actinogen was working on a program to discover and isolate Western Australian soil actinomycetes to produce new antibiotics, in particular against the methicillin resistant staphylococcus aureus and anti-cancer agents; acquired Celgenics for cancer testing; then changed focus to develop bio-fuels; and ran out of cash before being resurrected with a $100,000 draw down loan from Otsana Capital, with assistance from Dr Brendan de Kauwe and other entities including the Perth-based RM Capital’s health care analyst Dr Anton Uvarov (BD: Dec 13, 2010; Oct 4, Nov 9, 2011; Sep 24, 2013).
Actinogen was unchanged at 2.2 cents.

INVION

Invion says a US Food and Drug Administration request for smoking cessation trial protocol changes have resulted in a halt to enrolment.

Invion said the FDA had “concerns around certain technical aspects of the protocol”.

“The rationale for the clinical hold appears to be to align the titration and termination criteria for the study in [chronic obstructive pulmonary disease] patients with the criteria established in Invion’s ongoing study of nadolol in mild asthma patients ongoing under Invion’s [investigational new drug application] with the Division of Pulmonary, Allergy, and Rheumatology Products,” the company said.

Invion chief medical officer Dr Mitchell Glass said the company would respect the FDA’s rationale and comply with the request.

“While the two study populations are quite different, aligning the titration criteria will enable Invion to integrate the safety data from the two trials seamlessly, providing us with a more robust titration schedule for future studies whether in [chronic obstructive pulmonary disease] or more severely asthmatic patients,” Dr Glass said.

“Since responding to this requirement will generate a delay in recruitment, Invion is adding clinical trial sites to minimize the impact on the availability of interim results and study completion,” Dr Glass said.

Invion fell one cent or 10.5 percent to 8.5 cents.

IMUGENE

Imugene’s extraordinary general meeting has overwhelmingly approved all resolutions relating to the acquisition of Biolife for its Her-Vaxx technology (BD: Dec 19, 2013).

The company said that Paul Hopper would assume the role of executive chairman with Steve Harris resigning as chairman and a director.

The Trinity Beach, Queensland-based Webinvest said it had become substantial in Imugene with 55,500,000 or 5.86 percent.

Webinvest director Otto Buttula said the shares were acquired for $533,000 or 0.96 cents a share.

Imugene was up 0.1 cents or 7.1 percent to 1.5 cents.

ANTISENSE

Antisense has requested a trading halt “pending an announcement on the interim results of [its] ATL1103 phase II clinical trials”.

Trading will resume on December 24, 2013 or on an earlier announcement.

Antisense last traded at 16.5 cents.

GENETIC TECHNOLOGIES

Founder Dr Mervyn Jacobson says he has reduced his holding in Genetic Technologies from 136,473,684 shares (29.36%) to 106,473,684 shares (18.59%).

Dr Jacobson, who gave addresses in Dragor, Denmark and Luzern, Switzerland, said that he sold 30,000,000 shares on-market for $1,800,000 or six cents a share.

This week Genetic Technologies said Dr Jacobson and associates would sell 105,937,500 shares reducing from 23.83 percent to 6.15 percent (BD: Dec 18, 2103).

Genetic Technologies fell 0.2 cents or 3.5 percent to 5.5 cents with 2.3 million shares traded.

IM MEDICAL

IM Medical says it will acquire White Data for $9.1 million of ITS shares based on a notional issue price of two cents a share.

IM said that following the acquisition it would have “a single clear focus on development and management of data centre and cloud computing services”.

The company said it “believes that the proposed acquisition of White Data and change of business is in the interests of IMI shareholders and is a very positive step”.

IM Medical was attempting to commercialize cardiac testing in which the Federal Government reimbursed the tests.

In its most recent significant announcement in June 2012 the sold its shareholding in Capitol Health which was going to acquire IM’s radiology business (BD: Jun 19, 2012).

Mark Scott Group acquired IM Medical but the company saw a raft of board changes and dissent at meetings, which followed IM’s inability to commercialize its Intelliheart cardiac testing system (BD: Jun 20, 2008; Jun 10, 30, Nov 22, 2010; Feb 7, Mar 10, 2011).

IM Medical was unchanged at 0.3 cents with 2.2 million shares traded.

NUSEP

Nusep says that non-executive director Dr Stephen van der Mye will replace Prakash Patel as interim company secretary following Mr Patel’s promotion to managing director.

The company said it was reviewing its corporate and company secretarial requirements and intended to appoint an external company secretary in the next few months.

Nusep was up 0.6 cents or 13.6 percent to five cents.