Biotech Daily

Monday April 30, 2012

Daily news on ASX-listed biotechnology companies

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*** GENERA $1m SHARE PLAN**

*** USCOM LESS THAN SIX MONTHS CASH; SALES UP, COSTS CUT, CAPITAL**

*** HEARTWARE AGM FOR 1.5m DIRECTOR SHARES; 245k OPTIONS**

*** CELLMID EGM FOR 136m SHARES, $5m PLACEMENT, 5m CEO OPTIONS**

*** CONSEGNA APPOINTS DR NICHOLAS EDE TECHNOLOGY OFFICER**

MARKET REPORT

The Australian stock market climbed 0.79 percent on Monday April 30, 2012 with the S&P ASX 200 up 34.5 points to 4,396.6 points.

Thirteen of the Biotech Daily Top 40 stocks were up, 11 fell, 11 traded unchanged and five were untraded.

Prima was the best, up 1.5 cents or 7.5 percent to 21.5 cents with 7.9 million shares traded. Heartware climbed 4.4 percent; Biota and Prana were up more than three percent; Cochlear, Nanosonics, Pharmaxis, QRX, Starpharma and Tissue Therapies rose two percent or more; with Mesoblast and Reva up more than one percent.

Genera led the falls, down 4.5 cents or 16.1 percent to 23.5 cents with 39,999 shares traded. Circadian lost more than 7.4 percent; Viralytics was down 6.7 percent; Universal Biosensors was down 5.1 percent; Benitec and Phosphagenics fell more than four percent; Allied Health was down 3.7 percent; Anteo, Avita and Ellex shed more than two percent; with Impedimed down 1.15 percent.

UNIVERSITY OF QUEENSLAND, AXIOM MOLECULAR

Uniquest and Axiom Molecular have created Moleqular Pty Ltd in a $4.3 million strategic alliance for radio-pharmaceutical research, development and commercialization.

The University of Queensland's commercialization arm Uniquest said the University's Centre for Advanced Imaging would allow Axiom to use its facilities to produce positron emission tomography radio-pharmaceuticals for diagnosing cancer and brain disorders.

Uniquest said that Axiom had made an equity investment in the start-up company Moleqular, formed to research, develop and commercialize radio-pharmaceuticals.

Uniquest managing director David Henderson said the agreement was the first of its kind for both the University and Axiom.

Mr Henderson said that Axiom would use the University's Centre for Advanced Imaging (CAI) facilities to produce radio-pharmaceuticals to international standards, predominantly 18-fludeoxyglucose also known as 2-fluoro-2deoxy-D-glucose or FDG, also produced by Cyclopharm at Macquarie University.

Mr Henderson said the Centre's researchers would be able to use the laboratory area which Axiom Molecular would enhance to a good manufacturing practice environment, providing capability for its own research as well as collaborations with other Australian researchers and biotechnology companies.

Mr Henderson said that Axiom would fund scholarships for higher degree research students.

Axiom's managing director Mathew Farag told Biotech Daily that his company was a wholly-owned subsidiary of the Hong Kong-based Zuellig Group.

Mr Farag said the deal went beyond the $4.3 million cash and in-kind arrangement and was a "multi-million dollar, multi-year" arrangement.

Mr Farag said that FDG had a 110-minute half-life and local sources were required, so his Brisbane-based centre would not be competing with Cyclopharm's Sydney facility.

Cyclopharm managing director James McBrayer told Biotech Daily that his company was already servicing the Brisbane area "and another supplier in that market would be a competitor".

Mr McBrayer said he welcomed competition as long as it was on a level playing field and not subsidized by taxpayers through government agencies.

Earlier this month Cyclopharm won a Productivity Commission finding that the Australian Nuclear Science and Technology Organization breached competitive neutrality policy (BD: Apr 4, 2011).

"The formation of Moleqular and the strategic alliance with Axiom Molecular reflects the commitment of [the University of Queensland] and the CAI to work closely with private industry to make world-class university research and infrastructure available for the benefit of society," Mr Henderson said.

Uniquest said it would licence a radio-pharmaceutical technology, discovered by Centre researchers, to Moleqular, which would fund several radio-pharmaceutical research and development projects at the University.

Uniquest said that Moleqular would be responsible for commercializing the outcomes from the research and development projects.

Mr Farag said the alliance would deliver a major objective of its larger strategy to supply radio-pharmaceuticals to public and private hospitals throughout Australia and the Asia Pacific region.

The Centre for Advanced Imaging's director Prof David Reutens said the agreement would "provide researchers around the country with access to a radio-pharmaceutical … capability to test new radio-pharmaceuticals" adding value to the Centre which had funding from the University as well as Federal and Queensland Governments.

CORRECTION: AVEXA

In Friday's edition Biotech Daily incorrectly quoted Avexa chief executive officer Dr Jonathan Coates' estimate of the reduced cost of a 300-patient, 14-day endpoint, phase III pivotal trial as $300 million, when he said it was about $30 million.

Biotech Daily has dismissed the Friday sub-editor and appointed a new sub-editor competent with orders of magnitude.

Avexa fell 0.3 cents or 9.7 percent to 2.8 cents with 7.8 million shares traded.

PRANA BIOTECHNOLOGY

Prana says the first patient has been dosed in its six-month phase IIa clinical trial of PBT2 for Huntington's disease.

Last year, Prana said it hoped to begin a 100-patient phase II trial of PBT2 for Huntington's disease in 2011 and the US Food and Drug Administration approved the phase II trial earlier this year (BD: Apr 20, 2011; Jan 22, 2012).

Today, Prana said that the 'Reach2HD' trial was a double-blind, placebo-controlled study of patients with early to mid-stage Huntington's disease and the principal investigator was Johns Hopkins University's Dr Ray Dorsey.

Prana said it aimed to demonstrate cognitive improvements as already demonstrated in a phase IIa study in mild Alzheimer's patients treated with PBT2.

The company said the study would also investigate safety, functional, behavioral and motor benefits in the Huntington's patient population.

Prana said the trial would be conducted in about 20 sites across the US and Australia.

The company said that Huntington's disease was a complex and severely debilitating genetic, neurodegenerative disease, for which there was no cure.

Prana said the disease often affected young adults and, while associated with severe physical movement symptoms, it progressively impacted on the mind and emotions as well.

The company said the disease caused incapacitation and death about 15 to 25 years after onset and affected 30,000 people in the US and about 70,000 worldwide.

Prana said there was only one marketed drug for Huntington's disease, with limited utility and there were no drugs either available or in development that established clinical evidence for treating the cognitive decline associated with the disease.

Prana was up half a cent or 3.6 percent to 14.5 cents.

OSPREY MEDICAL

Osprey says the ASX has approved its listing from 10:30am on May 2, 2012 and it will trade under the code OSP.

The Eden Prairie, Minnesota-based Osprey raised $20 million through its initial public offer, supported by institutional and retail investors in Australia, including founding investors CM Capital and Brandon Capital Partners.

The company said the offer was underwritten by Shaw Corporate Finance and the funds would be used to conduct a pivotal clinical trial and seek US Food and Drug Administration clearance for its Cincor cardiac due removal system, developed at Melbourne's Baker IDI Heart and Diabetes Institute.

Osprey said the funds would also be used for further development and commercialization of the Cincor system and for working capital.

GI DYNAMICS

GI Dynamics says that 19 patients have been re-implanted with its Endobarrier demonstrating “the feasibility and safety of re-implantation” of the device.
GI Dynamics said that 24 obese patients with an average weight of 109kg and an average body mass index of 44 completed 12 months of Endobarrier therapy for obesity and type 2 diabetes, achieving a mean weight loss of 20 percent or 22kg.
The US National Institutes of Health classify a BMI of 18.5-25 as normal, describing a BMI of more than 30 as obesity.
GI Dynamics said that following their initial treatment period and at least 31 weeks of follow-up post Endobarrier removal, 19 of the eligible 24 obese patients were re-implanted with the Endobarrier.
The company said that the mean time from Endobarrier removal to re-implant was 39.4 weeks, with a range of 31 to 52 weeks.
GI Dynamics said that all the patients who participated in the study were successfully re-implanted with Endobarrier and there were no procedure-related complications.
The company said that the data was presented by the Pontificia Universidad Católica de Chile’s Dr Alex Escalona on April 26, 2012, in Barcelona, Spain at the meeting of the International Federation for the Surgery of Obesity and Metabolic Disorders.
“The efficacy of first-time Endobarrier therapy in weight loss and blood sugar control have been well established and these results demonstrate that Endobarrier can be safely re-implanted in patients who have previously undergone treatment with the device,” Dr Escalona said. “Re-implantation of the Endobarrier may facilitate additional weight loss and improvements in diabetes and other co-morbid conditions, and additional studies evaluating these clinical benefits are ongoing.”
GI Dynamics fell three cents or 2.9 percent to $1.01.

MEDICAL AUSTRALIA

Medical Australia says the first two Tutavet animal stem cell therapy procedures have been performed on a dog with renal failure and a dog with osteo-arthritis in the UK.
Medical Australia’s managing director Mark Donnison told Biotech Daily that in the two and a half weeks since treatment the two dogs “have new-found energy and their overall well-being has been improved”.
In a media release Medical Australia said that the procedures were conducted by veterinary surgeon Dr Stewart Halperin.
The company said it had established a laboratory in the UK to commercially cryo-preserve animal stem cells (BD: Apr 3, 2012).
Medical Australia said that Tutavet involved equipping veterinary practices to perform stem cell procedures in-house, at point-of-care, using a suite of supplied laboratory hardware and procedure packs.
Mr Donnison said “the successful completion of the first two animal stem cell treatment procedures in the UK is a significant achievement”.
Medical Australia was up 0.2 cents or 13.3 percent to 1.7 cents.

GENERA BIOSYSTEMS

Genera expects to raise $1.0 million through an underwritten share plan at the lesser of 22 cents or a 7.5 percent discount to its five-day volume weighted average price.
The record date is April 27 and the closing date is June 1, 2012.
Genera fell 4.5 cents or 16.1 percent to 23.5 cents.

USCOM

Uscom says its net operating cash burn for the three months to March 31, 2012 was $424,016, with cash at the end of the quarter of $763,460.
Uscom executive director Robert Phillips told Biotech Daily the company was reviewing its capital options, but expected to increase sales as well as reduce expenditure, impacted by one-off costs relating to the departure of the previous management.
Uscom was untraded at nine cents.

HEARTWARE

Heartware shareholders will vote to issue chief executive officer Doug Godshall 36,000 restricted stock units and other directors 8,000 stock units and options.
Heartware said each stock unit was equivalent to 35 Chess depositary interests (CDIs), implying the equivalent of 1,260,000 CDIs for Mr Godshall and 35,000 CDIs and options for each of six directors with 2,000 stock units and 1,000 options for Cynthia Feldman.
The company proposed the issue of 1,000 stock units and options to directors Robert Thomas, Seth Harrison, Timothy Barberich, Charles Raymond Larkin Junior, Robert Stockman and Denis Wade and said shareholders would vote on the 2012 incentive award plan as well as the re-election of directors Cynthia Feldman and Denis Wade.
The meeting will be held at the Ritz Carlton Hotel, 4375 Admiralty Way, Marina del Ray, California on May 31, 2012 at 4pm (US Pacific Time) or June 1, 2012 at 9am (AEST).
Heartware was up nine cents or 4.4 percent to $2.14.

CELLMID

Cellmid shareholders will vote to approve a prior and planned share issue, a further $5 million placement and issue chief executive officer Maria Halasz 5,000,000 options.
Cellmid said it wanted shareholder approval for the prior issue of 62,388,628 shares most of which were to La Jolla Cove Investors, along with permission to issue 73,450,019 shares as part of its $1.5 million placement (BD: Apr 26, 2012).
The company said shareholders would vote on a further placement of up to $5 million and to issue Ms Halasz 5,000,000 options, exercisable at a “100 premium to the closing price of the company’s shares on the date of shareholder’s approval” within five years.
The meeting will be held at the Grace Hotel, 77 York Street, Sydney on May 28, 2012 at 11am (AEST).
Cellmid was unchanged at 1.8 cents with 10.3 million shares traded.

CONSEGNA GROUP

Consegna says it has appointed Dr Nicholas Ede as its chief technology officer and as a member of the scientific advisory committee, replacing Dr Ross Macdonald.
Consegna said that Dr Ede had a record of evolving research concepts to commercial products and processes and had more than 25 years experience in drug discovery and business development at Chiron, Eqitx, Mimotopes and Adistem.
Consenga said that Dr Ede held a Ph D from Monash University and had published more than 50 scientific papers and patents.
Consegna was up 0.3 cents or 10 percent to 3.3 cents with 1.25 million shares traded.