Biotech Daily

Wednesday December 18, 2013

Daily news on ASX-listed biotechnology companies

* **ASX, BIOTECH DOWN: PRANA UP 10%; PRIMA DOWN 11%**

*** INNATE IPO RAISES $10m, HOPES TO TRADE ON MONDAY**

*** SIMAVITA QUICK IPO FOR $1m TO LIST ON ASX**

*** CELLMID: '574-PATIENT STUDY BACKS MIDKINE DISEASE BIOMARKER'**

*** BENITEC TRIBETARNA INCREASES NSCLC SURVIVAL IN MICE**

*** BIONOMICS RECEIVES $7m FEDERAL R&D TAX REFUND**

*** PROGEN EXPECTS $614k FEDERAL R&D TAX REFUND**

*** GENETIC TECHNOLOGIES' DR MERVYN JACOBSON DROPS TO 6%**

*** CORRECTION: MEDICAL AUSTRALIA**

*** BONE RECEIVES CORNERSTONE $200k BRIDGE LOAN**

*** ELLEX REQUESTS ACQUISITION, CAPITAL RAISING TRADING HALT**

*** ISONEA PLEADS SCHULTZ, LOST CEO TO ASX 19% FALL QUERY**

MARKET REPORT

The Australian stock market slipped 0.14 percent on Wednesday December 18, 2013 with the S&P ASX 200 down 7.1 points to 5,096.1 points. Ten of the Biotech Daily Top 40 stocks were up, 16 fell, nine traded unchanged and five were untraded.

Prana was the best, up seven cents or 10.1 percent to 76.5 cents with 1.9 million shares traded. Psivida climbed 7.7 percent; Phylogica was up 6.25 percent; Benitec, Bionomics and Cellmid were up three percent or more; Nanosonics, QRX and Starpharma rose one percent or more; with Cochlear and Mesoblast up by less than one percent.

Prima led the falls, down 0.5 cents or 10.9 percent to 4.1 cents with 7.4 million shares traded, followed by IDT down 10.0 percent to 36 cents with 30,699 shares traded. Clinuvel fell 9.1 percent; Anteo lost 6.25 percent; Impedimed, Living Cell, Pharmaxis and Universal Biosensors fell four percent or more; GI Dynamics was down 3.5 percent; Antisense, Avita and Reva shed more than two percent; Alchemia and Neuren were down more than one percent; with Acrux, CSL, Resmed and Sirtex down by less than one percent.

INNATE IMMUNOTHERAPEUTICS

Innate says it has raised $10 million through its initial public offer to list on the ASX and begin a phase IIb trial of MIS416, for secondary progressive multiple sclerosis.
Innate chief executive officer Simon Wilkinson told Biotech Daily that the company hoped to list on the ASX and begin trading on December 23, 2013 under the code IIL.
The company said the initial public offer "received strong support from existing international shareholders and new Australian institutional investors".
Innate said that Patersons Securities and Morgans Corporate were joint lead managers.
Innate said that as well as the new funding, prior debt holders participated in the offer by conversion of their debt and the company had no remaining loan obligations.
In November, Innate said it would offer up to 60,000,000 shares at 20.1 cents a share to raise up to $12,000,000 before costs. (BD: Nov 19, 2013).
"The IPO has provided the company with the funds to finance a placebo-controlled phase IIb efficacy study of MIS416 in Australian patients with [secondary progressive multiple sclerosis]," Mr Wilkinson said.
"These patients do not have access to effective long-term treatments and so with the close of the [initial public offer] we can now move rapidly to get the efficacy trial underway," Mr Wilkinson said.
Innate said that phase Ib/IIa trials in New Zealand showed that the drug raised no evident safety concerns and, in most patients treated for three months, showed clear signs of positive effect.
The company said those trials were funded in part by the US National Multiple Sclerosis Society and the New Zealand Government and it had made MIS416 available to a small group of former trial participants and other patients on compassionate grounds.
Innate said that 14 of the 17 patients treated for up to five years reported significant improvements in a range of their disease related disabilities.
Innate said it hoped to partner the drug on the successful completion of the phase IIb trial, expected in late 2015.

SIMAVITA

Simavita hopes to raise a further $1.1 million in an initial public offer at 41 cents a share to list on the ASX.
Earlier this month, Simavita raised $14 million to list on the Toronto Stock Exchange Ventures Market to commercialize its Sim incontinence assessment system and chief executive officer Philippa Lewis said she also hoped to list on the ASX. (BD: Dec 3, 2013).
Today, Simavita said it had released the prospectus and the offer would open tomorrow, December 18 and close on December 23, 2013.
The company said it would offer of up to 2.7 million CHESS Depositary Interests (CDIs) at 41 cents each and hoped to begin trading on the ASX early in 2014.
Simavita said that the funds would provide working capital to build inventory and support the US distribution agreement with Medline and would be used to develop new products.
Ms Lewis said that listing on the ASX "will help us to maintain the strong momentum that we have built around our North American distribution agreement and support our roll out in the US from January 2014".
"The Australian listing is important to Simavita," Ms Lewis said. "We are an Australian company and have spent years working with the aged care industry here to develop, test and improve our Sim incontinence device," Ms Lewis.
Last night on the TMX, Simavita was untraded at 39 Canadian cents (41.26 cents).

CELLMID

Cellmid says a two-year, 574-subject study investigating normal serum concentrations of midkine, supports midkine as a disease biomarker.

Cellmid said that the 'CK3000' study was the largest study of healthy volunteers and confirmed interim findings of healthy midkine levels in a statistically meaningful population size, providing insights into a small group of outliers, asymptomatic individuals presenting with elevated midkine levels.

The company said that of the 574 subjects, 21 otherwise healthy subjects had elevated midkine and available hospital records for six of the 21, showed that four of the six had been admitted to the hospital for cancer (glioblastoma, osteosarcoma), autoimmune disease (rheumatoid arthritis) and an acute inflammatory condition, with the reason for admission of the other two subjects not recorded.

Cellmid head of product development Darren Jones said that "finding a history of cancer and serious inflammatory disease that explains high midkine levels in apparently healthy subjects is powerful validation of the value of [midkine] as a disease biomarker".

"This is especially so in the absence of any other indication of disease," Mr Jones said.

The company said that the results were expected to be pivotal in future regulatory submissions for stand alone midkine diagnostic tests for monitoring health, disease recurrence or treatment efficacy in any cancer.

Cellmid said it began the CK3000 study in 2011 with Kumamoto University to determine, the normal midkine ranges for apparently healthy individuals in a statistically meaningful definitive study suitable for regulatory submission.

The company said the study took concurrent measurement of other biomarkers and collection of lifestyle data, with only individuals that tested within the normal ranges for other biomarkers qualified to participate in the midkine arm.

Cellmid said that blood samples were analyzed for kidney and liver function, in addition to markers for inflammation, cholesterol and diabetes, along with information on age, sex, alcohol and tobacco use.

The company said that blinded serum samples were tested for midkine levels using its European approved midkine-enzyme-linked immunosorbent assay (Elisa).

Cellmid said that 627 sequential serum samples were collected from 574 individuals and tested in a blood-screening program at Kumamoto University Hospital.

The company said that of the apparently healthy subjects 96.3 percent had serum midkine concentrations under 1000picograms per millilitre (pg/mL), with 90.7 percent below 500pg/mL.

Cellmid said that the frequency distribution and population statistics were in close agreement with previous smaller normal population studies published in the peer-reviewed literature and the data closely resembled that collected by the Berlin-based Biogenes GmbH during validation studies of Cellmid's midkine-Elisa kit.

The company said that midkine levels above1000pg/mL were considered to be abnormal and were investigated further and the 21 individuals, or 3.7 percent of all subjects, with elevated midkine showed no correlation with age, sex, smoking or alcohol intake, nor did any of the 21 subjects have elevated markers for inflammation, cholesterol and diabetes and their liver and kidney function tests were normal.

Cellmid chief executive officer Maria Halasz said that the company had "more than a dozen diagnostic collaborations in various disease indications and this data set will have significant impact on interpretation of patient data collected in those studies".

Cellmid was up 0.1 cents or 3.2 percent to 3.2 cents with 17.2 million shares traded.

BENITEC BIOPHARMA

Benitec says that experiments confirm the ability of Tribetarna to significantly increase survival in non-small cell lung cancer in mice.

Benitec said that after six weeks treatment with its DNA-directed RNA-interference (ddRNAi) Tribetarna 78 percent of animals dosed with a combination of Tribetarna and cisplatin lived, compared with only 20 percent of the animals in the control groups receiving cisplantin alone or with a non-specific construct ($p < 0.0001$).

The company said that cisplatin was the main chemotherapy drug used for advanced non-small cell lung cancer.

Benitec said that the study by partner University of New South Wales Children's Cancer Institute Australia confirmed previously reported results that silencing the gene target of Tribetarna, beta III tubulin, overcame the resistance of non-small cell lung cancer tumors to chemotherapy.

The company said that unlike previously reported experiments, the mice received multiple doses of Tribetarna and cisplatin (BD: Apr 4, 2013).

Children's Cancer Institute Australia's Prof Maria Kavallaris said that the orthotopic model used in the experiments consisted of human non-small cell lung cancer (NSCLC) cells grown in the lungs of mice and closely mimicked humans.

"These human NSCLC cells are strongly resistant to chemotherapy normally and we were able to demonstrate that three cycles of intravenous administration of Tribetarna, in combination with a standard chemotherapy drug, cisplatin, was able to significantly extend the survival of the animals," Prof Kavallaris said.

Benitec chief executive officer Dr Peter French said that Tribetarna "appears to offer a new option to overcoming chemotherapy resistance and thus could be a novel approach to enhance the efficacy of chemotherapy drugs and to increase patient survival".

Benitec said it had submitted a preliminary application to the US Food and Drug Administration for guidance on the design of investigational new drug application-enabling toxicity and bio-distribution studies for the new, systemic approach leading to a planned first-in-man clinical trial late in 2014 and the FDA had "indicated that a teleconference will be scheduled towards the end of February to discuss the submission".

Benitec was up 1.5 cents or 3.0 percent to 52 cents.

BIONOMICS

Bionomics says it has received $7.04 million from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Bionomics said the rebate related to research and development expenditure for the year to June 30, 2013.

The company said it had confirmation that overseas expenditure anti-cancer stem cell compound BNC101 and other programs totaling $17.42 million were eligible for the Research and Development Tax Incentive program for three years from July 1, 2012, along with previously announced eligibility for research and development spending on anti-anxiety drug BNC105 and BNC375 for Alzheimer's disease of $8.9 million for three years from July 1, 2011.

Bionomics chief executive officer Dr Deborah Rathjen said that "such a large injection of cash is important to Bionomics as we continue to progress a number of drug candidates along the pipeline including BNC101, which will enter the clinic for the first time in 2014".

"It is pleasing to know we will be eligible for the incentive for all these programs in the year to June 2014 as well," Dr Rathjen said.

Bionomics was up 2.5 cents or 3.7 percent to 70 cents with 2.1 million shares traded.

PROGEN PHARMACEUTICAL

Progen says it expects to receive $613,503 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.
Progen said the rebate related to research and development expenditure for the year to June 30, 2013 and was expected to be paid by June 30, 2014.
Progen was unchanged at 20 cents.

GENETIC TECHNOLOGIES

Genetic Technologies says founder and largest shareholder Dr Mervyn Jacobson and associates will sell 105,937,500 shares reducing from 23.83 percent to 6.15 percent.
In 2008, Dr Jacobson used his large shareholding in the company to dismiss two boards of directors (BD: Sep 18, 2008).
In 2012, Dr Jacobson reduced his substantial holding in Genetic Technologies from 150,200,800 shares (43.13%) to 136,473,684 shares (29.36%) (BD: Sep 11, 2012).
In November 2012, a second board was rolled with votes against chairman Dr Mel Bridges and director Greg Brown, triggering the resignation of chief executive officer Dr Paul MacLeman and the head of legal Dr David Sparling (BD: Nov 27, 2012).
Genetic Technologies said that on December 17, 2013, Dr Jacobson and the associated entities disposed of 30,000,000 shares and under a binding agreement the “Jacobson Entities” would exchange 75,937,500 shares at eight cents a share for 4,500,000 shares in subsidiary Immunaid at $1.35 a share, pending shareholder approval.
The company said that at the date of the agreement, the Immunaid shares had a carrying value in its balance sheet of about 84 cents a share.
Genetic Technologies said that the Jacobson Entities would not be able to vote at the extraordinary general meeting to approve the agreement.
The company said Immunaid would grant it 2,250,000 options to acquire Immunaid shares exercisable at $1.35 per share for up to three years from the date of grant and in return it would pay Immunaid $500,000, of which $351,618 would be satisfied forgiving debts and the balance of $148,382 in cash.
Genetic Technologies said that the transactions were subject to an acceptable independent valuation of the 4,500,000 Immunaid shares and an independent expert’s fairness report in respect of the transaction from the perspective of the its shareholders, as well as regulatory approvals, where required, and shareholder approval.
The company said that should the transactions proceed, the number of its shares would fall by 13.26 percent from 572,694,121 to 496,756,621, following the cancellation of the shares acquired from the Jacobson Entities, which would retain a total of 30,536,184 shares or 6.15 percent of the company’s then total issued capital.
Genetic Technologies said that Dr Jacobson would continue as the company’s head of licencing and intellectual property and as chief executive officer of Immunaid.
Genetic Technologies was in a trading halt to the news and last traded at 5.5 cents.

MEDICAL AUSTRALIA

Last night’s edition reported the dilution of Narelle and Andrew Fay in Medical Australia relating to the issue of shares for the Nexvet acquisition.
Medical Australia acquired Medivet, not Nexvet, which is a different company.
The Tuesday sub-editor had gone to the dogs and was being snaky, before making a monkey of himself and was ultimately euthanized to put us out of his misery.
Medical Australia fell three cents or 12 percent to 22 cents.

BONE MEDICAL

Bone Medical says it has received a bridging loan of $200,000 from Cornerstone Corporate as part of its recapitalization agreement (BD: November 28, 2013).
Bone said the funds would meet operating costs.
Bone was untraded at 0.1 cents.

ELLEX MEDICAL LASERS

Ellex has requested a trading halt pending the release of an announcement “related to an acquisition and an associated capital raising”.
Trading will resume on December 20, 2013 or on an earlier announcement.
Ellex last traded at 32 cents.

ISONEA

Isonea has told the ASX that it is not aware of any information it has not announced which, if known, could explain recent trading in its securities.
The ASX said the company’s share price fell 19.1 percent from 55 cents on December 12, to 44.5 cents on December 17, 2013 and noted an increase in trading volume.
Isonea said that on in November it announced that chief executive officer Michael Thomas was stepping down and “would transition from the role to officially leave the company in early May 2014” (BD: Nov 13, 2013).
The company said that “transition” had taken place and director Jerry Korten had assumed the role of executive director replacing Mr Thomas.
Isonea said it was currently interviewing chief executive officer candidates.
Isonea fell four cents or 9.3 percent to 39 cents with 1.4 million shares traded.