Biotech Daily

Friday March 21, 2014

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: BIONOMICS UP 17%, ONCOSIL DOWN 7%**

*** FDA APPROVES COCHLEAR NUCLEUS HYBRID**

*** ASCEND DRUG 'EFFECTIVE FOR CUTANEOUS B-CELL LYMPHOMA'**

*** SIMAVITA LAUNCHES IN THE US, PREPARES FOR EUROPE**

*** VIRAX REQUESTS CAPITAL RAISING TRADING HALT**

*** ANTISENSE COMPLETES PHASE II ATL1103 ACROMEGALY RECRUITMENT**

*** ONCOSIL DIRECTOR LAWRENCE GOZLAN, 11m LOAN SHARES EGM**

MARKET REPORT

The Australian stock market climbed 0.83 percent on Friday March 21, 2014 with the S&P ASX 200 up 44.1 points to 5,338.1 points.

Fifteen of the Biotech Daily Top 40 stocks were up, 14 fell, six were unchanged and five were untraded.

Bionomics was the best, recovering from Wednesday's 30 percent fall, up nine cents or 17.3 percent to 61 cents with 7.4 million shares traded.

Uscom climbed 9.5 percent; Reva was up 6.5 percent; Antisense, Phosphagenics and Prana were up five percent or more; Avita and Cochlear rose more than four percent; Mesoblast and Psivida were up more than three percent; Benitec and Circadian rose more than two percent; Neuren, Pharmaxis, Sirtex and Tissue Therapies were up more than one percent; with CSL up half a percent.

Oncosil led the falls, down one cent or 6.7 percent to 14 cents with 796,000 shares traded.

Admedus, Living Cell, Nanosonics and Osprey lost more than three percent; Anteo, Impedimed and Medical Developments shed two percent or more; Acrux, GI Dynamics, QRX, Starpharma and Viralytics were down more than one percent; with Alchemia and Resmed down by less than one percent.

COCHLEAR

Cochlear says the US Food and Drug Administration has approved the Cochlear Nucleus Hybrid L24 implant system for sensori-neural hearing loss for commercial release.
Cochlear said the approval followed “the unanimous recommendation for approval by the FDA advisory panel (BD: November 11, 2013).
The company said that the Nucleus Hybrid L24 implant system was “a first of its kind system designed for the treatment of adults with severe to profound sensori-neural hearing loss in the high frequencies, but who can still hear low-frequency sounds with or without a hearing aid”.
Cochlear said that the Nucleus Hybrid System combined acoustic amplification of low frequencies with the electrical stimulation of high frequencies in one device.
The company said that it was designed to deliver patients superior quality and clarity of sound in even the most difficult hearing situations, especially hearing in noisy environments.
Cochlear was up $2.38 or 4.2 percent to $58.96 with 582,019 shares traded.

ASCEND BIOPHARMACEUTICALS

Ascend says 11 of 13 cutaneous b-cell lymphoma patients responded to treatment with its ASN-002, formerly Transgene’s TG1042.
Ascend said it licenced TG1042 from Transgene in July 2013 as an immunotherapeutic injection for multiple cancers including cutaneous b-cell lymphoma and planned to begin clinical studies with TG1042 in basal cell carcinoma later in 2014 (BD: Feb 21, 2014).
The company said the study was an open label, multi-centre trial conducted by Transgene involving 13 cutaneous b-cell lymphoma patients injected directly with TG1042 into their cancers.
Ascend said that the delivery of TG1042 into the lesions resulted in seven patients (54%) having a complete response where all lesions disappeared and four patients (31%) having a partial response where at least half of all treated lesions disappeared.
The article, entitled ‘TG1042 (Adenovirus-interferon-gamma) in Primary Cutaneous B-cell Lymphomas: A Phase II Clinical Trial’ was published in the Public Library of Science – One.
An abstract is at: http://www.plosone.org/article/info:doi/10.1371/journal.pone.0083670.
University of Zurich professor and principal investigator Prof Reinhard Dummer said that primary cutaneous B-cell lymphomas were rare “but a disfiguring disease with significant unmet medical needs”.
“Intra-lesional TG1042 therapy is well tolerated and results in lasting tumor regressions,” Prof Dummer said.
“Both radiation therapy and surgery show a high initial response rate but up to 50 percent of patients relapse following the initial treatment,” Prof Dummer said.
Ascend chief executive officer Dr Clement Leong said the study showed that TG1042 had a favourable risk/benefit ratio and the potential to be developed as an alternative to surgery or radiation therapy treatment to minimize risk of cancer recurrence in cutaneous B-cell lymphomas.
The company said that primary cutaneous b-cell lymphomas had an annual incidence rate of approximately 3.1 per 1,000,000 persons and comprised up to 25 percent of all cutaneous lymphomas.
Ascend said that treatment options for CBCL are confined to surgery or radiation therapy and there are no registered drugs for this indication.
Ascend is a public unlisted company.

SIMAVITA

Simavita chief executive officer Philippa Lewis says that US distribution partner, the Chicago-based Medline Industries, signed the first US customer last week.
In a presentation to investors at Melbourne's Royal Automobile Club of Victoria, Ms Lewis said the company already had Australian sales, expected Canadian sales of its smart incontinence management (SIM) technology by October 2014, with European sales expected in 2015 (BD: Dec 3, 2013).
Ms Lewis said that a trial of the technology would begin in Denmark in April 2014.
Ms Lewis said that all patients arriving in nursing and aged care homes were assessed on arrival but incontinence assessment was manual and could be inaccurate.
She said the SIM technology consisted of a sensor attached to proprietary incontinence pads that accurately measured fluid output and sent the date to a central point.
Ms Lewis said the system could capture 'big data' including patient fluid inputs, history, behavioral issues and personal requirements.
Ms Lewis said a great many staff-hours were spent on changing patients pads and taking them to the toilet and an accurate assessment could considerably reduce those hours.
Aged care provider Arcare's Queensland manager Karen Carey told the meeting that using the Simavita technology, her nursing homes had reduced toileting of patients from eight times a day to an average 3.5 times a day.
Ms Carey said that nursing homes made claims to, and were reimbursed by, the Federal Government and if an audit questioned incontinence observations, the claim could be challenged, "but SIM is undeniable".
Ms Carey said that her aged care facilities spent an average of $2 per patient per day on incontinence but that fell to $1.20 a day using the SIM diagnostic.
Ms Lewis said that the Federal Government spent $1.5 billion a year on incontinence products and aged care was a rapidly growing industry.
Aged Car advisor Sue Macri worked on the Productivity Commission Inquiry into aged care and said that neither the current Conservative Government nor the Labor Opposition really understood the issue of "baby-boomers in 2030".
Ms Macri said that the number of Australians aged more than 85 years in 2010 was 400,000 and was expected to rise to 1.8 million by 2050, with the number of dementia patients increasing from 275,000 in 2010 to more than 981,000 in 2050.
Ms Macri said that the previous Government commissioned the review and "cherry-picked" the results but the current Government placed aged care lower on its priorities than disability and was currently reviewing the National Disability Insurance Scheme.
Ms Macri said that currently each Australian aged 65 years or more was supported by five people of working age, which was expected to fall to 2.7 people of working age.
Ms Macri said that four times the current number of nursing and aged care staff would be required by 2050 and information technology was one of the solutions.
Ms Lewis said that using her company's technology, nursing homes and aged care facilities would spend less on buying incontinence products, as well as reduced labor time, send less waste to landfill and improve the toileting of patients.
Simavita was up 1.5 cents or 1.9 percent to 81.5 cents.

VIRAX HOLDINGS

Virax has requested a trading halt "pending the release of an announcement in relation to a significant capital raising".
Trading will resume on March 25, 2014 or on an earlier announcement.
Virax last traded at 1.5 cents.

ANTISENSE THERAPEUTICS

Antisense says that all 24 patients have been enrolled and randomized to the two treatment regimens in its phase II trial of ATL1103 for the growth disorder, acromegaly.
Antisense said that following positive results from the interim analysis of the serum insulin-like growth factor-I (sIGF-I) data from the eight patients who had completed the full 13 weeks of dosing in the trial, a further eight had completed dosing.
The company said that, to date, no patients dosed with ATL1103 had withdrawn from the study nor have there been any reports of treatment-related serious adverse events.
Antisense said it expected to report the results of the trial “by mid-2014”.
The company said that reducing sIGF-I levels was the primary marker of ATL1103 activity in the trial and acromegaly patients had elevated sIGF-I levels compared to the normal population, so reduction of sIGF-I to within a normal range in a significant proportion of patients was the goal in phase III registration trials for acromegaly treatments.
Antisense managing director Mark Diamond said that completion of patient recruitment was “a major milestone”.
Antisense was up one cent or 5.4 percent to 19.5 cents with 1.5 million shares traded.

ONCOSIL MEDICAL

Oncosil will vote to appoint Lawrence Gozlan as a director and issue 11,038,464 loan shares.
Oncosil said it proposed to issue 7,500,000 loan shares to Mr Gozlan at 13 cents, a discount of 13 percent to the current market price, with a term of five years from issue, vesting over four escrow periods.
The company said that Mr Gozlan would then own 2.1 percent of its shares capital.
Oncosil said the loan would be repayable “one month after the date of the participant's resignation or cessation of office/engagement/employment (as the case may be) other than if the participant is removed from office, if the company does not renew the participant's employment agreement or engagement terms, or where the company dismisses the participant other than for cause”; or six months after death.
The company said that the loan for the shares would be “interest free, provided that if the loan [was] not repaid by the repayment date ... the loan [would] incur interest at nine percent per annum after that date”.
Oncosil further proposes to issue 461,539 loan shares to join company secretary Peter Casey; 769,231 loan shares to the head of clinical research Natalie Ruffles; and 2,307,694 loan shares to chief scientific officer Dr Peter Knox and head of European operations Dr Drew Ferguson, with all loan shares at 13 cents, vesting after three years and pending certain other conditions.
The company said that it had previously issued 25,000,000 loan shares, at 10 cents each, with 20,000,000 to chief executive officer Dr Neil Frazer and 5,000,000 to chairman Martin Rogers.
Oncosil said it would ask shareholders to approve the employee share plan.
The meeting will be held at Level 8, 1 Alfred Street, Sydney on April 29, 2014 at 10am (AEST).
Oncosil fell one cent or 6.7 percent to 14 cents.