Biotech Daily

Thursday May 15, 2014

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: MEDICAL DEV UP 12%, LIVING CELL DOWN 14%**

*** PRIMA: 'FINAL DATA SHOWS CVAC OVARIAN CANCER BENEFIT'**

*** PROGEN TREATS FIRST THREE PG545 SOLID TUMOR PATIENTS**

*** ELLEX 24 MONTH DATA BACKS 2RT FOR AMD**

*** VIRALYTICS POSTER BACKS CAVATAK FOR MELANOMA**

*** AVITA: 'RECELL SUPERIOR FOR HYPO-PIGMENTED SCARS'**

*** USCOM RAISES $1.4m**

*** OTSUKA DROPS LIVING CELL NTCELL, $2m OPTION**

*** GENERA PLEADS SCHULTZ TO ASX 34% QUERY**

*** WALKER GROUP CALLS FOR QRX BOARD SPILL**

*** CDPP DROPS CHARGES, VANDA GOULD CYCLOPHARM CHAIRMAN**

*** VIRAX APPOINTS DR ROB CROMBIE M-D, STARTS ON $300k**

MARKET REPORT

The Australian stock market was up 0.26 percent on Thursday May 15, 2014 with the S&P ASX 200 up 14.3 points to 5,510.8 points. Eleven of the Biotech Daily Top 40 stocks were up, 14 fell, 12 traded unchanged and three were untraded.

Medical Developments was the best, up 14.5 cents or 12.3 percent to $1.325 with 39,175 shares traded, followed by Osprey up 10 percent to 55 cents with 53,400 shares traded. Prima climbed 6.25 percent; Biotron was up 5.5 percent; both Atcor and Oncosil were up 4.2 percent; Antisense and Benitec were up more than three percent; Genetic Technologies rose 2.5 percent; GI Dynamics and Sirtex were up more than one percent; with CSL and Resmed up by less than one percent.

Living Cell led the falls, down 0.9 cents or 13.85 percent to 5.6 cents with 257,600 shares traded. Compumedics and Universal Biosensors lost nine percent or more; Avita fell 8.3 percent; Analytica and Starpharma were down more than six percent; Prana lost 5.7 percent; Anteo fell 4.55 percent; Bionomics and Nanosonics were down more than three percent; Pharmaxis shed 2.7 percent; with Acrux, Mesoblast and Neuren down one percent or more.

PRIMA BIOMED

Prima says its 63-patient CAN-003 phase II trial of CVac showed “a clinically meaningful improvement in progression-free survival in second remission ovarian cancer patients”.
Last year, top-line analysis of the CAN-003 trial failed to show significant progression-free survival, which led to a change of endpoint for the phase II/III CAN-004 trial to overall survival (BD: Sep 19, 2013).
Today, Prima said the trial evaluated CVac compared to an observational standard-of-care arm in epithelial ovarian cancer patients in complete remission after first or second line treatment and that final progression-free survival analysis indicated stronger trends toward improved clinical outcomes for CVac-treated patients than top-line data announced in September 2013 had suggested.
The company said the strong efficacy signal supported its CAN-004-B phase II trial of 210 ovarian cancer patients with relapsed platinum-sensitive disease in second remission.
Prima said that in 20 second remission patients the median progression-free survival for CVac was estimated to be greater than 12.91 months, compared to median progression-free survival of 4.94 months for the control group ($p = 0.04$), but progression-free survival was not improved for patients in first remission.
Prima chief executive officer Matthew Lehman said the CAN-003 progression-free survival data “strongly supports our continued development of CVac in second remission ovarian cancer patients”.
Prima said that the final CAN-003 data would be presented by lead investigator Dr Heidi Gray at the American Society of Clinical Oncology meeting in Chicago on May 31, 2014.
The company said that an abstract entitled ‘Progression-free survival in ovarian cancer patients in second remission is improved with mucin 1-autologous dendritic cell therapy’ was available at: http://abstracts.asco.org/144/AbstView_144_134878.html.
Prima said that overall survival data would mature for analysis by the end of 2014.
Prima was up 0.3 cents or 6.25 percent to 5.1 cents with 44.9 million shares traded.

PROGEN PHARMACEUTICALS

Progen says it has treated the first three-patient cohort in its 25-patient phase I trial of PG545 for solid tumors (BD: Oct 29, 2013)
Progen said that safety data had been reviewed with an independent medical monitor and the coordinating investigator and the trial would progress to the next higher dose.
The company said that the patients were treated at the Perth, Western Australia Sir Charles Gairdner Hospital and each patient received once-weekly 25mg doses of PG545.
Progen said that no dose-limiting toxicities or significant adverse events were reported following at least four weeks of treatment.
The company said that each of the patients in the second group would receive 50mg doses of PG545 at once-weekly intervals.
Progen drug development director Dr Keith Dredge said that with the change from subcutaneous injection to intravenous infusion, patients in the current trial did experienced the local injection site reactions which ended the previous trial.
Progen said that the primary objective of the study was the determination of the maximum tolerated dose as defined by significant dose limiting toxicity with secondary objectives including the assessment of the safety and tolerability of PG545; the pharmacokinetic parameters of PG545 and to explore pharmacokinetic and pharmacodynamic relationships; and to document any anti-tumor activity observed with PG545.
The company said the trial was being carried out at three sites in Australia.
Progen fell 3.5 cents or 3.4 percent to 99 cents.

ELLEX MEDICAL LASERS

Ellex says its 2RT laser treatment reduces drusen in 35 to 40 percent of eyes following 12 and 24 months, compared to five to 11 percent in a natural history cohort.
Ellex said that the 24-month data from the 51-patient pilot study investigating the efficacy of the retinal rejuvenation therapy (2RT) in the treatment of early age-related macular degeneration was presented by the University of Melbourne's Prof Erica Fletcher as a scientific poster at the Association for Research in Vision and Ophthalmology conference in Orlando, Florida on May 9, 2014.
Ellex said that the study was conducted from 2009 to 2011 at Melbourne's Centre for Eye Research and patients received a single treatment to one eye with the 2RT laser and the drusen area in each eye was graded at baseline after 12 and 24 months.
Ellex said that changes in drusen, or accumulations of extra-cellular material, area in the treated eyes were compared with a natural history age-related macular degeneration cohort of similar age range and degeneration severity.
The company said that drusen were an important risk factor for progression of age-related macular degeneration.
Ellex said that current treatments addressed advanced or late-stage complications of the disease, but its 2RT technology was designed to offer treatment earlier in the disease process, with the aim of slowing or reversing its progression.
Ellex said that Prof Fletcher conducted pre-clinical studies to validate a mouse model of age-related macular degeneration and compare it with human data.
Ellex chief executive officer Tom Spurling said the mouse model "will assist us in unlocking the mechanism action of 2RT, minimizing the need for long term studies".
"2RT laser treatment thins Bruch's membrane via mechanisms involving altered extra-cellular matrix turnover," Prof Fletcher said. "Similar mechanisms may also explain the reduction in drusen area observed in patients with intermediate [age-related macular degeneration] following nanosecond laser treatment."
"This important data confirms the results of the 12-month data and provides additional information to assist in the controlled commercial rollout of 2RT," Mr Spurling said.
Ellex said that the details of Prof Fletcher's work were confidential as the work was being assessed for publication by a peer-reviewed journal.
Ellex was unchanged at 32 cents.

VIRALYTICS

Viralytics says a poster on its phase II Calm trial of Cavatak for melanoma shows the drug is "a promising novel oncolytic immunotherapeutic agent with good tolerability".
Viralytics said the poster, entitled 'CALM study: A phase II study of an intratumorally delivered oncolytic immunotherapeutic agent, Coxsackievirus A21, in patients with stage IIIc and stage IV malignant melanoma' would be presented by lead study investigator the Utah-based Huntsman Cancer Institute's Dr Robert Andtbacka at the American Society of Clinical Oncology meeting in Chicago from May 30 to June 3, 2014.
The abstract is at: http://abstracts2.asco.org/AbstView_144_134927.html and concluded that intra-lesional Coxsackievirus A21 was "a promising novel oncolytic immunotherapeutic agent in the treatment of unresectable stage IIIC-IV M1c melanoma based on good patient tolerability, with both local and distant tumor responses".
Viralytics met its primary endpoint in the 54 patient trial last year when the tenth patient reached immune-related progression-free survival at six month (BD: Sep 18, 2013).
Viralytics said that a randomized phase II clinical trial was planned.
Viralytics was unchanged at 27.5 cents.

AVITA MEDICAL

Avita says that an 18-patient trial German trial of Recell shows it has “clinically superior results for the treatment of hypo-pigmented scars”.

Avita said that the study by Prof Matthias Aust found that areas treated with Recell, combined with a scar treatment technique called medical needling, showed statistically significant re-pigmentation, while the areas treated with medical needling alone and not treated with Recell, did not.

The company said that results of the study entitled ‘Combination of Medical Needling and Recell - a promising method?’ were presented at the Association of German Aesthetic Plastic Surgeons meeting.

Avita research and technology vice-president Andrew Quick said the results demonstrated the benefits of using Recell to treat hypo-pigmented scars.

“This is a particularly important study for Recell as it is a randomized, controlled design with an objective measure showing statistically significant re-pigmentation outcomes,” Mr Quick said.

Avita said that each of the 18 participants had some hypo-pigmented scar area treated with needling and another hypo-pigmented scar area treated with a combination of needling and Recell.

The company said that in the 12 months following the Recell treatment, the participants were monitored using a medical device that detected levels of melanin in the skin.

Avita said that medical needling, or percutaneous collagen induction, improved many properties of scar tissue, but often did not restore pigment, particularly for large areas.

“We believe that we have found a method for preparation of the treatment site without removing any skin tissue and that with both needling and Recell, we can reliably achieve improvement in re-pigmentation,” Prof Aust said.

Avita fell one cent or 8.3 percent to 11 cents with 1.05 million shares traded.

USCOM

Uscom says it has raised $1.4 million in a placement to institutional and sophisticated investors in Australia at 24 cents a share.

Uscom said the 24 cents price was a 17 percent discount to the last closing price of the company’s shares on May 12, 2014.

The company said that the proceeds were for working capital associated with the manufacture and commercialization of its products the Uscom 1A and the BP+.

Uscom said that Hawkesbury Partners acted as lead manager for the placement.

Uscom was untraded at 29 cents.

LIVING CELL TECHNOLOGIES

Living Cell says that Otsuka Pharmaceutical Factory will not exercise its option to develop NTCell through Diatranz Otsuka and won’t pay the $2 million option fee instalment.

Otsuka and Living Cell created the Diatranz Otsuka joint venture to develop Diabecell.

Living Cell said that it retained all the intellectual property for therapeutic use of NTCell in Parkinson’s disease and other neurological diseases.

The company said it would continue the regulatory process to resume recruitment of the remaining three patients in the phase I/IIa clinical trial of NTCell in Parkinson’s disease.

Living Cell acting chief executive Dr Ken Taylor said that the newly restructured company could focus on developing and commercializing NTCell and retain all the benefits.

Living Cell fell 0.9 cents or 13.85 percent to 5.6 cents.

GENERA BIOSYSTEMS

Genera 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 rose 34.4 percent from 16.0 cents on May 13 to 21.5 cents on May 15, 2014 and noted an increase in the trading volume.
Genera was up 1.5 cents or 8.8 percent to 18.5 cents with 2.8 million shares traded.

QRX PHARMA

QRX says it has received a requesting a general meeting to replace Dr Peter Farrell and Dr Gary Pace with Dr Richard Treagus and Bruce Hancox.
QRX said the meeting was requisitioned under section 249D of the Corporations Act 2001 and attached a copy of the requisition notice from Walker Group Holdings.
The Walker Group said that Lang Walker and three related companies held 16,443,120 shares or 10.0 percent of QRX.
In a teleconference last month Walker Group director Mr Hancox expressed serious concern about previously unknown US Food and Drug Administration criticism of the QRX Moxduo drug application (BD: Apr 23, 2014).
In yesterday's announcement, QRX said that in accordance with section 249D of the Corporations Act 2001, the board was required to call a general meeting of shareholders within 21 days of the notice being given to the company and this meeting must be held within two months of the notice being given to the company.
In last night's News Flash, Biotech Daily said it missed the original announcement to the market which was headlined 'Notice under Sections 249D & 203D of the Corporations Act' and was not flagged by the company as market sensitive.
ASX media and communications general manager Matthew Gibbs told Biotech Daily today that companies decided what was material, but the ASX placed the price sensitive flags, "according to a predetermined set of announcements" including takeover offers, financial reports, capital raisings, dividend payments but not requisition notices.
Biotech Daily apologizes unreservedly for any imputation.
QRX was up half a cent or 5.3 percent to 10 cents with two million shares traded.

CYCLOPHARM

Cyclopharm says that the Commonwealth Director of Prosecutions has withdrawn all charges against Vanda Gould and he has been reinstated as chairman.
Last year, Mr Gould stepped aside while contesting two charges relating to tax and money laundering offences and having been released on $5 million bail (BD: Oct 17, 23, 2013).
Today, Cyclopharm said that Mr Gould had "consistently maintained his innocence of any wrongdoing in relation to these charges" and remained on the board as a non-executive director, while these matters were being resolved.
The company said that director David Heaney was appointed interim chairman.
"This has been a challenging time for Mr Gould as a result of the negative publicity surrounding the charges and he can now begin the process of restoring his credibility," Cyclopharm said.
Cyclopharm was untraded at 21 cents.

VIRAX HOLDINGS

Virax says it has appointed Dr Rob Crombie as managing director, effective from June 16, 2014.

Virax said Dr Crombie had held senior management roles at Arana Therapeutics and Evogenix and was currently a consultant providing specialist advice to start up innovation companies.

The company said that Dr Crombie was instrumental in driving Arana from an initial public offering through a $318 million cash sale within five years and was involved in repositioning Evogenix to maximize traction in the therapeutic antibody market.

Virax executive chairman Dr Wayne Millen said Dr Crombie had an “outstanding” track record in the international life science and biotechnology sectors”.

Dr Millen said that Dr Crombie had doctoral qualifications in molecular oncology and commercial biotechnology experience in partnerships, mergers and acquisitions and licencing agreements with global pharmaceutical companies.

Dr Crombie holds a Bachelor of Arts in genetics from Trinity College in Dublin and a Doctorate of Philosophy from the University of Glasgow.

Virax said that Dr Crombie would be entitled to an annual salary, including superannuation, of $300,437, subject to annual review.

The company said that Dr Crombie would receive a performance-based bonus, with short-term incentives up to 20 percent of the annual salary and subject to shareholder approval, up to 40,000,000 options as a long-term incentive.

Virax said the options would be exercisable at the closing price of the company’s shares on the date of shareholder approval, expiring four years from the date of grant and vesting in four tranches.

Virax was unchanged at 0.8 cents or 17.0 million shares traded.