Biotech Daily

Monday August 17, 2015

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: REVA UP 16%, ANALYTICA DOWN 14%**

*** MESOBLAST: 'FASTER PHASE III HEART TRIAL', REVENUE DOWN, LOSS UP**

*** INVION: HIGH DOSE INV103 (CPN10, XTOLL) POTENTIAL FOR LUPUS**

*** PARADIGM IPO RAISES $8m FOR BONE BRUISING, RESPIRATORY**

*** DORSAVI SIGNS 4th CROWN CONTRACT, LARGEST TO DATE**

*** AVITA, HUDDERSFIELD UNI STUDY RECELL MECHANISM OF ACTION**

*** BIOXYNE EXPECTS $200k NPAT**

*** AIRXPANDERS RELEASES 845k ESCROW US SHARES (2.5m CDIs)**

*** UBS AG TRADES, RETURNS ACRUX SHARES BELOW 5%**

*** HOCKINGS TAKE 28% OF PHYLOGICA**

*** SIETSMA INCREASE, MAINTAIN 9% OF PHYLOGICA**

MARKET REPORT

The Australian stock market was up 0.21 percent on Monday August 17, 2015 with the ASX200 up 11.2 points to 5,367.7 points. Sixteen of the Biotech Daily Top 40 stocks were up, 13 fell, eight traded unchanged and three were untraded. All three Big Caps were up.

Reva was the best, up eight cents or 16.3 percent to 57 cents with 117,500 shares traded, followed by Actinogen up 11.5 percent to 6.8 cents with 948,728 shares traded.

Prima climbed 9.6 percent; Benitec and IDT were up more than seven percent; Atcor was up 6.8 percent; Sirtex climbed 4.2 percent; Cellmid, Clinuvel, Ellex, Starpharma and Viralytics rose more than two percent; Admedus, Anteo and Bionomics were up more than one percent; with Cochlear, CSL, Nanosonics and Resmed up by less than one percent.

Analytica led the falls, down 0.1 cents or 14.3 percent to 0.6 cents with 4.4 million shares traded. Oncosil lost 8.3 percent; Acrux, Living Cell, Optiscan, Pharmaxis and Polynovo fell more than four percent; Genetic Technologies and Neuren were down more than three percent; Mesoblast shed 2.7 percent; Medical Developments and Psivida were down more than one percent; with Osprey down 0.6 percent.

MESOBLAST

Mesoblast says that new information of “overwhelming efficacy” could lead to early completion of its phase III chronic heart failure trial, run by Teva Pharmaceuticals.

Mesoblast said the data, from its 2011, 60-patient, phase II trial of mesenchymal precursor cells for what was then called “congestive heart failure”, showed overwhelming efficacy in prevention of recurrence of heart failure major adverse cardiovascular events (HF-MACE) (BD: Nov 15, 2011; Jul 15, 2015).

In 2013, the company said the phase III trial was a double-blinded, one-to-one randomized, placebo-controlled study evaluating a single dose of 150 million mesenchymal precursor cells (MPCs) delivered via trans-endocardial injection catheter for heart failure patients with New York Heart Association class II or III disease and an ejection fraction of less than or equal to 40 percent (BD: Oct 31, 2013).

Mesoblast said at that time that the primary efficacy endpoint was a time-to-first event analysis of heart failure-related major adverse cardiac events.

Today in a telephone conference to announce the company’s preliminary final report, chief executive Prof Silviu Itescu said that discussions between Teva and the US Food and Drug Administration had led to changes to the trial that could expedite approval, including renaming it “chronic heart failure”.

Prof Itescu said that the phase II trial demonstrated a reduction in health care burden due to a reduction in recurrent events.

“If we see anything like the phase II results the bar for overwhelming efficacy will be lowered,” Prof Itescu said.

Prof Itescu said that the total number of patients in the original phase III trial would be reduced from 1,730 to 1,165 but a second parallel trial of about 500 patients would begin “using recurrent HF-MACE as the primary endpoint”.

Prof Itescu said that a second primary endpoint had been added to the original trial with an interim analysis when 50 percent of the major adverse cardiovascular events had occurred which included a test for superiority “allowing for the possibility of early stopping of the trial based on overwhelming efficacy”.

Prof Itescu said that the trial was originally expected to conclude by August 2018 but the changes to the trial design could bring the conclusion forward.

He said that so far there had been no restrictions of hindrances to recruitment and no adverse events of concern at this stage of the trial.

“Teva is doing a terrific job driving recruitment,” Prof Itescu said. “I couldn’t be more pleased about how our two teams are working together on this trial.”

Prof Itescu said that other trials including the phase III trials of the company’s stem cells for low back pain and acute graft versus host disease were recruiting well, along with programs for diabetic kidney disease, rheumatoid arthritis and Crohn’s disease.

Mesoblast said that revenue for the 12 months to June 30, 2015 fell 2.3 percent to $23,748,000, with the net loss after tax up 47.4 percent to $119,368,000.

The company said it had cash on hand of $144.1 million at June 30, 2015, compared to $196.4 million at June 30, 2014.

Mesoblast said that research and development expenditure increased by 40.3 percent to $77,593,000 or 47.9 percent of the $161,916,000 in expenses, with manufacturing costs comprising a further 18 percent or $29,206,000, while management and administration costs were 22 percent of total expenses or $36,172,000.

The company said that underlying US dollar denominated content increased from 74 percent to 80 percent and would continue to ,increase so reporting from the 2015-’16 financial year would be in US dollars.

Mesoblast fell 10 cents or 2.7 percent to $3.61 with 429,702 shares traded.

INVION

Invion says its 28-subject, phase II trial of chaperonin 10 or INV103 for systemic lupus erythematosus (SLE) has met its objectives and warrants further studies.

Invion said that the trial was entitled 'Double-blinded, randomized, placebo-controlled study to investigate the safety, tolerability, pharmacokinetics, and biochemical activity of intravenous Cpn10 administration in subjects with SLE'.

The company said that the decision to complete the trial was based on the review of safety and biochemical markers of effect in 28 subjects across four cohorts, which showed that the study had met its objectives and supported the continued development of INV103 or Cpn10 in longer and larger trials in patients with autoimmune diseases.

Invion said that three sets of data were reviewed from subjects who received twice-weekly doses of 10mg, 30mg or 100mg of ala-Cpn10, or placebo.

The company said that adverse events and clinical chemistry profiles showed that increasing the dose 10-fold over levels used previously in the development of the drug could be achieved safely.

In 2011, INV103, then known as CBio's XToll, failed to meet the primary endpoint of a 155-patient phase IIa safety and efficacy trial of a 10mg dose of the drug for rheumatoid arthritis (BD: Aug 1, 2011).

CBio later merged with Inverseon to become Invion (BD: Jul 2, 2012).

Invion said that serum biomarkers of vascular inflammation were too variable in all cohorts to draw absolute conclusions about biological effect, but significant data was derived from extracting white blood cells from patients before and after certain doses and stimulating these cells, the peripheral blood monocytic cells or PBMCs, to produce inflammatory signals.

The company said that PBMCs were hypothesized to play a critical role in autoimmune diseases.

Invion said that subjects in the first cohort, received 10mg intravenously twice-weekly for four weeks and showed no consistent effect on stimulated PBMC production of the three key cytokines, interleukin-1 beta, interleukin -6 and tumor necrosis factor-alpha, measured at two time points.

The company said that in contrast, subjects in the second cohort of 30mg intravenously twice-weekly for four weeks showed a consistent decrease in production of all three cytokines measured at the same two time points in stimulated PBMC.

Invion said that data from the third cohort of 100mg intravenously twice-weekly for four weeks supported findings from the second cohort, although, like the placebo data, had some variability.

Invion research and development executive vice-president and chief medical officer Dr Mitchell Glass said the data supported the dose escalation that had underpinned the strategy for ala-Cpn10.

"Although we report the data here as means, the data are quite variable as is to be expected from PBMC assays," Dr Glass said.

"However we are pleased at the consistency of the responses," Dr Glass said.

"INV103 … will need scale-up and longer term toxicology to extend these findings from one month to longer term studies in larger groups of subjects," Dr Glass said.

"We will be providing these data to potential partners in the near term, with a view to partnering the program," Dr Glass said.

Invion was unchanged at 2.1 cents with 2.6 million shares traded.

PARADIGM BIOPHARMACEUTICALS

Paradigm says it has raised $8 million in an “over-subscribed” initial public offer and expects to list on the ASX on August 19, 2015 at 11am under the code PAR.

Paradigm said that the funds would enable the completion of a phase IIa bone marrow oedema, or bone bruising, clinical trial in 2017 and the start of trials on a novel treatment for allergic rhinitis and other respiratory diseases, including allergic asthma and chronic obstructive pulmonary disease (BD: Jun 18, 2015).

The company said that prior to the initial public offer it acquired intellectual property over exosomes, which were thought to have the regenerative potential to repair chronically injured and degenerating tissue.

Paradigm said that Lodge Corporate was the lead manager for the offer and underwrote the minimum $5 million subscription.

DORSAVI

Dorsavi says it has signed its fourth contract with Crown Resorts, its single largest commercial project to date, but did not disclose the contract value.

Dorsavi said the contract positioned Crown “as a global leader in workplace safety” and would be implemented over 18 months with an additional annual annuity in the form of a licence fee for its Visafe wearable body movement sensors system.

Crown Resorts is the parent body of the Crown casino and hotel establishments.

The company said its Visafe system would assess the movement of Crown workers in Melbourne and Perth to build an occupational health and safety database and job analysis library.

Dorsavi said that the company could see how its workers were moving, identify higher risk areas of work and proactively manage this to create a safer working environment.

The company said that Crown would implement the Visafe program across all business areas in both Melbourne and Perth, with plans to implement a similar program at the Sydney site within two to three years.

Crown health safety and wellbeing group manager Tony Graham said “the safety of Crown workers is paramount and Dorsavi’s Visafe revolutionary technology provides the business with an easy and efficient way to understand the workplace risks and proactively manage it across the two properties”.

“By having a better view of how our employees move, across roles and businesses, we will not only be able to create a safer workplace, but we will also be able to reduce costs and improve work practices,” Mr Graham said.

Dorsavi chief executive officer Dr Andrew Ronchi said that Crown had 13,000 employees in Melbourne and Perth.

“Crown’s vision for safety in the workplace shows leadership in its industry at a national and international level,” Dr Ronchi said.

Dr Ronchi said the contract was “a significant milestone and highlights the forward-thinking nature and value that Crown places on best-practice [occupational health and safety]”.

“The contract is one of more than a dozen signed over the last six weeks in [occupational health and safety] and it is pleasing but not unexpected that we are seeing an acceleration in sales with new and existing customers across the globe,” Dr Ronchi said.

Dorsavi was up two cents or 7.7 percent to 28 cents.

AVITA MEDICAL

Avita says it has partnered with England's University of Huddersfield to explore the mechanism of regenerative epithelial suspension of its Recell device for wounds.
Avita said that the aim of the study was to better understand Recell's ability to effectively treat burns, hard-to-heal wounds and skin trauma and provide greater understanding of the cellular interactions present in regenerative epithelial suspension (RES) and the roles these played in regenerating natural, healthy skin.
The company said that the research would help enable clinicians make more informed patient selection leading to superior clinical outcomes.
Avita said that the University of Huddersfield Institute of Skin Integrity and Infection Prevention's Dr Nikolaos Georgopoulos and Dr Karen Ousey would assess Recell using donated human skin to produce the regenerative epithelial suspension and would examine the behavior of the skin cells in the suspension "using sophisticated analysis techniques to reveal on-going cellular interactions".
Avita chief executive officer Adam Kelliher said the goal of the study was "to further unlock understanding of the mechanism within the active suspension, so that we will be able to further discern the intricacies behind why Recell is so effective for wound treatment".
Avita said that following the collaboration it and the University intended to finalize a longer term strategy to explore the regenerative epithelial suspension mechanism.
Avita was untraded at 7.5 cents.

BIOXYNE

Bioxyne says that despite lower revenue than the prior year it expects to report a net profit after tax of no less than $200,000 for the year to June 30, 2015.
Bioxyne said that for the year to June 30, 2014 it posted a net profit after tax of $261,220.
The company said that it had previously reported an operating cash out-flow for the three months to June 30, 2015 quarter of $190,000 that took into account a payment of $101,000 for prior years' royalties.
Bioxyne said that with brought forward accumulated tax losses, no income tax expense was applicable and for the 2014-'2015 financial year, lower revenue was offset by lower operating costs, including marketing and business development costs that were not incurred in the prior year.
Bioxyne was unchanged at 1.3 cents.

AIRXPANDERS

Airxpanders says that 845,406 US shares equivalent to 2,536,218 Chess depository instruments (CDIs) will be released from ASX escrow on September 4, 2015.
Airxpanders company secretary Brendan Case told Biotech Daily the company had a total of 70,424,230 US shares equivalent to 211,272,690 CDIs on issue, of which some were held in ASX escrow and some in voluntary escrow.
Mr Case said that following the September 4 release from escrow of the 845,406 US shares, Airxpanders would have a further 1,022,776 US shares and 58,290 CDIs, equivalent to 3,126,618 CDIs held in ASX escrow and to be released in three tranches until June 18, 2017.
According to the Airxpanders disclosure document, a further 43,098,902 US shares and 2,772,156 CDIs, equivalent to 132,068,862 CDIs held in voluntary escrow, to be released in two tranches on June18, 2016 and June 18, 2017.
Airxpanders was up two cents or 2,4 percent to 85 cents.

ACRUX

The Singapore-based UBS AG and related bodies corporate say they have reduced their holding in Acrux from 12,493,473 shares (7.50%) to below five percent.
Earlier this month, UBS AG said it had increased the holding in Acrux from 10,771,754 shares (6.47%) to 12,493,473 shares (7.50%) in more than 80 mainly very small trades (BD: Aug 7, 2015).
Today, UBS AG said that it bought and sold shares, but primarily "returned" stock between August 10 and August 12, 2015.
Acrux fell three cents or 4.05 percent to 71 cents.

PHYLOGICA

Dr Bernard and Dianne Hockings have increased their substantial shareholding in Phylogica from 255,468,182 shares (25.49%) to 568,933,332 shares (28.39%).
The substantial shareholder notice said that BEF and DC Hockings bought 57,300,328 shares at various prices between July 17 and August 13, 2015 and acquired 370,765,578 shares in the one-for-one rights issue at one cent a share (BD: Jul 2, Aug 12, 2015).
In January, Phylogica appointed Perth cardiologist Dr Hockings as a director of the company (BD: Jan 24, 2014).
Phylogica was up 0.1 cents or 10 percent to 1.1 cents with 5.7 million shares traded.

PHYLOGICA

The Sydney-based Sietsma Holdings says it has increased its substantial shareholding in Phylogica from 90,000,000 shares (8.98%) to 179,273,017 shares (8.95%).
Last week, Phylogica's one-for-one rights issue at one cent a share raised a total of $10,020,694 (BD: Jul 2, Aug 12, 2015).
The Sydney-based Sietsma Holdings, with David and Elizabeth Sietsma, said they acquired 89,273,017 shares for $890,000.