Biotech Daily

Friday August 2, 2013

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: PRANA UP 14%, IMPEDIMED DOWN 11%**

*** ATCOR: 'STUDY BACKS CENTRAL PRESSURE FOR CLINICAL PRACTICE'**

*** AVITA BEGINS RECELL VENOUS LEG ULCER TRIAL**

*** RESMED RECORD REVENUE, PROFIT**

*** ANTISENSE ATL1103 PHASE II ACROMEGALY SLOW ENROLMENT**

*** ACTINOGEN $595k RIGHTS ISSUE FAILS**

*** CELLMID EARNS $569K PACIFIC EDGE TEST MILESTONE**

*** UNIVERSAL BIO H1 REVENUE DOWN 35% TO $9.6m, LOSS UP 125%**

*** IMUGENE RELEASES 100m ESCROW SHARES**

*** PRANA HIRES DR PETER SMITH, MORE APPOINTMENTS**

*** SMALL TECH CLUSTER 'MEDTECH'S GOT TALENT' COMPETITION**

MARKET REPORT

The Australian stock market climbed 1.09 percent on Friday August 2, 2013 with the S&P ASX 200 up 55.3 points to 5,116.8 points. Twenty of the Biotech Daily Top 40 stocks were up, 10 fell, eight traded unchanged and two were untraded. All three Big Caps were up.

Prana was the best, up five cents or 13.9 percent to 41 cents with 922,807 shares traded, followed by Reva up 10.7 percent to 62 cents with 38,350 shares traded. Atcor climbed eight percent; Medical Developments and Compumedics were up more than seven percent; Cellmid, Circadian and Tissue Therapies were up more than six percent; Living Cell, Neuren and Genetic Technologies were up more than five percent; Phosphagenics rose 4.8 percent; Anteo and Heartware were up more than three percent; Alchemia and Resmed rose more than two percent; Allied Health, Bionomics, CSL and Mesoblast were up more than one percent; with Acrux, Cochlear and Sirtex up by less than one percent.

Impedimed led the falls, down one cent or 6.7 percent to 14 cents with 102,500 shares traded, followed by Antisense down 6.25 percent to 1.5 cents with 33.7 million shares traded. Patrys and Phylogica fell more than four percent; Nanosonics and Pharmaxis shed more than two percent; GI Dynamics and Optiscan were down more than one percent; with Starpharma and Universal Biosensors down by less than one percent.

ATCOR MEDICAL

Atcor says a study has determined the cut-off values for optimal levels of central blood pressures and for the diagnosis of hypertension or high blood pressure.

Atcor, which has developed the Sphygmocor measure of non-invasive central aortic blood pressures and arterial stiffness, said the study was “a significant advancement to support adoption of central blood pressure measurement into clinical practice”.

The company said that the study, entitled ‘Derivation and Validation of Diagnostic Thresholds for Central Blood Pressure Measurements Based on Long-Term Cardiovascular Risks’ and published in the Journal of the American College of Cardiology, “was the first to determine and validate diagnostic thresholds of central blood pressure for the diagnosis of hypertension”.

An abstract is at: http://www.ncbi.nlm.nih.gov/pubmed/23850921.

Atcor said that the study followed two groups, comprising more than 3,700 people, for up to 15 years to determine diagnostic thresholds for central blood pressure and to validate those thresholds.

The company said that previously, only age-specific reference values by gender had been validated.

Atcor said that the current guidelines relied on cuff blood pressure measurements made at the clinic or the home, and the study results facilitated the use of central blood pressure in clinical practice.

The company said that one cohort of 1272 individuals was employed to determine diagnostic thresholds for central blood pressure by using current guideline-endorsed cut-offs for brachial cuff blood pressure and the second cohort of 2501 individuals had their central blood pressure measured using the Sphygmocor system to validate the diagnostic thresholds.

Atcor said that based on statistical modeling, the authors determined that optimal central aortic blood pressure was 110/80 mmHg and that 130/90 mmHg was the central aortic blood pressure threshold for hypertension.

The company said that using these values they reported highly significant hazard ratios based on elevated central aortic blood pressures for cardiovascular death of 3.08 times greater than normal central pressure; all cause death of 2.14 times greater than normal central pressure; and stroke death of 6.12 times greater than normal central pressure.

Atcor said that by comparison, the use of traditional cuff systolic blood pressures was predictive of total death and stroke death, but was not predictive of cardiovascular death.

Atcor said that the authors concluded that the report “represents an important step” toward the application of the central blood pressure concept to clinical risk factor profiles for cardiovascular disease.

The company said that the results were consistent across age and gender and other cardiovascular risk factor subgroups.

Atcor chief executive officer Duncan Ross said the publication was “the first major study to establish thresholds of central pressure in diagnosing hypertension, above which there is significantly increased risk of serious cardiovascular events”.

“The paper is important as it addresses the need for more specific reference standards for central blood pressure that can be used as guidelines for clinical decision making,” Mr Ross said.

Atcor was up one cent or eight percent to 13.5 cents with 2.2 million shares traded.

AVITA MEDICAL

Avita says it has begun initial enrolment of three of 65 patients in its European clinical trial use of Recell Spray-on Skin for venous leg ulcers.

Avita said the multi-centre, randomized, controlled trial, known as the Restore study was based on positive preliminary results with Recell in the treatment of more than 50 venous leg ulcer patients.

The company said that the first three patients had unhealed ulcers for a minimum of 12 months and were enrolled at Addenbrooke's Hospital in Cambridge, UK under consultant vascular and endovascular surgeon and investigator Dr Paul Hayes.

Avita said that following a two-week observation period, patients would be randomly assigned for treatment with Recell or the current standard of care and would be followed for a minimum of 12 weeks post-treatment.

The company said that it expected additional study centres in Denmark, France and Germany would participate in the trial.

Avita chief executive officer Dr William Dolphin said that chronic wounds, of which venous leg ulcers were the most common, were "a major burden to patients, health care professionals and health care systems globally".

"Preliminary results with the use of Recell have been extremely encouraging and we are confident that this study will demonstrate the clinical efficacy of Recell in treating lower limb ulcers," Dr Dolphin said.

"Chronic wounds represent a large and growing market throughout the world and we believe that Recell will provide an important treatment option for a large segment of this population," Dr Dolphin said.

The company said that lower limb ulcers, including venous leg ulcers and diabetic foot ulcers were a major healthcare problem in developed countries due to their prevalence, high cost of treatment and significant impact on patient quality of life.

Avita said that lower limb ulcers afflicted about 1.5 percent of the general population in Western developed countries and up to three percent of people over the age of 70 years and venous ulcers accounted for up to 85 percent of all leg ulcers and were expected to increase in prevalence with the growing elderly population.

Avita said that the costs to patients include associated morbidity, pain, lack of mobility and lost work days and wages.

The company said that treatment options included compression therapy, skin grafts and regular dressing changes but were costly and there was no effective or definitive treatment for lower limb ulcers.

Avita said Recell offered "a promising potential to address this major unmet clinical need".

Avita was unchanged at 13.5 cents.

RESMED

Resmed has posted record revenue of $US1,514.5 million up 10.7 percent and net profit after tax up 20.5 percent to $US307.1 million for the 12 months to June 30, 2013.

Resmed said diluted earnings per share was $US2.10, a 22.8 percent increase over the 12 months to June 30, 2012.

Resmed said research and development expenditure for the year was up 9.5 percent to $US120.1 million, or 7.9 percent of revenue.

Resmed said it would pay a dividend for the three months to June 30, 2013 of 25 US cents a share, with a record date of August 20, to be paid on September 17, 2013.

Resmed was up 13 cents or 2.4 percent to $5.45 with 13.95 million shares traded.

ANTISENSE THERAPEUTICS

Antisense says enrolment in its 24 patient, phase II trial of ATL1103 for acromegaly has been slower than expected with results expected up to six months later than planned.
Antisense said that the randomized, open-label, parallel group study of the safety, tolerability, pharmacokinetics and efficacy of two subcutaneous dosing regimens of ATL1103 was enrolling patients, confirming the trial's viability, but the enrolment rate has been slower than originally anticipated.
The company said that acromegaly was a rare disease and patient recruitment rates in rare disease trials could be hard to predict.
Antisense said that to improve the enrolment rate it had made changes to the study protocol in consultation with the clinical research organization Orion and the clinical trial investigators to help attract additional acromegaly patients.
The company said the changes would not compromise the quality of the trial data and it was "well-advanced in the establishment of additional clinical trial sites in Central Europe and Australia".
The company said that all 24 patients should be enrolled into the trial by the end of the year, and dosing completed by April 2014 with the key results including ATL1103's effects on serum insulin-like growth factor I (sIGF-I) reduction to follow by July 2014, instead of the previously estimated end of 2013.
Antisense said it began dosing in April with at 11 sites in the UK, Spain and France, with five trial sites in the UK and two in Spain initiated and ready to recruit patients and French sites to be initiated by June (BD: April 10, 2013).
Antisense said that so far six patients had entered the study and been dosed with ATL1103, two of whom have completed or are about to complete dosing with a further six patients currently being evaluated for potential enrolment.
"To date no patients dosed with ATL1103 have withdrawn from the study nor have any serious adverse events been reported," Antisense said.
The company said it intended to submit a protocol amendment for approval to undertake an interim analysis of the trial data to be conducted on all patients having completed dosing by November this year.
Antisense said that the interim analysis would assess the available sIGF-I data with the results of the analysis to be reported by the end of this calendar year.
The company said that the interim analysis was expected to provide important indicative data on the efficacy of ATL1103 in the phase II trial, but, unlike the final analysis of the efficacy results at the completion of the trial, the company does not anticipate the interim data to be sufficiently powered for statistical significance.
Antisense said that depending on the outcomes in the interim analysis, it could help direct future development plans beyond phase II and bring forward discussions with prospective partners on ATL1103 ahead of the final trial results.
Antisense fell 0.1 cents or 6.25 percent to 1.5 cents with 33.7 million shares traded.

ACTINOGEN

The ASX says that deferred settlement trading of Actinogen securities has been suspended due to the company not proceeding with its entitlement offer.
Actinogen proposed a one-for-three non-renounceable pro-rata rights issue two cents a share, with one free attaching option, exercisable at 20 cents expiring on September 30, 2015 for every two new shares issued.
The company said that the right issue hoped to raise $595,098 if all rights are taken up.
Actinogen last traded at 1.7 cents.

CELLMID

Cellmid says it has been issued 1,084,622 milestone shares by Pacific Edge Limited for the use of midkine as one of the biomarkers in the bladder cancer test Cxbladder.
Pacific Edge is listed on the New Zealand stock exchange and last traded at 59 New Zealand cents, valuing the payment at $566,913.
Cellmid said that the licence with Pacific Edge provided for a milestone fee, payable in Pacific Edge shares, and due at the time Cxbladder sales begin in the US along with royalties on Cxbladder revenues.
The company said that Pacific Edge has achieved “solid progress since the licence was signed and has recently received [Clinical Laboratory Improvement Amendment] registration of its Pennsylvania labs clearing the way for the launch of Cxbladder in the US and enabling Pacific Edge to begin its sales and marketing program to urologists.
Cellmid said the 1,084,622 shares completed Pacific Edge’s milestone obligations.
Cellmid was up 0.2 cents or 6.45 percent to 3.3 cents with 3.1 million shares traded.

UNIVERSAL BIOSENSORS

Universal Biosensors says revenue for the six months to June 30, 2013 was down 35 percent to $9,579,427, with a net loss after tax up 125 percent to $7,683,444.
Universal Biosensors said that a reduction in revenue from services and manufacturing activities were partly offset by an increase in quarterly service fees.
The company said it had expected strip sales to be impacted by the recall of Lifescan's OneTouch Verio devices and sales were down nine percent in the three months to June 30, 2013 compared to the prior quarter, but strip sales for the six months were up 58 percent compared to the previous corresponding period, with a strong rebound in strip sales in June.
Universal Biosensors said it had an 82 percent decrease in revenue from research and development services to $780,000 and it was not currently undertaking any contract research and development program with Lifescan or any other third party, but received $US500,000 reimbursement for costs incurred in additional development work undertaken for Siemens.
Universal Biosensors said its net tangible assets per share fell 10 percent to 18 cents and basic loss per share was up 100 percent to four cents.
The company said it had cash and cash equivalent of $18,095,399 at June 30, 2013 compared to $14,709,678 at June 30, 2012.
Universal Biosensors fell half a cent or 0.7 percent to 70 cents.

IMUGENE

Imugene says 100,000,000 shares held in ASX escrow were released on July 31, 2013.
Imugene chief executive officer Dr Nicholas Ede told Biotech Daily that following the release of the shares, his company would have 376,162,516 shares available for trading.
Imugene was untraded at half a cent.

PRANA BIOTECHNOLOGY

Prana says it has appointed former Alchemia chief executive officer Dr Peter Smith to drive business development.

Prana said the appointment of Dr Smith was “the first of several key appointments in the near term to advance PBT2 into late stage and pre-market clinical development … as a treatment for Alzheimer’s and Huntington’s diseases”.

The company said that results from its phase II clinical trials for Huntington’s and Alzheimer’s disease were expected in October 2013 and March 2014, respectively.

Prana said it would also make senior appointments in toxicology, manufacturing and clinical operations to support plans to accelerate PBT2 into prospective phase III studies.

Prana said that Dr Smith had experience in negotiating licencing deals, finance and operational roles and was Alchemia chief executive officer from 2006 until earlier this year where he secured a partnership with Dr Reddy’s Laboratories.

The company said that prior to Alchemia, Dr Smith was chief executive officer of Amrad, executive chairman of Cerylid Biosciences and founded the UK-based cancer vaccine company Onyvax and had held senior roles in the banking industry.

Prana executive chairman Geoffrey Kempler said the appointments were “essential as we plan for the future in delivering innovative therapies in these diseases for which today, there is no cure”.

Prana was up five cents or 13.9 percent to 41 cents.

VICTORIA’S SMALL TECHNOLOGIES CLUSTER

Victoria’s Small Technologies Cluster (STC) has launched a competition to encourage university students and graduates to create or develop medical technologies.

Entitled ‘Medtech’s Got Talent’ the program hopes to develop a more entrepreneurial culture and to increase Victoria’s medical technology cluster.

The Cluster said that participants needed to submit an executive summary by October 31, 2013 and the top 30 applicants would participate in a ‘rapid fire round, in which eight product development mentors would select two teams of 16 semi-finalists to mentor intensively through a one-month training program.

The STC said that the finalists would have three minutes to pitch their business concepts and five category winners would each receive a $20,000 voucher to undertake “an intensive three-month accelerated technology road-mapping with their mentors” along with service prizes from Victoria’s enabling technology sponsors.

The STC said that at the conclusion of the three months, the winners would pitch to investors in a closed-door investor boardroom event

The Cluster said that each business concept must be led by a currently enrolled student in a Victorian university, a currently employed post-doctoral student in a Victorian university, research institute, hospital or company, or a recent graduate from any university and residing in Victoria.

The Cluster said that ‘Medtech’s Got Talent’ was supported by the Victorian Government’s Department of State Development, Business and Innovation, as an initiative of the Enabling Technologies Skills Strategy Small Technologies.

The STC said the service sponsors were Griffith Hack, Second-Nature and the Bio-Melbourne Network and the Cluster was working with marketing and media partners.

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