

Biotech Daily

Tuesday November 19, 2013

Daily news on ASX-listed biotechnology companies

- * ASX, BIOTECH DOWN: CELLMID UP 7%, COMPUMEDICS DOWN 9%
- * WEHI CELEBRATES 10 YEARS OF DRUG DISCOVERY
- * MESOBLAST STEM CELLS BENEFIT HEART PUMP PATIENTS
- * INNATE TO RAISE UP TO \$12m FOR MIS416 FOR MULTIPLE SCLEROSIS
- * COGSTATE LOSS WARNING, CUTS STAFF, \$7.55m RAISING
- * CORRECTION: CYNATA (ECO QUEST)
- * NSW UNI ASSIGNS PITNEY PATENTS TO PHARMAUST
- * ALLAN GRAY TAKES 8% OF ACRUX, 13% OF QRX

MARKET REPORT

The Australian stock market fell 0.59 percent on Tuesday November 19, 2013 with the S&P ASX 200 down 31.8 points to 5,352.9 points.

Fourteen of the Biotech Daily Top 40 stocks were up, 18 fell, five traded unchanged and three were untraded.

Cellmid was the best, up 0.3 cents or 7.3 percent to 4.4 cents with 28.2 million shares traded.

Atcor and Avita climbed five percent or more; Anteo, Impedimed and Pharmaxis were up more than four percent; Bionomics and Psivida were up more than three percent; Living Cell and Universal Biosensors rose two percent or more; CSL, IDT and Patrys were up more than one percent; with Cochlear, Medical Developments and Sirtex up by less than one percent.

Compumedics led the falls, down one cent or 9.1 percent to 10 cents with 68,374 shares traded.

Tissue Therapies lost 8.9 percent; Antisense fell 6.1 percent; Prana was down 5.4 percent; Benitec, Neuren and Viralytics fell more than four percent; Allied Health, GI Dynamics, Prima and Starpharma shed two percent or more; Acrux, Clinuvel, Mesoblast and QRX were down more than one percent; with Alchemia, Nanosonics, Resmed and Reva down by less than one percent.

THE WALTER AND ELIZA HALL INSTITUTE FOR MEDICAL RESEARCH

The Walter and Eliza Hall Institute today celebrated a decade of translating research into commercializable medical technologies.

WEHI director Prof Doug Hilton welcomed about 200 scientists, researchers and drug development specialists to the seminar and said that drug development effectively began when the Institute hired former Merck Canada high-throughput screening specialist Dr Ian Street, whom Prof Hilton met at the Victoria Government-founded Amrad in Burnley. Prof Hilton said he had to convince then director Prof Suzanne Cory of the wisdom of the appointment and it was allowed on the condition that the work be described as 'medium-throughput screening' so as not to look like pharmaceutical company competitition. Representing Victoria's Minister for Innovation Gordon Rich-Phillips, the Department of Innovations' Dr Amanda Caples said that there had been a long-term commitment to the

sector from successive Victorian Governments and more than \$1.8 billion had been invested in the Parkville Precinct including the Melbourne Brain Centre, the Cancer Centre and the Peter Doherty Institute.

Dr Caples said that Federal and State Governments and philanthropy had contributed more than \$3 billion to the precinct with contributions covering staff training programs and equipment.

Dr Caples said that the aim of the Victorian Government was to create the environment for the translation from discovery to drugs and the WEHI Biotechnology Facility had been involved in 92 collaborations, which had led to 19 granted patent families and 200 patents with a WEHI staff member named as inventor on each one.

Dr Caples said the multi-disciplinary teams along with the "who dares wins" approach of WEHI and the Institute's staff were the key to its translational success.

Edinburgh University professor of translational biology and former Novartis executive Prof Manfred Auer gave a highly technical plenary lecture on 'Integrated chemical biology and biophysics process based on tagged [one bead one compound] libraries and confocal scanning, spectroscopy and imaging'.

Prof Auer said that pharmaceutical companies needed early drug development and that provided opportunities for academic research to develop drug candidates.

WEHI chemical biologist Dr Guillaume Lessene discussed the 'targeting of the BCL-2 family of proteins to treat cancer: from academic drug-discovery to public-private collaboration' a project initiated by Prof Cory in 2003 (BD: Apr 22, 2013).

Dr Lessene said that drug discovery "requires a highly collaborative team delivering druglike small molecules and tackling difficult targets".

As well as a WEHI laboratory head, Dr Street is chief scientific officer of the Cancer Therapeutics Cooperative Research Centre, which he said was "set-up to shepherd projects across the translational valley of death [when they were] too applied for academic funding and too risky for commercial investments".

Dr Street said the solution was milestone-driven drug discovery and academically driven target biology and the Cancer Therapeutics CRC was on the way to achieving its goal of providing four optimized leads to commercial partners by June 2014.

Dr Street outlined the work initiated by WEHI and former Cytopia scientist Dr Chris Burns on focal adhesion kinases and triple kinases for cancer, which was close to being licenced to a company to take to human clinical trials.

WEHI post-doctoral fellow Dr Brad Sleebs described the work begun by Dr Street with Bionomics in developing anti-anxiety drug BNC210, from a review of the literature in 2005 to trials of the then C4 against diazepam (Valium) and fluoxetine (Prozac) and development of the compound to BNC210, which had been licenced to the Cambridge, Massachusetts-based Ironwood Pharmaceuticals (BD: Jan 22, 2012).

MESOBLAST

Mesoblast says its mesenchymal precursor cells could benefit end-stage or class IV heart failure patients with left ventricular assist devices.

Mesoblast said that the phase II research was led by the Mount Sinai Hospital school of medicine with a multi-center team of researchers in the US National Institutes of Health-funded Cardiothoracic Surgical Trials Network.

The company said the research found the patients might "obtain specific benefit to their native heart from a single dose of Mesoblast's proprietary mesenchymal precursor cells injected directly into their heart during surgery".

Mesoblast said that the researchers reported that a single injection into the native heart of 25 million allogeneic, or off-the-shelf, mesenchymal precursor cells (MPCs) resulted in an improvement in cardiac function at the pre-specified key efficacy endpoint of 90 days, as measured by the ability of the native heart to support the circulation with the left ventricular assist device temporarily turned down.

The company said the results, entitled 'Intramyocardial Injection of Allogeneic Mesenchymal Precursor Cells in Left Ventricular Assist Device Patients' were presented on November 18, 2013 at the American Heart Association meeting in Dallas, Texas. Mesoblast said that the double-blind, placebo-controlled multi-center trial was performed at 11 sites in the US and randomized 30 end-stage heart failure patients two-to-one to receive either a single 25 million dose injection of MPCs or control media into the native heart at the time of device implantation.

The company said that device weaning, defined as a transient reduction in pump speed for at least 20 minutes, was attempted in all patients at predetermined intervals to assess native myocardial function and patients were followed for one year or until heart transplantation, whichever came first.

Mesoblast said that at 90 days, 50 percent of MPC-treated patients were able to tolerate being temporarily weaned from their devices compared with 20 percent of controls. The company said that none of the 20 MPC-treated patients died compared with three of 10 control patients.

Mesoblast said that improved cardiac function was sustained over the 12-month follow-up period with 85 percent of MPC-treated patients weaned successfully on multiple occasions compared with 40 percent of controls.

The company said that there were no cell-related serious adverse events noted nor any difference in human leukocyte antigen sensitization between treated and control groups. The study's lead author Mount Sinai Prof Deborah Ascheim said the trial results "provide important data about the safety and potential efficacy of a single MPC injection at the time of [left ventricular assist device] implantation".

"These mesenchymal precursor cells have shown their potential to safely facilitate early heart tissue repair in advanced heart failure," Dr Ascheim said.

Mesoblast said that 5.7 million Americans had chronic congestive heart failure, with about 10 percent with advanced or class IV heart failure.

Mesoblast chief executive Prof Silviu Itescu said the company was "very encouraged by the data" and class IV heart failure patients were a substantial population for whom there were no alternatives other than assisted circulatory support or transplantation.

"The results suggest that our MPCs may be effective in patients with advanced or ... class IV heart failure, and we intend to conduct further studies in this important group," Prof Itescu said. "This is in addition to patients with class II and III heart failure who have been shown to benefit from our MPCs in an earlier phase II trial using catheter-based cell delivery."

Mesoblast fell seven cents or 1.2 percent to \$5.95 with 277,957 shares traded.

INNATE IMMUNOTHERAPEUTICS

Innate hopes its initial public offer will raise \$10 million to \$12 million for a phase IIb trial of its drug candidate MIS416 to treat secondary progressive multiple sclerosis.

Innate said that it would offer up to 60,000,000 shares at 20.1 cents a share to raise up to \$12,000,000 before costs.

The company said the minimum subscription was \$10 million and it had commitments for \$5 million including \$3 million from Australian Ethical Smaller Companies Trust.

Innate company said that it would also offer 23,525,455 shares, together with one free attaching conversion options for every four new shares subscribed, to the holders of the company's redeemable preference shares, convertible promissory notes and

counterparties to short term loans granted to the company, with the subscription monies owed being set off against monies owed by the company to these parties.

Innate said that the 5,881,469 conversion options would be exercisable at 30 cents on or before the second anniversary of the date of issue.

The offer opens on November 26 and closes on December 11, 2013.

Innate said that Patersons and Morgans were joint lead managers and the prospectus is available at: <u>http://www.innateimmunotherapeutics.com/investor-centre/ipo-prospectus</u>. Innate said that 30 percent of all multiple sclerosis sufferers had secondary progressive multiple sclerosis and there were no approved drugs for the safe and effective, ongoing treatment of this highly disabling form of the disease (BD: Sep 5, 2013).

COGSTATE

Cogstate says it expects revenue for the six months to December 31, 2013 to be \$5 million to \$5.5 million with an operating loss of \$2.75 million to \$3.25 million.

Cogstate said that for the six months to December 31, 2012 revenue was \$6.1 million with a net loss after tax of \$494,161 (BD: Feb 20, 2013).

Cogstate said it would raise \$3.5 million in a placement to two US investors and raise a further \$4.05 million in a rights issue, all at 37 cents a share.

The company said that the Dagmar Dolby Trust would acquire 8,108,108 shares and Douglas Rosenberg would acquire 1,256,757 shares.

Cogstate said that the one-for-eight share rights issue was fully underwritten by Taylor collision with a record date of November 28, opening on December 3 and closing on December 18, 2013.

The company said the funds would be to accelerate the commercialization and expansion of the Cognigram point-of-care computerized test for cognitive impairment, which was being used in Canada to identify cognitive impairment associated with dementia and other neurological conditions.

Cogstate said that the number and value of sales contracts signed in the clinical trials business "fluctuated greatly from quarter to quarter" reflecting the level of research activity by customers in their development programs.

The company said that since signing \$US7.5 million of sales contracts in the three months to December 31, 2012, it had signed \$US5.5 million of sales contracts in the subsequent nine months.

Cogstate said the level of contracts signed did not coincide with a reduction in sales opportunities, which it was hopeful of converting to signed contracts.

The company said it would reduce staff by about 14 percent, predominantly from the area of software development, but would not impact on the ability of the clinical trials business to service new contracts or the activity planned for Cognigram.

Cogstate fell six cents or 13.3 percent to 39 cents.

CYNATA (FORMERLY ECO QUEST)

Last night's edition inadvertently reported that Cynata would have the ASX code of CYN. The correct ASX code for Cynata is CYP.

Biotech Daily apologizes unreservedly for the error which was made by the highlystressed former sub-editor, who is now receiving daily Freudian therapy.

Cynata remains in a suspension and is expected to resume trading "towards the end of this month".

PHARMAUST

Pharmaust says the University of New South Wales has assigned the intellectual property rights of Pitney Pharmaceuticals three anti-cancer platforms.

Pharmaust said the University's commercialization arm Newsouth Innovations had assigned the "entire right, title and interest" in the intellectual property.

The company said that Pitney had an exclusive royalty-free worldwide non-transferable licence from Newsouth Innovations to use, make, develop, sell and commercially exploit the technology.

In consideration of the assignments, Pitney agreed to acknowledge the University of New South Wales' contribution as the creator of the intellectual property.

Pharmaust fell 0.1 cents or 7.1 percent to 1.3 cents with 36.6 million shares traded.

<u>ACRUX</u>

Allan Gray Australia has increased its substantial holding in Acrux from 11,246,933 shares (6.75%) to 13,059,434 shares (7.84%).

Allan Gray said that between October 30 and November 18, 2013 it bought 1,812,501 shares for \$4,788,510 or an average price of \$2.64 a share.

Acrux fell three cents or 1.15 percent to \$2.57 with 666,178 shares traded.

QRX PHARMA

Allan Gray Australia has increased its substantial holding in QRX, from 17,683,669 shares (12.21%) to 20,903,390 shares (13.29%).

Allan Gray said it bought 3,219,721 shares between July 10 and November 13, 2013 for \$2,224,673 or an average price of 69.1 cents a share.

QRX fell one cent or 1.6 percent to 62 cents.