Biotech Daily

Wednesday September 30, 2015

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: AVITA UP 17%, BIOTRON DOWN 39%**

*** AVITA WINS UP TO $77m BARDA RECELL BURNS CONTRACT**

*** MESOBLAST: 'STEM CELL EFFICACY FOR WORST HEART PATIENTS'**

*** BIOTRON: 'TRIAL DROPOUTS MAR BIT225 HEP C SIGNIFICANCE'**

*** ADMEDUS, EAR SCIENCE INST WORK ON ADAPT STEM CELL DELIVERY**

*** RESAPP CLAIMS 95% ACCURACY FOR ASTHMA, VIRAL PNEUMONIA**

*** ANALYTICA CEO GEOFF DALY PERICOACH ROADSHOW**

*** ALLAN GRAY REDUCES TO 13% OF ALCHEMIA**

*** MEDICAL DEVELOPMENTS DAVID WILLIAMS SELLS 5m SHARES TO 32%**

MARKET REPORT

The Australian stock market recovered 2.1 percent on Wednesday September 30, 2015 with the ASX200 up 103.2 points to 5,021.6 points.

Eighteen of the Biotech Daily Top 40 stocks were up, 13 fell, seven traded unchanged and two were untraded. All three Big Caps were up.

Avita was the best, up 1.2 cents or 17.1 percent to 8.2 cents with 17.1 million shares traded, followed by Optiscan up 11.4 percent to 4.9 cents with 250,000 shares traded.

Antisense, Pharmaxis and Oncosil climbed seven percent or more; Reva and Starpharma were up more than six percent; Atcor was up 4.4 percent; Compumedics, Orthocell and Resmed were up more than three percent; Cochlear and Neuren rose more than two percent; CSL, Ellex, Nanosonics, Universal Biosensors and Viralytics were up more than one percent; with Clinuvel, Impedimed and Sirtex up by less than one percent.

Biotron led the falls, down 4.1 cents or 39.05 percent at 6.4 cents with 5.9 million shares traded, followed by Genetic Technologies down 15 percent to 1.7 cents with 3.2 million shares traded.

Mesoblast lost 8.9 percent; Actinogen and Benitec fell more than seven percent; Cellmid and Polynovo were down more than six percent; IDT fell 5.3 percent; Acrux and Psivida were down more than three percent; Circadian and Tissue Therapies shed more than two percent; with Osprey down 0.7 percent.

AVITA MEDICAL

Avita says it has been awarded a US Government contract worth up to $US53.9 million ($A76.99 million) to provide more than 5,000 Recell wound treatment units.

Avita said that the Biomedical Advanced Research and Development Authority (BARDA) would provide $US16.9 million ($A24.14 million) over five years “to establish an inventory so that Recell can be deployed to help deal with a mass casualty scenario involving burn injuries”.

The company said it had the potential to receive up to $US37 million ($A52.85 million) when contract options were executed providing support for further clinical studies potentially required by the US Food and Drug Administration as part of post-market surveillance, or as needed to expand the use of Recell to the paediatric population.

Avita said that additional contract options provided the US government with surge capacity, supplementing a national stockpile of Recell devices with total procurement under the contract covering more than 25,000 devices.

The company said that BARDA was a US Department of Health and Human Services agency within the Office of the Assistant Secretary for Preparedness and Response wit a core aim to develop medical countermeasures to mitigate the medical consequences from potential chemical, biological, radiation and nuclear threats.

Avita said the single-use device was “simple to use, and allows medical professionals to quickly make a regenerative epithelial suspension which can be immediately applied to a burn” using small skin samples, significantly reducing the need for skin donor sites.

Avita chief executive officer Adam Kelliher said the BARDA agreement was a “transformational opportunity” for the company and “a momentous milestone”.

“US authorities have conducted a detailed evaluation of our technology and this contract further validates the opportunity afforded by our unique regenerative medicine,” Mr Kelliher said. “Further, this deal highlights the importance of preparedness for mass casualties.”

Avita climbed 1.2 cents or 17.1 percent to 8.2 cents with 17.1 million shares traded.

MESOBLAST

Mesoblast says that further data from its 2011 phase II trial of mesenchymal precursor cells for chronic heart failure shows the most at risk patients benefitted the most.

Mesoblast said that the data, presented at the Heart Failure Society of America in National Harbor, Maryland, September 26 to 29, 2015, had implications for its current phase III trial.

The company said that the higher dose of 150 million mesenchymal precursor cells (MPCs) had the greatest cardio-protective effect in the subset of patients with more advanced heart failure (BD: Nov 15, 2011).

Mesoblast said that the post-hoc analysis in 30 patients who had been randomized to receive either placebo or a single administration of 150 million MPCs suggested that “patients with advanced heart failure may be an optimal target” for stem cell treatment.

The company said that left ventricular end systolic volume (LVESV) of more than 100ml was more than three standard deviations above normal and a predictor of poor long-term outcomes in patients with chronic heart failure.

Mesoblast said that in these patients, a single administration of 150 million MPCs resulted in a significant cardio-protective effect and prevention of any heart failure major adverse cardiovascular events (HF-MACE) over 36 months of follow up.

The company said the Teva Pharmaceuticals-funded phase III trial was enriched for patients expected to have adverse outcomes and the majority of patients would have LVESV of more than 100ml and high rates of HF-MACE (BD: Oct 31, 2013).

Mesoblast fell 31 cents or 8.9 percent to $3.16 with 1.15 million shares traded.

BIOTRON

Biotron says a high number of withdrawals from the BIT225 arm of its hepatitis C genotype 3 trial, led to non-significant efficacy results, but the drug is safe.

Biotron said that the phase II Thailand trial had 30 patients in the genotype 3 arm and 30 patients in the genotype 1 arm, with 10 receiving placebo and 20 receiving BIT225 in each arm for 12 weeks, and all in combination with both pegylated interferon alfa-2b and ribavirin.

The company said that genotype 3 arm continued with all patients receiving interferon and ribavirin for 24 weeks, with a 12-week follow-up, while the on-going genotype 1 arm continues with all patients receiving interferon and ribavirin for 48 weeks, with a 12-week follow-up.

The company said that 12 of the 20 patients in the genotype 3 BIT225 arm dropped out of the trial, while none of the placebo group dropped out.

Biotron said that, of the patients who completed the trial, seven of eight (88%) in the BIT225 arm had a sustained virologic response at 12 weeks and nine of the 10 (90%) placebo patients had a sustained virologic response at 12 weeks.

The company said that the historic sustained virologic response at 12 weeks rate for interferon and ribavirin treatment was 68 percent.

Biotron chief executive officer Dr Michelle Miller told Biotech Daily that despite the unusual number of patient drop-outs in the active group meaning that the efficacy data was not significant, the trial had provided further robust safety data.

Dr Miller said that of the 20 active BIT225 patients in the genotype 3 group, three had dropped out for personal reasons, three had adverse events and six had withdrawn due to a stopping rule relating to extended electrocardiogram (ECG) QT intervals, or QTc, that had not been seen before.

Biotron said that the ECG data had been sent to US cardiology experts which “concluded that none of the six patients demonstrated a clear cardiac safety issue”.

“This indicates that the precautionary withdrawal of these individuals was premature and unnecessary,” Biotron said.

“We do not have a QTc issue with this drug,” Dr Miller said.

“We have robust data from these trials and this drug is unremarkable in terms of its toxicity,” Dr Miller said.

Dr Miller said that of the 30 patients in the genotype 3 group, nine of 10 in the placebo group has a sustained virologic response at 12 weeks, while seven of the eight remaining in the BIT225 group had a sustained virologic response at 12 weeks.

Dr Miller said that the genotype 1 group was being treated with pegylated interferon alfa-2b and ribavirin to week 48 and the data from that arm was due by April 2016.

Biotron said that the primary endpoint was safety and tolerability of repeat doses of BIT225 and the secondary endpoint was the pharmaco-kinetic and anti-viral efficacy of BIT225.

Biotron said that it was not aware of issues associated with the withdrawals until the trial was fully recruited, dosing completed and the data was unblinded and made available.

The company said that “unfortunately, once a trial is underway, additional subjects cannot be recruited to replace those lost to the study”.

Biotron said that the absence of serious toxicity at the higher than anticipated blood levels of the drug provided “confidence that BIT225 is acceptably safe and tolerable”.

The company said that the results “support the submission of a comprehensive data package on BIT225” to the US Food and Drug Administration for an investigational new drug application and discussions with potential partners.

Biotron fell as much as 5.7 cents or 54.3 percent to 4.8 cents, before closing down 4.1 cents or 39.05 percent at 6.4 cents with 5.9 million shares traded.

ADMEDUS

Admedus says it will work with the Ear Science Institute Australia to deliver stem cells on its Adapt-treated tissue in both in-vitro and in-vivo models.

Admedus said that the studies with the Perth, Western Australia-based Institute would investigate a range of bone marrow-derived mesenchymal stem cells and adipose-derived stem cells delivered on a variety of its Adapt-treated tissues for their regenerative capacity.

Admedus chief executive officer Lee Rodne said the studies would "further validate the utility of Adapt tissue as a delivery platform for stem cells and other cellular therapies".

"The research using Adapt tissue and stem cells is part of the Admedus strategy to develop a number of regenerative tissue products based on the Adapt tissue engineering technology, which produces tissues that limit calcification and are effectively remodelled, making them ideal for a broader range of surgical products," Mr Rodne said.

Admedus said the studies would explore the levels of regeneration, vascularisation and cell differentiation when Adapt tissue was used with stem cells.

The company said that previous data in heart valves had shown a strong level of autologous regeneration and vascularisation around the Adapt tissue that was facilitated by cells.

Admedus said that when it identified the most suitable stem cell population, it would move into a separate larger scale in-vivo study of tissue regeneration, including functional remodelling of the heart after myocardial infarct and the data from the studies would assist it in developing its Adapt scaffolds "as the ideal stem cell delivery platform to improve repair in a wide range of indications, including heart tissue after myocardial infarct".

Admedus was unchanged at 6.3 cents with 2.3 million shares traded.

RESAPP HEALTH

Resapp says that preliminary results from its paediatric breath sounds diagnostic study shows a greater than 95 percent accuracy for identifying asthma and viral pneumonia.

Resapp said that the 211 patient trial being conducted at the Perth, Western Australia Joondalup Health Campus identified three groups "due to their clinical relevance and the fact that they were present in relatively large numbers", namely a normal group of 39 healthy volunteers with no discernible respiratory illness at the time of measurement, an asthma group of 52 subjects with a diagnostic classification of asthma or viral induced wheeze, with or without upper respiratory tract infection (URTI) as a comorbidity, and a viral pneumonia group of 25 patients with a diagnostic classification of viral pneumonia alone or with comorbidities of URTI and/or viral induced wheeze.

The company said the dataset included 95 patients diagnosed with URTI, croup, bronchiolitis, bacterial pneumonia or other respiratory diseases that were not considered in this preliminary analysis.

Resapp said that for asthma the diagnostic had more than 97 percent sensitivity, 92 percent specificity and greater than 95 percent accuracy for separating the asthma group from the normal group using cough sounds.

The company said that for viral pneumonia diagnosis there was a greater than 91 percent sensitivity, greater than 95 percent specificity and greater than 96 percent accuracy for separating the viral pneumonia group from the normal group using cough sounds.

Resapp said the results were prepared by the University of Queensland's Prof Udantha Abeyratne who said the results "provide an excellent beginning to our studies in the developed world … [and] further reinforce our hypothesis that cough sounds carry characteristic signatures of respiratory illnesses such as asthma and pneumonia."

Resapp was up 0.1 cents or 2.9 percent to 3.6 cents with 75.6 million shares traded.

ANALYTICA

Analytica chief executive officer Geoff Daly has an interesting and useful technology to sell but is finding the going fairly rough, with low sales and share price volatility.

A co-inventor of the Pericoach intra-vaginal, pelvic floor strength diagnostic and monitor system, Mr Daly is enthusiastic about its potential for women with incontinence, particularly after childbirth, while acknowledging that the take-up has been slower than expected.

Mr Daly said that the device had sensors to measure internal pelvic muscle strength and contractility and the data was sent via a smart-phone or wireless-enabled computer and then stored in Analytica's cloud-based database.

Mr Daly said the device "directly measures the muscles that matter and can detect which muscles are being strengthened" and the data could simultaneously be sent to the patient's doctor, physiotherapist and/or incontinence nurse.

Analytica has previously said that it was targeting women to assist in strengthening muscles prior to child-birth, when pelvic floor damage was most likely to occur and that women undertaking fitness regimes including weight lifting also faced potential pelvic floor damage. (BD: Nov 27, 2013).

Mr Daly said the company had taken a battering on the stock market, frequently rising the most, then falling the hardest, among the Biotech Daily Top 40 Index, following the exit of a significant shareholder who needed to convert their shares to cash.

The share sale coincided with a drop in price, but the company has fallen from a high of 4.7 cents in June 2014 to a low of half a cent on September 7, 2015 and appears to have become a plaything of the day-traders.

Mr Daly said the board had discussed the volatility but no decision had been made in how to combat it, other than continuing to deliver on the company's promises.

In Melbourne as part of an extended roadshow, the Brisbane-based Mr Daly said he had met with investors in Perth and was on his way to Sydney, before flying to New York and South East Asia.

He said there was effectively no competition to the Pericoach and although the company had user testimonies, the 100-patient trial had been slow at recruiting with about one third of the subjects randomized and with more centres being added.

Mr Daly said that the Pericoach had Australian Therapeutic Goods Administration, Conformité Européenne (CE) mark and US Food and Drug Administration 510k approvals and a pipeline of improvements for usability and functionality, including the ability to determine whether a woman was exercising properly or not.

He said that a priority would be to expand the indications beginning with the use of the Pericoach to strengthen the pelvic floor to reduce prolapse following childbirth.

Mr Daly said that Pericoach users had also reported benefits for lower back pain, supra-pubic and lower abdomen pain and increased sexual function.

He said that Analytica was discussing potential partnerships, but the conclusion of the 100-patient trial was important for negotiations.

Analytica was unchanged at 0.6 cents.

ALCHEMIA

Allan Gray Australia says it has reduced its holding in Alchemia from 56,755,167 shares (17.48%) to 43,124,804 shares (13.28%).

Allan Gay said that between June 24 and September 25, 2015 it sold 13,630,363 shares for $856,142 or 6.3 cents a share.

Alchemia fell 0.1 cents or 1.3 percent to 7.5 cents with 3.3 million shares traded.

MEDICAL DEVELOPMENTS INTERNATIONAL

Medical Developments chairman David Williams has sold 4,640,000 shares reducing his holding from 23,370,890 shares (40.49%) to 18,731,990 shares (32.45%).

In May, Mr Williams said he sold 7,000,000 shares at $2.40 to mainly institutional investors "to increase liquidity in the company" (BD: May 12, 2015).

Today, Mr Williams said he sold the shares, held through Lawn Views Pty Ltd, Moggs creek Pty Ltd, Pari Passu Pty Ltd, Kidder Peabody Pty Ltd, Ward Williams and Saul Williams, between September 24 and 29, 2015, for $15,273,000 or $3.29 a share.

Medical Developments was unchanged at $3.29.