Biotech Daily

Wednesday July 15, 2015

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: ANTISENSE UP 10%; TISSUE THERAPIES DOWN 15%**

*** MESOBLAST: 'HIGH DOSE MPCs MAY HAVE HEART FAILURE EFFICACY'**

*** BIOTRON SHARE PLAN RAISES $2m, TOTAL $4m**

*** CYNATA RAISING $5m**

*** RESAPP DIAGNOSTICS OPENS ON THE ASX**

*** MEDLAB OPENS ON THE ASX**

*** CLINICAL GENOMICS SIGNS PHILIPPINES, NZ DISTRIBUTORS**

*** MEDIBIO LODGES US PATENT APPLICATION**

*** USCOM REQUESTS CAPITAL RAISING, TRANSACTION TRADING HALT**

*** DORSAVI LOSES CFO JEROME WHELAN**

MARKET REPORT

The Australian stock market climbed 1.05 percent on Wednesday July 15, 2015 with the ASX200 up 58.8 points to 5,636.2 points. Eighteen of the Biotech Daily Top 40 stocks were up, eight fell, 11 traded unchanged and three were untraded.

Antisense was the best, up one cent or 10 percent to 11 cents with 371,377 shares traded.

Living Cell climbed 9.5 percent; Osprey was up 8.6 percent; Compumedics and Prima rose more than seven percent; Anteo was up 5.5 percent; Avita and Biotron were up more than four percent; Impedimed, Neuren, Prana and Psivida were up more than three percent; CSL and IDT rose more than two percent; Acrux, Mesoblast and Nanosonics were up more than one percent; with Benitec and Resmed up by less than one percent.

Yesterday's best, Tissue Therapies, led the falls, retreating one cent or 14.7 percent to 5.8 cents, with 4.7 million shares traded.

Ellex lost 3.2 percent; Atcor fell 2.7 percent; Clinuvel and Optiscan were down more than one percent; with Cochlear, Medical Developments, Sirtex and Viralytics down by less than one percent.

MESOBLAST

Mesoblast says its phase II trial of mesenchymal precursor cells for congestive heart failure shows the cells were feasible and safe and high-doses may provide benefits.

Mesoblast said that the article, entitled 'A Phase II Dose-Escalation Study of Allogeneic Mesenchymal Precursor Cells in Patients With Ischemic or Non-Ischemic Heart Failure' was co-authored by chief executive Prof Silviu Itescu and was published in the American Heart Association journal Circulation Research.

An abstract is available at: http://bit.ly/1dZHFxR.

In 2011, Mesoblast first reported the results saying one of 45 heart failure (HF) patients treated with Revascor mesenchymal precursor cells (MPCs) died, compared with three of the 15 untreated controls (BD: Nov 15, 2011).

Prof Itescu told Biotech Daily at that time that the low dose increased left ventricular ejection fraction, while the higher doses didn't, but more important than the volume of ejected blood, was the incidence of hospitalization or death, along with measures such as the six-minute walk test and the time to major adverse cardiac event.

Prof Itescu said that none of 15 patients in the high dose 150 million Revascor cell group died or was hospitalized at 18 months of follow-up.

The journal article concluded that "trans-endocardial injections of allogeneic MPCs were feasible and safe in chronic [heart failure] patients [and] high-dose allogeneic MPCs may provide benefits in this population".

The article said that major adverse cardiac events (MACE) were seen in 15 patients: 10/45 (22%) treated with MPCs and 5/15 (33%) control patients.

"We found no differences between MPC-treated and control patients in survival probability, MACE-free probability, and all-cause mortality," the article said.

"We conducted a post-hoc analysis of HF-related MACE (HF hospitalization, successfully resuscitated cardiac death, or cardiac death); events were significantly reduced in the 150 million cell group (0/15) versus control (5/15;33%), 25m (3/15;20%), and 75m (6/15;40%); the 150m group differed significantly from all groups … over three years (p = 0.025 for 150m compared to control)," the article said.

Mesoblast said that treatment with MPCs was not associated with any clinically significant immune response

The company said that 150m dose patients showed the greatest improvement in left ventricular re-modelling compared to controls, which was evidenced by significant reductions in left ventricular end systolic volume (p = 0.015) and left ventricular end diastolic volume (p = 0.02) at six months post-treatment relative to controls.

Mesoblast said that 150m dose patients showed the greatest improvement in functional exercise capacity compared to controls (p = 0.062) at 12 months.

Texas Heart Institute stem cell centre director and lead author and investigator Dr Emerson Perin said the results "suggest that a high-dose of Mesoblast's allogeneic cell-based therapy may decrease major clinical events associated with progressive heart failure for at least three years, including repeated hospitalizations or death".

"These effects appear to be due to the ability of these cells to positively impact on adverse cardiac re-modelling associated with chronic heart failure,' Dr Perin said.

"If these results are confirmed in the on-going phase III trial currently recruiting at our institution and elsewhere, this new therapy has the potential to change the paradigm for the management of patients with advanced heart failure and a high risk of hospitalization and death," Dr Perin said.

Mesoblast said that partner Teva Pharmaceutical was enrolling patients in a phase II North American phase III trial of the 150m dose.

Mesoblast was up six cents or 1.5 percent to $3.97 with 1.3 million shares traded.

BIOTRON

Biotron says its share plan at 11.52 cents a share has raised the full $2 million and with its June $2 million placement the company has raised a total of $4 million.
In June, Biotron said that Patersons Securities had received firm commitments for the $2.0 million which later settled on June 23 (BD: Jun 18, 2015).
The company said it was finalizing plans for the further development of BIT225 for HIV including a phase II HIV trial and the funds would support that trial, strengthen the balance sheet and improve its position for negotiating a commercialization transaction.
Biotron was up half a cent or 4.55 percent to 11.5 cents with 955,012 shares traded.

CYNATA THERAPEUTICS

Cynata says it has definitive agreements to raise $5 million through the issue of 6.67 million shares at 75 cents each from US institutional investors.
Cynata said that for every two shares acquired, investors would receive one attaching 13-month option exercisable at 80 cents each and one attaching five-year option exercisable at $1.00 each.
The company said it expected to close the placement about July 20, 2015, subject to
Cynata said that the exercise price would be “subject to future adjustment for various events required under ASX Listing Rules, such as stock splits”.
The company said that HC Wainwright & Co was the exclusive placement agent.
Cynata said that it would use the proceeds to accelerate its Cymerus mesenchymal stem cell program and investigate its use in developing engineered cellular therapies to target cancer and a number of other conditions.
Cynata fell 12 cents or 13.8 percent to 75 cents with 2.1 million shares traded.

RESAPP DIAGNOSTICS (FORMERLY NARHEX LIFE SCIENCES)

Resapp has completed its back-door listing through Narhex Life Sciences, opening on the ASX under the code RAP yesterday at 2.3 cents and closing at 2.2 cents.
The company previously said that its placement at two cents a share was oversubscribed, raising $4,000,000 (BD: Apr 24, May 11, Jun 12, Jul 3, 2015).
Resapp said it would develop mobile telephone applications for the diagnosis and management of respiratory diseases (BD: Oct 2, 2014).
In a media release to the ASX, Resapp said its 150-patient study at Joondalup hospital was fully enrolled and was gathering data from patients with a variety of respiratory conditions to further optimize the Resapp algorithms for pneumonia and asthma as well as broadening the validation to other common respiratory conditions.
The company said it was working with the University of Queensland to analyze the data and expected initial preliminary results by October, 2015.
Resapp was unchanged at 2.2 cents with 9.1 million shares traded.

MEDLAB CLINICAL

Medlab opened on the ASX under the code MDC yesterday at 20.5 cents and closed at 20 cents.
Medlab said it was developing bacteria-based medicines, guided by the view that poor gut health caused certain chronic health problems and its most advanced program was in human trials for depression and obesity (BD: May 12, Jul 13, 2015).
Medlab fell half a cent or 2.5 percent to 19.5 cents.

CLINICAL GENOMICS

Clinical Genomics says it has signed a distributor for its colorectal cancer screening products in the Philippines and re-signed its New Zealand distributor.
Clinical Genomics said the Manila-based Hi Precision would distribute its faecal immunochemical test in the Philippines, marketed as Insure Fit, replacing the older 'guaiac' technology which was being phased out of many colorectal screening programs.
The company's Asia-Pacific vice-president Warren Bingham said the Philippines had "a population of nearly 100 million people and colorectal cancer is their fourth highest cause of cancer-related death".
Clinical Genomics said that it had renewed an exclusive distribution deal with Green Cross Health in New Zealand for its test branded as Bowelscreen Aotearoa.
"These deals represent important milestones as part of the company's expansion in the Asia-Pacific region," Mr Bingham said.
Clinical Genomics is a private company.

MEDIBIO

Medibio says it has lodged a provisional patent application entitled 'Method and System for Assessing Mental State', with the US Patent office.
Medibio said that the patent would extend the use of its circadian heart rate technology for the diagnosis of depression and other mental health disorders and covered discoveries made over the past 18 months.
The company said that it intended to seek patent protection in major jurisdictions including Australia, the US, the UK, EU, Japan, China and Russia and the patent lodgement was "an important step in … protecting its dominant and exclusive position in the use of circadian heart rate technology in the area of mental health diagnosis".
Medibio said that its existing patent covered the use of circadian heart rate for mental health medical diagnosis and would expire in 2018 and the new filing, based on algorithm development for medical diagnostics that would need regulatory approval, would, if granted, provide an additional 20 years of protection.
The company said that the patent application covered the use of circadian heart rate technology for determining the effectiveness of treatment as well as initial diagnosis.
Medibio was unchanged at 34 cents.

USCOM

Uscom has requested a trading halt "pending an announcement in relation to a potential capital raising and transaction".
Trading will resume on July 17, 2015 or on an earlier announcement.
Uscom last traded at 18 cents.

DORSAVI

Dorsavi says that chief financial officer Jerome Whelan has tendered his resignation effective from October 12, 2015.
Dorsavi said it would begin an executive search for a suitable replacement.
Dorsavi was up half a cent or 1.8 percent to 28 cents.