Biotech Daily

Wednesday March 15, 2017

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH EVEN: ATCOR UP 7%, AVITA DOWN 5%**

*** MESOBLAST: 'STEM CELLS AID LOWER BACK PAIN FOR 36-MONTHS'**

*** RHINOMED RAISES $2.2m AT 16% PREMIUM**

*** REVA EXPECTS CE MARK, CASH SOON; SALES BY JULY**

*** PRIMA RECRUITS 2nd COHORT IN IMP321 MELANOMA TRIAL**

*** RHINOMED $280k R&D TAX INCENTIVE; 1-FOR-10 CONSOLIDATION**

*** GENETIC SIGNATURES TO RELEASE 18.7m ESCROW SHARES**

*** MGC REQUESTS CAPITAL RAISING HALT**

*** ADMEDUS EX-CHAIR, NOW CEO, WAYNE PATERSON STARTS ON $787k**

*** BIO-MELBOURNE NETWORK BREAKFASTS ON EUROPE**

MARKET REPORT

The Australian stock market was up 0.26 percent on Wednesday March 15, 2017, with the ASX200 up 14.9 points to 5,774.0 points.

Twelve of the Biotech Daily Top 40 stocks were up, 11 fell, 13 traded unchanged and four were untraded. All three Big Caps fell.

Atcor was the best, up 0.4 cents or 6.7 percent to 6.4 cents with 75,000 shares traded, followed by Benitec up 6.45 percent to 16.5 cents with 141,197 shares traded.

Genetic Signatures climbed 5.4 percent; Cyclopharm and ITL were up more than three percent; Factor Therapeutics and Impedimed rose more than two percent; with Nanosonics, Neuren, Opthea, Pharmaxis and Pro Medicus up more than one percent.

Avita led the falls, down half a cent or 4.8 percent to 10 cents with 484,981 shares traded.

Polynovo and Prima lost three percent or more; Bionomics, Medical Developments, Oncosil and Universal Biosensors shed more than two percent; Airxpanders, Cochlear, Mesoblast, Viralytics and Resmed were down more than one percent; with CSL and Sirtex down by less than one percent.

MESOBLAST

Mesoblast says that a single dose of 6,000,000 mesenchymal precursor cells gave durable pain and function improvements for 41 percent of patients for 36 months.

Last year, Mesoblast said that 24-month results from its 100-patient, four-arm, randomized, placebo-controlled phase II trial of MPC-06-ID for chronic low back pain showed that a single injection of its allogeneic mesenchymal precursor cells into patients with moderate to severe chronic low back pain, due to degenerative disc disease, was well tolerated and provided substantial improvement in pain and function over 24 months compared with control therapies (BD: Aug 1, 2016).

Mesoblast previously said the 100 patients were randomized to receive direct intra-disc injection of saline (n = 20), hyaluronic acid (n = 20), 6,000,000 mesenchymal precursor cells (MPCs) in hyaluronic acid (n = 30) or 18,000,000 MPCs in hyaluronic acid (n = 30).

Last year, the company said that the 6,000,000 cell dose, resulted in the greatest proportion of patients meeting the phase III primary endpoint of overall treatment success, a composite of both pain and functional responder status.

Today, Mesoblast did not provide the number of patients assessed in each group but said the primary endpoint composite over 24 months was achieved by 41 percent of patients who received 6,000,000 MPCs, 35 percent of the 18,000,000 MPC group, 18 percent of the hyaluronic acid group and 13 percent of the saline group, using the pre-specified per protocol population analysis.

The company said that pain responder criteria, of a 50 percent pain reduction with no additional intervention at both 12 and 24 months, was achieved by 52 percent of the 6,000,000 MPC group compared with 13 percent of the saline group ($p < 0.05$).

Mesoblast said that functional responder criteria was achieved by 48 percent of the 6,000,000 MPC group compared with 13 percent of the saline group ($p < 0.05$).

The company said similar results were seen for the primary endpoint composite over 24 months using the intent-to-treat analysis, with 38 percent of the 6,000,000 MPC group patients) achieving the outcome compared with 10 percent of the saline group ($p < 0.05$).

Mesoblast said that 82 percent of the 6,000,000 MPC group who achieved the primary endpoint composite at 24 months maintained treatment success using this composite endpoint at 36 months.

The company said that 86 percent of the 6,000,000 MPC group who met the pain responder criteria, remained pain responders through 36 months, and 92 percent of the 6,000,000 MPC group who met the functional responder criteria, remained functional responders through 36 months.

Mesoblast said there were no significant differences in measurements of safety between cell-treated patients and controls over 36 months.

The company said that the 36-month trial results supported the on-going 360-patient phase III trial of MPC-06-ID for chronic low back pain and “if similar clinical durability is seen in the phase III program, it is anticipated such data will translate into meaningful health economic benefits including increased productivity that may support attractive product reimbursement”.

Mesoblast said it had an agreement with Mallinckrodt Pharmaceuticals to negotiate a commercial and development partnership for MPC-06-ID in the treatment of chronic low back pain due to disc degeneration.

The Los Angeles, California-based Cedars Sinai Spine Center professor of surgery and trial investigator Prof Hyun Bae said that the “sustained benefits on pain and function over three years seen with a single injection of Mesoblast’s cell therapy have the potential to transform the treatment paradigm for chronic low back pain due to disc degeneration”.

Mesoblast fell four cents or 1.9 percent to $2.03 with 706,987 shares traded.

RHINOMED

Rhinomed says it has raised $2,198,430 in a private placement to two US investors at 1.8 cents a share, a 16 percent premium to its 20-day volume-weighted average price.
Rhinomed said 105,135,000 shares would be issued to Sprott Asset Management executive Whitney George, who increased his holding to 17.73 percent of the company, with 17,000,000 shares to be issued to an unnamed investment group, with both placements subject to a cleansing prospectus to facilitate secondary trading of shares.
Rhinomed said that the proceeds would be used to expand its retail distribution footprint and for strategic initiatives.
Rhinomed was up 0.1 cents or 5.9 percent to 1.8 cents with 1.4 million shares traded.

REVA MEDICAL

Reva says it expects to receive funds to cover the period until it receives revenue from European sales of its Fantom stent and raises capital in a Nasdaq initial public offer.
Reva chief executive officer Dr Reggie Groves told a teleconference that the $US6.7 million in cash at December 31, 2016 was expected to last into April with the “terms of financing” being discussed with potential investors.
Dr Groves said that a convertible debt was a possibility.
“I’m not worried about our cash position,” Dr Groves said.
“2017 will be a critical year for Reva, as we head to the CE mark for Fantom,” Dr Groves said.
Dr Groves said that the company expected its bio-resorbable Fantom stent to receive Conformité Européenne (CE) mark approval in the next few weeks with sales expected to begin by July 2017.
Dr Groves said that the company was still considering pricing but said that competitor products sold for about $US1,200 and the Fantom was likely to be priced in the same order of magnitude.
She said that Reva initially expected to take five to 10 percent of the patient population, growing to 15 to 20 percent and had agreements with centres that treated between 1,000 and 3,000 patients a year.
Dr Groves said that the company had met with the US Food and Drug Administration and expected the regulator would allow conditional approval for a trial which could start by December 2017.
She said that an FDA-directed trial was not expected to be completed and the Fantom approved until 2019 or 2020.
Reva was untraded at 97 cents.

PRIMA BIOMED

Prima says the second cohort of six patients has been recruited in its 24-patient trial of two active immune-therapeutics for melanoma, the Tactimel trial.
Prima said that patients with unresectable or metastatic melanoma that had a suboptimal response to Keytruda were dosed with the higher 6mg dose of IMP321 in combination with Keytruda.
The company began the multicentre, open label phase I trial of IMP321 for melanoma at the Greenslopes Private Hospital in Queensland last year (BD: Jan 27, 2016).
Prima said last year that the study would evaluate safety as the primary endpoint and anti-tumor activity and the immune response to the combination as secondary endpoints.
Prima fell 0.1 cents or 3.1 percent to 3.1 cents with 3.4 million shares traded.

RHINOMED

Rhinomed says it has received a $279,859 Federal Government Research and Development Tax Incentive and will conduct a one-for-10 stock consolidation.
Rhinomed said that it received the Federal Government Research and Development Tax Incentive payment of $279,859 for the year to June 30, 2016.
The company said that the payment reflected a $621,911 investment in research and development in its sleep and respiratory technology platform.
Rhinomed said it would hold an extraordinary general meeting to approve a one-for-10 capital management initiative and allow an unmarketable parcel program.
The company said it proposed to consolidate its 936 million issued securities to 93.6 million after completion of the 1.8 cent a share placement (see above).
Rhinomed said that the unmarketable parcel facility would enable it to reduce administrative costs and provide an opportunity for investors with small holdings to dispose of them in a cost effective manner.

GENETIC SIGNATURES

Genetic Signatures says that 15,802,625 shares in voluntary escrow and 2,872,355 shares in mandatory escrow will be released on March 30, 2017.
Genetic Signatures said that the 15,802,625 shares were held by Asia Union Investments.
The company said that 104,286,937 shares were quoted on the ASX.
Genetic Signatures was up two cents or 5.4 percent to 39 cents.

MGC (MEDICAL GRADE CANNABIS) PHARMACEUTICALS

MGC has requested a trading halt “pending a material announcement in relation to a capital raising”.
Trading will resume on March 17, 2017 or on an earlier announcement.
MGC last traded at 8.7 cents.

ADMEDUS

Admedus says that former chairman, now chief executive officer, Wayne Paterson will be paid a base salary of $US595,000 ($A787,156).
Admedus said that Mr Paterson would be entitled to a performance-based short term incentive of 60 percent and long term incentive of 40 percent subject to company objectives.
The company said that Mr Paterson had been acting chief executive officer since May 2016 and had “overseen a major restructure involving a substantial reduction in costs with significant increases in both revenue and profitability”.
Admedus said that “a thorough executive search has been conducted during this time … [but] the board has unanimously determined that it is in the best interests of the company that [Mr] Paterson continues to lead the business”.
Last month, Admedus said that revenue for the six months to December 31, 2016 was up 86.4 percent to $12,241,195, with its net loss after tax down 50.3 percent to $6,397,387 (BD: Feb 24, 2017).
For the year to June 30, 2016 Admedus said revenue was up 39.6 percent to $14,151,000 with net loss after tax down 4.9 percent to $24,014,000.
Admedus was unchanged at 34 cents.

BIO-MELBOURNE NETWORK

The Bio-Melbourne Network says that its March 21, 2017 Bio-Breakfast will explore 'Pathways to Europe: Pitfalls and Strategies for Success'.

The Bio-Melbourne Network said that biotechnology, medical technology, pharmaceutical and digital health companies considering European market entry should attend the Bio-Breakfast, featuring Medical Developments chief executive officer and the 2016 Biotech Daily CEO of the Year John Sharman along with Clinuvel regulatory affairs director Nicoletta Muner, Universal Biosensors business development manager Pierre Nathie and Grey Innovation director Jefferson Harcourt.

Bio-Melbourne Network interim chief executive officer Lusia Guthrie said "the major economies of Western Europe are significant markets for the biotechnology, medical technology, pharmaceutical and digital health products".

"While many companies look to key destinations such as Germany, France and the UK, there is an emerging trend to target smaller markets such as Scandinavia and Switzerland, for initial European market entry," Ms Guthrie said.

The Network said that the panel will share insights from their experience on European market strategies and tactics, regulatory frameworks, business processes, barriers to entry and risk management approaches and would participate in a panel discussion around these issues and on the current commercial opportunities in Europe.

The Bio-Breakfast will be held in the Cube at the Australian Centre for the Moving Image in Melbourne's Federation Square, on March 21, 2017, with registration from 7.15am, for a 7.30am networking breakfast followed by presentations and discussion from 8am until 9am.

To register go to: http://bit.do/europebiobreakfast.