Biotech Daily

Monday February 13, 2017

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: PRANA UP 12%, ADMEDUS DOWN 6%**

*** MESOBLAST MPCS REDUCE RHEUMATOID ARTHRITIS IN SHEEP**

*** CORRECTION: VIRALYTICS**

*** BIOTRON STARTS BIT225 HIV TRIAL; $1.6m R&D TAX INCENTIVE**

*** PRIMA EARNS $860k FRENCH R&D TAX PAYMENT**

*** VIRALYTICS RECEIVES $4.3m FEDERAL R&D TAX INCENTIVE**

*** SIRTEX TELLS INVESTOR TODD HAYWARD: 'SEE YOU IN COURT'**

*** MMJ STARTS CANNABINOID PTL101 FOR PAEDIATRIC EPILEPSY TRIAL**

*** UK APPROVES ONCOSIL PANCREATIC CANCER TRIAL**

*** IMUGENE: REFORMULATED HER-VAXX 'SIGNIFICANT IMPROVEMENT'**

*** USCOM H1 REVENUE UP 29% TO $2m, LOSS UP 1% TO $846k**

*** MACH7 TO 'BREAK-EVEN'; UNMARKETABLE PARCEL FACILITY**

*** FACTOR THERAPEUTICS OFFERS UNMARKETABLE PARCEL FACILITY**

*** CRYSTAL AMBER TAKES HUNTER HALL GI DYNAMICS SHARES TO 39%**

*** MESOBLAST TO RELEASE 1.3m ESCROW SHARES**

*** BIOTECH CAPITAL REQUESTS 'CAPITAL RAISING' TRADING HALT**

MARKET REPORT

The Australian stock market climbed 0.7 percent on Monday February 13, 2017 with the ASX200 up 40.1 points to 5,760.7 points. Five of the Biotech Daily Top 40 stocks were up, 17 fell, 16 traded unchanged and two were untraded.

Prana was the best, up 0.6 cents or 12.0 percent to 5.6 cents with 486,190 shares traded, followed by Reva up 11.1 percent to $1.00 with 50,526 shares traded. Uscom was up 4.35 percent; Mesoblast rose two percent; with CSL and Pro Medicus up less than one percent.

Admedus led the falls, down two cents or 6.15 percent to 30.5 cents with 1.1 million shares traded. Benitec, Clinuvel and Orthocell lost more than five percent; Anteo fell 4.4 percent; Actinogen was down 3.3 percent; IDT, Neuren and Viralytics shed more than two percent; Airxpanders, Bionomics, Opthea and Pharmaxis were down more than one percent; with Cochlear, Ellex, Impedimed, Resmed, Sirtex and Starpharma down by less than one percent.

MESOBLAST

Mesoblast says a single intravenous infusion of 150 million of its allogeneic off-the-shelf STRO-3 mesenchymal precursor cells improved rheumatoid arthritis in sheep.

In 2012, Mesoblast said that a trial of its allogeneic, or off-the-shelf adult mesenchymal precursor cells (MPCs) in 30 sheep showed the cells were effective in treating a rheumatoid arthritis model (BD: July 24, 2012).

Mesoblast said in 2012 that a single intravenous injection of the MPCs in sheep with collagen-induced arthritis concomitantly affected T cells, monocytes, macrophages and synoviocytes to shut down tumor necrosis factor alpha (TNF-alpha) and recombinant proteins interleukin-6 and interleukin-17 cytokine pathways and improve joint pathology.

Today the company said the new 16-sheep study "significantly improved clinical disease severity, reduced joint cartilage erosions, and improved synovial inflammation and histopathology in a large animal model of early rheumatoid arthritis".

Mesoblast said it was "the first study to show that intravenously administered STRO-1-STRO-3 immuno-selected [mesenchymal precursor cells] can ameliorate clinical and histopathologic disease severity in a large animal model of collagen-induced arthritis.

The article, co-authored by Mesoblast chief executive Prof Silviu Itescu, and entitled 'Immunoselected STRO-3+ mesenchymal precursor cells reduce inflammation and improve clinical outcomes in a large animal model of monoarthritis' was published in the journal Stem Cell Research and Therapy, with an abstract available at: https://stemcellres.biomedcentral.com/articles/10.1186/s13287-016-0460-7.

Mesoblast said that University of Melbourne Faculty of Veterinary and Agricultural Sciences researchers compared treatment with a single intravenous infusion of either 150 million allogeneic, STRO-3 immuno-selected and culture-expanded sheep mesenchymal precursor cells, or saline, in 16 sheep with early collagen-induced arthritis.

The company said that within two days, the MPC-treated group showed significantly faster decline of elevated neutrophil numbers in the blood than saline-treated controls, a white blood cell type that played a critical role in the clinical manifestations of rheumatoid arthritis, gout and other inflammatory joint diseases in humans.

Mesoblast said that within four days, and over the two-week study period, the MPC-treated group had a significantly lower composite clinical score of lameness, joint swelling and pain compared with saline-treated controls, with significant improvements seen in each of these clinical parameters.

The company said that markers of inflammation in the blood, interleukin 17 and activin A, were significantly reduced in the MPC-treated group compared with controls over two weeks and at the end of the study, the MPC-treated group showed significantly less joint destruction and joint inflammation compared with saline-treated controls.

Mesoblast said the treated sheep had significantly reduced joint cartilage erosions; significantly reduced levels of activated synovial fibroblasts and fibrosis; significantly reduced infiltration of synovial tissues with monocytes and CD4 T cells; and significantly reduced blood vessel formation within the synovial tissues.

The company said that all the histopathologic components ameliorated by MPC treatment were key features associated with progressive joint disease and destruction in patients with active rheumatoid arthritis.

Mesoblast said the study showed its MPCs could "significantly ameliorate inflammatory arthritis and provides important mechanistic and translational support for the improved clinical outcomes previously reported in the on-going phase II trial with [its] product candidate MPC-300-IV in patients with [rheumatoid arthritis] who are refractory to TNF-alpha inhibitors and other biologic agents.

Mesoblast was up three cents or 2.0 percent to $1.54.

VIRALYTICS

Friday's edition described Merck's Keytruda as a chemotherapy agent, but the company has told Biotech Daily that it is in fact a programmed cell death PD1 antibody checkpoint inhibitor.

We apologise for the confusion. The sub-editor has chosen to assist the White House with the provision of alternative facts and resigned before she could be dismissed.

Viralytics fell three cents or 2.8 percent to $1.03.

BIOTRON

Biotron says it has begun a 36-patient, phase II trial of BIT225 and the combination anti-retroviral therapy Atripla in treatment naïve HIV-1 patients.

Biotron said the Thailand-based, BIT225-009 trial was a multi-centre, randomized, placebo-controlled, double-blind study, with nine patients receiving the Atripla in addition to 12 weeks with 100mg BIT225 or placebo, while a second group of 27 patients would receive 200mg BIT225 once daily, or placebo, together with Atripla and at the conclusion of the trial, patients would remain on Atripla as per standard treatment protocols.

Biotron said the trial had started at the Thai Red Cross AIDS Research Centre in Bangkok, with a second site, pending ethics and regulatory approvals.

The company said that the primary objectives were to determine the efficacy of 12 weeks of BIT225 treatment in HIV-1 infected subjects receiving Atripla by measuring plasma viral load decay and modelling HIV-1 decay as well as determine the safety and tolerability of BIT225 administered once daily for 12 weeks in HIV-1 infected subjects on Atripla.

Biotron said that the secondary objectives were to determine if 12 weeks of BIT225 treatment in addition to Atripla would impact levels of sCD163, a primary biomarker of monocyte immune activation and evaluate the pharmacokinetics of 100mg BIT225 administered once daily for 12 weeks in combination with Atripla.

The company said it aimed to show accelerated reduction of HIV-1 in patients treated with BIT225 in combination with Atripla, indicating that BIT225 could significantly improve current standard of care antiHIV-1 treatment and the reduction in HIV-1-induced immune activation, indicating that BIT225 was targeting viral reservoirs not impacted by Atripla.

Biotron managing-director Dr Michelle Miller said the trial was "an important step towards demonstrating the clinical benefit that BIT225 could bring to the treatment of HIV-1".

"BIT225 has the potential to play a key role in the eradication of HIV-1 by targeting and clearing HIV- 1 from cellular reservoirs," Dr Miller said.

Dr Miller said she expected results by October 2017.

Separately, Biotron said it had received $1,613,724 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Biotron said that the incentive refund resulted from expenditure on its anti-viral drug development program for the year to June 30, 2016.

Biotron was up 0.4 cents or 11.4 percent to 3.9 cents.

PRIMA BIOMED

Prima says its French subsidiary Immutep SAS, has received EUR618,307 ($A860,000) as a tax credit from the French Crédit d'Impôt Recherche scheme.

Prima said that the cash payment was for expenditure on European research and development on its LAG-3 program in 2015, and the tax credit reimbursed companies for up to 30 percent of eligible expenditure.

Prima was unchanged at 3.5 cents.

VIRALYTICS

Viralytics says it has received $4,300,325 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.
Viralytics said the rebate related to research and development expenditure in its financial year to June 30, 2016.
The company said the funds would be used for the “ongoing and future planned [Cavatak] clinical trial program in the US, UK and Australia”.

SIRTEX MEDICAL

Sirtex says it will see aggrieved shareholder Todd Hayward in court where it will “vigorously defend the proceeding” relating to a profit warning and share price fall.
Earlier this month, Sirtex said it received a letter and draft statement of claim, foreshadowing legal proceedings from Portfolio Law’s Anthony Zika on behalf of client Mr Hayward who acquired 340 Sirtex shares for $9,449 on December 1, 2016 and held them at the time that the company share price fell following a profit warning on December 9, 2016 (BD: Feb 1, 2017).
Sirtex said at that time that the statement of claim alleged breaches of its continuous disclosure obligations and alleged misleading and deceptive conduct, arising from a statement on August 24, 2016, regarding “double digit dose sales growth”.
Today, Sirtex said it had “declined” an invitation to enter into settlement discussions with Mr Zita and Mr Hayward and they had begun the legal action in the Federal Court.
Sirtex fell two cents or 0.1 percent to $14.70 with 435,013 shares traded.

MMJ PHYTOTECH

MMJ says it has begun a 15-patient, phase II trial of its marijuana-derived cannabinoid PTL101 capsules for children with epilepsy.
MMJ said that the trial would be held at the Tel Aviv, Israel-based Sourasky Medical Centre, with Prof Uri Kramer as primary investigator.
The company said the open-label, single-centre study would evaluate the safety, tolerability and efficacy of oral administration of PTL101 as an adjunct treatment.
MMJ said that the efficacy endpoints would assess the seizure frequency and global impression of improvement in patient's clinical condition.
The company said that about 100,000 children in North America had refractory epilepsy, a treatment-resistant category of the disease, causing uncontrollable seizures.
MMJ said that drug therapy was ineffective in the treatment of epileptic seizures for about 30 percent of refractory epilepsy patients in North America, with a number of epilepsy drugs having significant side effects including the impairment of a patient’s motor skills and cognitive abilities.
MMJ managing-director Andreas Gedeon said the start of the phase II trial was “a key step towards the potential commercial development of the capsules for treating refractory epilepsy in children”.
“Importantly, the phase II clinical trial has the potential serve as a significant value catalyst for MMJ’s shareholders, in addition to the Harvest One transaction which has been strongly supported to date,” Mr Gedeon said.
MMJ was unchanged at 29 cents with 1.2 million shares traded.

ONCOSIL MEDICAL

Oncosil says the UK Medicines and Health Care Products Regulatory Agency has approved its pancreatic cancer clinical trial.
Oncosil chief executive officer Daniel Kenny said the approval was “a further endorsement of our clinical data package”.
In August, Oncosil said the US Food and Drug Administration had approved the investigational device exemption application for the multi-centre, randomized, open-label ‘Oncopac-1’ safety and efficacy trial for patients with locally advanced, unresectable pancreatic adeno-carcinoma (BD: Aug 2, 2016).
Oncosil was unchanged at 9.3 cents.

IMUGENE

Imugene says its reformulated HER-Vaxx as drug candidate IMU-131 is a significant improvement on the originally acquired Her-Vaxx.
Imugene said that IMU-131 was “a next generation HER-2 cancer therapy” using B cell peptides harnessing the body’s ability to develop antibodies against the disease and the immunological characterisation of the IMU-131 formulation demonstrated superior activity to the previously tested HER-Vaxx.
The research article, entitled, ‘Enhanced and long term humoral and cellular immunogenicity of a Her-2/neu hybrid-CRM197 peptide vaccine, using the Th1-driving adjuvant Montanide’ was published in BMC Cancer and is available at: https://bmccancer.biomedcentral.com/articles/10.1186/s12885-017-3098-7.
The article was co-written by Imugene chief scientific officer Prof Ursula Wiedermann, scientific adviser Prof Christophe Zielinski and chief technology officer Dr Nicholas Ede and included in-vitro and mouse studies conducted at the Medical University of Vienna.
“The formulation P467-CRM-Montanide which makes up the IMU-131 vaccine is a meaningful step forward in the quality of the multi-B cell peptide vaccine against Her-2/neu, including the potent CRM carrier and strong adjuvant Montanide, inducing both higher antibody levels and Th1-biased cellular responses,” Prof Wiedermann said.
“The current formulation of HER-Vaxx therefore is superior over the previous HER-2 peptide vaccine used in phase I clinical trials, which included single B cell peptides conjugated to virosomes,” Prof Wiedermann said.
Imugene said that the research showed strong growth inhibitory activity of HER-Vaxx antibodies alone, and in combination with trastuzumab, or Herceptin, at a constant dose, against a human HER-2+ cancer cell line.
The company said that the anti-HER-2 antibodies produced by HER-Vaxx possessed anti-tumor growth inhibitory properties higher than by Herceptin alone.
Imugene said an in-vitro study showed that HER-Vaxx antibodies combined with Herceptin significantly increased the inhibition of growth than Herceptin alone.
Imugene was up 0.2 cents or 11.8 percent to 1.9 cents with 3.9 million shares traded.

USCOM

Uscom says that revenue for the six months to December 31, 2016, was up 28.7 percent to $1,900,533 with net loss after tax up 1.1 percent to $846,175.
Uscom said that diluted loss per share fell 11.1 percent from 0.9 cents at December 31, 2015, to 0.8 cents at December 31, 2016, with cash and cash equivalents of $1,880,517 at December 31, 2016 compared to $2,839,773 at June 30, 2016.
Uscom was up one cent or 4.35 percent to 24 cents.

MACH7 TECHNOLOGIES

Mach 7 says it expects to “break-even” for the year to June 30, 2017 and has established an unmarketable parcel facility at 30 cents a share.
Mach7 said it was “on track to produce a break-even or better earnings before interest, tax and depreciation result for the financial year … [and] expects to maintain revenue growth levels and achieve profitability”.
The company said it the unmarketable parcel facility was available to shareholders with less than $500 in shares on February 8, 2017.
Mach7 was up 4.5 cents or 15.5 percent to 33.5 cents.

FACTOR THERAPEUTICS

Factor Therapeutics says it has established an unmarketable parcel sale facility to acquire parcels of shares worth less than $500 each.
Factor Therapeutics said that the facility would be open to shareholders at the record date of February 10, 2017 and based on the ASX closing price of 6.2 cents a share an unmarketable parcel was any shareholding of 8,064 shares or fewer, comprising a total of 987 unmarketable parcels comprising 2,802,174 shares.
Factor Therapeutics was unchanged at 6.2 cents.

GI DYNAMICS

The Crystal Amber Fund says it has increased its substantial shareholding in GI Dynamics from 123,525,992 shares (22.65%) to 216,047,954 shares (38.73%).
The London and St Peter Port, Guernsey Island-based Crystal Amber Fund said it acquired 92,521,963 shares for $2,313,049 or 2.5 cents each on February 8, 2017.
Last week, Hunter Hall Investment Management reduced its holding in GI Dynamics from 100,657,157 shares (18.46%) to 6,200,000 shares (1.11%), saying it sold 92,521,962 shares on February 8 at 2.5 cents a share (BD: Feb 10, 2017).
GI Dynamics was up 0.6 cents or 23.1 percent to 3.2 cents with one million shares traded.

MESOBLAST

Mesoblast says that 1,277,210 shares held in voluntary escrow will be released on February 24, 2017.
Mesoblast chief financial officer Charlie Harrison told Biotech Daily that following the release of the shares, the company would have 381,654,048 shares available for trading, with no further shares in either ASX or voluntary escrow, at this time.

BIOTECH CAPITAL

Biotech Capital has requested a trading halt “pending an announcement to the market concerning a capital raise”.
Trading will resume on February 15, 2017 or on an earlier announcement.
Biotech Capital last traded at 12 cents.