Biotech Daily

Friday December 23, 2016

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH EVEN: DIMERIX UP 14%, FACTOR THERA DOWN 6%**

*** MALLINCKRODT BUYS $30m STAKE IN MESOBLAST FOR 2 LICENCES**

*** PRANA XMAS PRESENT: 'MORE PBT2 WORK FOR HUNTINGTON'**

*** BENITEC SIGNS NANTWORKS HEAD, NECK CANCER SUB-LICENCE**

*** PERPETUAL REDUCES TO 8% OF SIRTEX**

*** ITL CHAIRMAN BILL MOBBS REDUCES TO 37% TO 'SHARE THE VALUE'**

MARKET REPORT

The Australian stock market fell 0.3 percent on Friday December 23, 2016 with the ASX200 down 16.0 points to 5,627.9 points.

Fifteen of the Biotech Daily Top 40 stocks were up, 15 fell, six traded unchanged and four were untraded. All three Big Caps fell.

Dimerix was the best, up 0.1 cents or 14.3 percent to 0.8 cents with 125,006 shares traded, followed by Benitec up 13.6 percent to 12.5 cents with 990,332 shares traded.

Prima climbed 5.6 percent; Admedus, Compumedics and Ellex improved more than four percent; Acrux and Impedimed were up more than three percent; Genetic Signatures, IDT and Mesoblast rose more than two percent; Atcor, Bionomics and Osprey were up more than one percent; with Pro Medicus up 0.2 percent.

Factor Therapeutics led the falls, down 0.4 cents or 5.9 percent to 6.4 cents with 900,647 shares traded.

Living Cell and Polynovo fell more than three percent; Oncosil lost 2.4 percent; Actinogen, Airxpanders, Cochlear, Medical Developments, Orthocell, Pharmaxis and Viralytics were down more than one percent; with Clinuvel, CSL, Nanosonics, Opthea, Resmed, Sirtex and Starpharma down by less than one percent.

MESOBLAST

Mesoblast says that London's Mallinckrodt Pharmaceuticals will buy $30 million in new shares and licence its stem cells for low back pain and graft versus host disease.

Mesoblast said that Mallinckrodt would have nine months to "exclusively negotiate a commercial and development partnership" for MPC-06-ID for the treatment or prevention of moderate and severe chronic low back pain due to disc degeneration and MSC-100-IV for acute graft versus host disease in all territories outside Japan and China.

Mesoblast chief executive Prof Silviu Itescu told Biotech Daily that the licence deal would include up-front fees, milestone payments and royalties and was expected to be concluded "in a short period of time".

Prof Itescu said that the two companies would partner and share costs for the current clinical trials of the graft versus host disease product for adults and for the lower back pain product, but did not state the amount or percentage Mallinckrodt would contribute.

Prof Itescu said the deal would allow the development of the two technologies while reducing his company's cash burn.

According to its website, the $US5,508 million ($A7,632 million) Mallinckrodt was founded in St Louis, Missouri, has corporate headquarters in Staines near London and is domiciled in Dublin, Ireland.

Mesoblast said that Mallinckrodt would pay about $29.58 million for about 20.04 million or 4.99 percent of its shares at $1.4761 a share for the exclusive negotiation period.

The company said that Mallinckrodt was a "specialty pharmaceutical company with a major focus within the hospital acute and critical care settings, including pain management, autoimmune and rare diseases and specialty generic pharmaceuticals", with branded products generating "multi-billion dollar revenues" including repository corticotrophin injection HP Acthar Gel, the Therakos immunotherapy platform, the acetaminophen injection Ofirmev, and Inomax nitric oxide gas, for inhalation.

Mesoblast said Mallinckrodt recently entered regenerative medicine buying an investigational human keratinocyte-based platform for its pipeline of hospital products with an off-the-shelf skin substitute "beginning phase III testing for partial thickness burns".

In a media release Prof Itescu said that Mallinckrodt had "a track record of success in commercializing medicines for immune-mediated diseases and pain management and we believe that its major footprint in hospitals addressing acute care needs can be leveraged to realize the full commercial and clinical value of our innovative cellular medicines".

Mallinckrodt chief scientific officer Dr Steven Romano said that the agreement "provides Mallinckrodt with a potential opportunity to extend our regenerative medicine pipeline in areas of high unmet patient need".

"We see Mesoblast as a leader in developing innovative cell-based medicines and look forward to establishing a fruitful partnership," Dr Romano said.

Mesoblast said that MPC-06-ID was being evaluated in a 360-patient phase III trial as a treatment for moderate and severe chronic low back pain due to disc degeneration in patients who failed other non-surgical options, including steroid injections and opioids.

The company said that MSC-100-IV was being evaluated in a 60-patient, open-label phase III trial for children with steroid-refractory acute graft versus host disease.

Mesoblast said that the graft versus host disease trial was "recently successful in a pre-specified interim futility analysis" with full results expected during 2017.

The company said that based on guidance from the US Food and Drug Administration it believed that positive data from the phase III trial might be sufficient for filing for accelerated approval of MSC-100-IV and it planned to broaden the use of its therapy to adult patients with high-risk steroid-refractory acute graft versus host disease.

Mesoblast was up 3.5 cents or 2.5 percent to $1.44 with 993,694 shares traded.

PRANA BIOTECHNOLOGY

After the ASX closed for Christmas, Prana said that European regulators wanted more pre-clinical work before allowing a phase III trial of PBT2 for Huntington's disease.
Prana said it met with the UK Medical and Healthcare Regulatory Agency in London and Sweden's Medical Products Agency in Stockholm to clarify the next steps required for a phase III trial in Huntington disease.
The company said that both agencies "were encouraging of [its] development program for PBT2 but recommended further non-clinical work be undertaken and completed to establish the reversibility of the neurotoxicity effects seen in a dog study before further consideration of the phase III trial".
Prana said it was determining the best commercialization pathway for PBT2 including a collaboration to undertake the further non-clinical work to start a phase III Huntington disease trial, the use of PBT2 at lower doses, as permitted by the US Food and Drug Administration, or using PBT2 for acute indications requiring shorter term use, all with the aim of realizing shareholder value.
Last year, Prana said the FDA issued a partial clinical hold limiting the dose of PBT2 that could be given to patients with Huntington disease (BD: Feb 13, 2015).
Prana said at that time that the partial clinical hold was based on pre-clinical, animal, findings following the company's end of phase II trial discussions trial and subsequent correspondence and it was able to continue trials but at a dose that it did not consider to be clinically relevant.
Prana said that the FDA had provided options to remove the partial clinical hold and to move to clinical trials of PBT2 at a clinically relevant dose and, it would conduct additional animal neurotoxicity studies or identify a strategy for safely using a clinically relevant dosage in humans in the planned phase III trial in Huntington's disease.
Prana was untraded at 4.75 cents.

BENITEC BIOPHARMA

Benitec says it has executed its sub-licencing agreement with Nantworks to develop an antisense technology for head and neck squamous cell carcinoma (BD: Nov 23, 2016).
Benitec said that the technology used a gene-silencing approach targetting the epidermal growth factor receptor (EGFR).
Benitec said it expected to finalize the terms of its collaboration with Nantworks on January 27, 2017.
Benitec was up 1.5 cents or 13.6 percent to 12.5 cents.

SIRTEX MEDICAL

Perpetual and its subsidiaries have reduced their substantial shareholding in Sirtex from 5,314,335 shares (9.21%) to 4,700,509 (8.15%).
Perpetual said that it traded shares from November 11 to December 20, 2016 at prices ranging from $27.92 to $13.85, with many of the trades about $14.90.
The company failed to identify which trades were purchases and sales as required un the Corporations Act.
In November, prior to Sirtex downgrading dose sales and chief executive officer Gilman Wong stepping aside for an investigation of his share sales, Perpetual acquired 581,373 shares at prices ranging from $26.95 to $33.77 (BD: Nov 15, 2016).
Sirtex fell five cents or 0.35 percent to $14.23 with 460,561 shares traded.

ITL

ITL founder and executive chairman Bill Mobbs says he has reduced his substantial shareholding from 39,734,286 shares (41.79%) to 35,118,802 shares (36.61%).

Mr Mobbs said he sold 4,615,384 shares for $1,200,000 or 26 cents a share.

Mr Mobbs said that the shares were sold to non-executive director Mark Peatey and an unnamed “specialist small cap fund manager … [who had] been trying to take a position in ITL for many months”.

“After failing to find a sizable parcel from other investors, I decided it would be good for ITL to have both these entities on the register, with the opportunity for them to work with ITL to grow the value of the company,” Mr Mobbs said.

ITL climbed four cents or 13.8 percent to 33 cents.