Biotech Daily

Thursday April 7, 2016

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: ORTHOCELL UP 8%; PRANA DOWN 6%**

*** NEUREN STARTS 2nd PHASE II TROFINETIDE RETT SYNDROME TRIAL**

*** ELLEX RAISES $5m**

*** CYNATA: 'CYP-001 STEM CELLS PROLONG GVHD SURVIVAL IN MICE'**

*** US ALLOWS 3rd LBT APAS PATENT**

*** M&G REDUCES TO 12% OF GI DYNAMICS, TAKES $2.5m-$5m LOSS**

*** AUCKLAND'S MILFORD DILUTED BELOW 5% OF LIVING CELL**

*** SABBY REDUCES TO 5% OF BENITEC**

MARKET REPORT

The Australian stock market climbed 0.37 percent on Thursday April 7, 2016 with the ASX200 up 18.2 points to 4,964.1 points.

Nineteen of the Biotech Daily Top 40 Index companies were up, 10 fell, nine traded unchanged and two were untraded. All three Big Caps were up.

Orthocell was the best, up three cents or 7.7 percent to 42 cents with 236,599 shares traded.

Ellex and Uscom climbed more than five percent; Benitec, Biotron, Genetic Technologies, Impedimed and Sirtex were up more than four percent; Anteo, Compumedics and Universal Biosensors were up more than three percent; Actinogen, Admedus, Antisense, Medical Developments and Psivida rose more than two percent; Acrux, Bionomics, Cochlear, CSL and Resmed were up more than one percent with Nanosonics up 0.95 percent.

Prana led the falls, down 0.4 cents or 5.8 percent to 6.5 cents with 122,281 shares traded.

Avita fell four percent; Clinuvel and IDT lost more than three percent; Prima and Tissue Therapies shed more than two percent; Living Cell and Viralytics were down more than one percent; with Mesoblast and Pro Medicus down by less than one percent.

NEUREN PHARMACEUTICALS

Neuren says it has begun its 64 patient, phase II clinical trial of trofinetide (NNZ-2566) in children and adolescents with Rett syndrome.

Neuren said the program was receiving support from www.rettsyndrome.org, including grant funding towards the cost of this paediatric trial, which it expected to complete by the end of 2016.

The company said that the randomized, double-blind, placebo-controlled, dose-ranging study in subjects aged five to 15 years was being conducted at up to 12 sites across the US, led by clinicians experienced in Rett syndrome including those who led the first trial in adolescents and adults.

In 2014, Neuren said its phase II trial of NNZ-2566 for Rett syndrome in 53 subjects aged 16 to 45 years “exceeded ... expectations” and would lead to applications for orphan drug and breakthrough therapy designation (BD: Nov 12, 2014).

Neuren said published detailed results in 2014 showing that the two trial doses of 35mg/kg and 70mg/kg twice daily were safe and well-tolerated, with no drug related serious adverse events and that the higher dose met several of the efficacy secondary endpoints.

Neuren said it had orphan drug designation in the US and Europe for trofinetide in Rett syndrome, but failed to win US Food and Drug Administration ‘breakthrough designation’ with the regulator citing “insufficient evidence to demonstrate substantial improvement over existing therapies using conventional statistical methods” (BD: Mar 2, 2015).

Today, Neuren said it would evaluate the safety, efficacy and pharmacokinetics of three dose levels of trofinetide, 50mg/kg, 100mg/kg and 200mg/kg each taken orally twice daily, with a 10-week follow-up.

The company said that efficacy outcome measures included the motor behavior assessment, a measure that captured clinical symptoms of Rett syndrome.

Neuren said that the previous phase II trial “demonstrated clinical benefit from treatment with trofinetide in subjects aged 16 to 45 years at a dose level of 70mg/kg twice daily”.

Neuren said the trial would evaluate the safety and efficacy of trofinetide in a younger age group, at higher doses and for a longer duration of treatment, as well as confirming the optimum dose levels for the subsequent phase III trial in children, adults and adolescents.

Neuren executive chairman Dr Richard Treagus said the company was “excited as we take this next step in the development of trofinetide as a potential treatment for Rett syndrome”.

Neuren was unchanged at 11 cents.

ELLEX MEDICAL LASERS

Ellex says it has raised $5,005,000 in a placement at 77 cents a share to Australian and New Zealand institutional investors.

Ellex said that the funds would be applied to support business growth including working capital to support expected sales of its lasers, ultrasound and Itrack products.

The company said that the funds would also be applied to its manufacturing facility at Mawson Lakes, South Australia to provide expanded production capability, along with investment in sales, marketing, regulatory and legal for Itrack expansion in Asia, as well as product development.

Ellex chief executive officer Tom Spurling said that the company was “a significant participant in the global ophthalmic industry and … [was] reviewing product and regional opportunities for growth”.

Ellex said that the placement was jointly managed by Taylor Collison and Petra Capital.

Ellex climbed 4.5 cents or 5.8 percent to 81.5 cents.

CYNATA THERAPEUTICS

Cynata says it has “extremely positive interim data” from a proof-of-concept study of its mesenchymal stem cell product CYP-001 for graft versus host disease in mice.
Cynata said that a humanized mouse model of severe acute graft versus host disease was induced by infusing human peripheral blood mononuclear cells into mice and the interim data showed that CYP-001 “substantially prolonged survival in this model”.
The company said that the animals in the control group had a median survival time of 25.5 days, compared to more than 54 days in the CYP-001-treated groups ($p = 0.0011$).
Cynata said that all control animals succumbed to the disease between 24 and 31 days after induction, compared to CYP-001-treated animals surviving 31- 68 days with three animals still alive at the date of the interim review and further analysis would be performed when the last three animals completed the study.
The company said that mice were randomly assigned to control or treatment groups and received either one or two doses of CYP-001, while control animals received saline.
Cynata product development head Dr Kilian Kelly said the initial results were “consistent with the substantial body of evidence we have generated from in-vitro laboratory testing”.
Dr Kelly said the data showed that the Cymerus stem cells had a “pronounced immune-modulatory effects” and was consistent with the critical limb ischemia mouse study, which “augurs well for our initial planned clinical trial in patients with graft versus host disease”.
Cynata said than an additional study was underway, in which graft versus host disease was induced using a lower dose of human peripheral blood mononuclear cells, so that the symptoms were less severe and progressed less rapidly and the study would investigate alternative CYP-001 dose levels and additional outcome measures.
Cynata said that the majority of animals in the study were yet to reach the study endpoint, so the extent of the treatment was not yet known, but results were expected soon.
Cynata was up one cent or 2.6 percent to 40 cents.

LBT INNOVATIONS

LBT says that the US Patent & Trademark Office has allowed a patent protecting the image capture technology of its automated plate assessment system (APAS).
LBT said the application, entitled ‘Image capture and lighting apparatus’ would provide protection until March 2, 2032 and was the third US approved for APAS which assessed “microbiology samples for the presence of disease-causing bacteria, with significant implications for laboratory efficiency”.
The company said that the core APAS technology was subject of an US Food and Drug Administration 510(k) de novo submission for approval as a class II medical device.
LBT said the patent application covered the image capture and lighting apparatus of the technology and followed an allowance issued last year for the key systems and analytical software, as well as a 2015 issued patent for a method used to color calibrate images, and the three patents and notices were part of a portfolio of four APAS inventions.
LBT said the first instrument, the APAS Independence, would be launched at the European Congress of Clinical Microbiology and Infectious Diseases in Amsterdam on April 9, 2016, by LBT and Hettich AG joint venture Clever Culture Systems AG.
The company said that the launch would be accompanied by a poster on the validation of APAS as an effective device for screening urine specimens, to be presented by the Albuquerque, New Mexico-based Tricore Reference Laboratories infectious diseases scientific director Prof Stephen Young.
LBT said that a large-scale APAS clinical trial was conducted at Tricore last year.
LBT was up one cent or eight percent to 13.5 cents.

GI DYNAMICS

M&G Investment Funds says it has reduced its holding in GI Dynamics from 63,190,038 Chess depository instruments (13.34%) to 58,243,737 CDIs (12.24%).
In 2014, the London-based M&G group said it acquired 2,000,000 shares in a placement at 52 cents as well as 7,411,464 shares for an average of 54.2 cents a share between August 8 2013 and April 8, 2014 (BD: May 2, 12, 2014).
Today, M&G said that between March 17 and April 5, 2016 the company sold 4,946,301 CDI s for $106,067 or an average of 2.1 cents a share.
In 2011, GI Dynamics raised $80 million of a hoped-for $95 million in an initial public offer at $1.10 per CDI, implying that M&G lost between $2.5 million and $5.4 million in the recent sale (BD: Aug 30, 2011).
GI Dynamics was unchanged at two cents.

LIVING CELL TECHNOLOGIES

The Auckland New Zealand-based Milford Asset Management says it has been diluted below the five percent substantial shareholder level.
In February, Milford said it became a substantial shareholder Living Cell with 24,313,934 shares or 5.08 percent, buying 12,577,578 shares on February 17, 2016 at 5.47 cents a share (BD: Feb 19, 2016).
On Monday, Living Cell said its share plan raised $482,607 through the issue of 9,532,034 shares at 5.063 cents a share and in February, the company said it raised $2,764,621 through a placement at the same price (BD: Feb 17, Apr 4, 2016).
Living Cell fell 0.1 cents or 1.8 percent to 5.4 cents.

BENITEC BIOPHARMA

Sabby Management and associated parties say they have decreased their holdings from 12,697,331 shares (8.70%) to 7,351,471 shares (5.02%).
Sabby said that on March 10, 2016 it sold 5,345,860 shares for $682,752 or 12.8 cents a share.
Benitec was up half a cent or 4.35 percent to 12 cents.