Biotech Daily

Thursday October 30, 2014

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH EVEN: PHARMAXIS UP 21%, ONCOSIL DOWN 5%**

*** J&J OPENS ASIA PACIFIC INNOVATION CENTRES FOR COLLABORATION**

*** PHARMAXIS STARTS 3rd PHASE III BRONCHITOL CYSTIC FIBROSIS TRIAL**

*** GERMAN EYE ADVOCACY GROUP BACKS ELLEX CANALOPLASTY**

*** ANALYTICA READY FOR 100-PATIENT PERICOACH INCONTINENCE TRIAL**

*** MESOBLAST TO RELEASE 70k ESCROW SHARES**

*** VIRAX 40m M-D OPTIONS, PRESCIENT NAME CHANGE AGM**

*** ISONEA AGM FOR 11m DIRECTOR OPTIONS**

*** BIOXYNE AGM FOR 2.6m DIRECTOR OPTIONS**

*** IDT TAKES ACQUISITION, CAPITAL RAISING HALT TO SUSPENSION**

*** ADVANCED SURGICAL REQUESTS 'SIGNIFICANT FUNDING' TRADING HALT**

*** JULIE PHILLIPS ELECTED AUSBIOTECH CHAIR, NEW DIRECTORS**

*** RESONANCE CSO PROF TIMOTHY ST PIERRE RESIGNS AS DIRECTOR**

MARKET REPORT

The Australian stock market rose 0.52 percent on Thursday October 30, 2014 with the ASX 200 up 28.5 points to 5,476.2 points. Twelve of the Biotech Daily Top 40 stocks were up, 13 fell, 13 traded unchanged and two were untraded.

Pharmaxis was the best, up 0.9 cents or 21.4 percent to 5.1 cents, with 984,761 shares traded. Uscom climbed 9.1 percent; GI Dynamics was up 7.7 percent; Universal Biosensors rose 6.25 percent; Tissue Therapies was up five percent; Patrys climbed 4.55 percent; Analytica, Medical Developments and Osprey were up more than three percent; with Avita, Clinuvel, CSL and Psivida up more than one percent.

Oncosil led the falls, down 0.5 cents or 4.55 percent to 10.5 cents with 1.8 million shares traded. Compumedics lost 4.35 percent; Admedus, Anteo, Living Cell and Viralytics fell three percent or more; Alchemia shed two percent; with Acrux, Atcor, Nanosonics, Neuren and Starpharma down more than one percent.

JOHNSON & JOHNSON INNOVATION

Johnson & Johnson Innovation says it has opened its Shanghai China-based Asia Pacific Innovation Center with satellite office in Singapore, Australia and Japan.

Johnson & Johnson said that the Asia Pacific Innovation Center extended the network of innovation centers "in life sciences hotspots around the globe".

A media release from Johnson & Johnson said that "with local science and technology experts and deal-making capabilities, the Center will identify and develop promising early-stage opportunities across the company's three areas of focus, pharmaceuticals, medical devices and diagnostics and consumer healthcare products.

Johnson & Johnson chief scientific officer Dr Paul Stoffels said the Asia-Pacific Center built on the London, California and Boston centres "to collaborate with the best minds in the region to advance new technologies and deliver transformative solutions for the people of China and Asia Pacific at large, and throughout the world".

Johnson & Johnson said the Centers had more than 80 collaborations, including six in Australia and China, announced yesterday at the opening of Ausbiotech conference.

Johnson & Johnson Innovation Asia Pacific Innovation Center head Dong Wu said there was "an explosion of growth in the Asia Pacific region, and China in particular, as well as significant medical needs".

"The Asia Pacific Innovation Center plans to build on the company's track record of collaboration in the region and advance the most promising science ... [and] play a key role in sourcing early stage science in the region for the development of new medicines, medical devices, and consumer products," Mr Wu said.

Johnson & Johnson said it was working with stakeholders in China including the Government, industry and academic partners to accelerate innovation and that through the Center, entrepreneurs and scientists had one-stop access to support for promising early-stage ideas and technologies including funding and commercial expertise.

The media release said that subsidiary Janssen-Cilag (Janssen Australia) and Johnson & Johnson Innovation had a collaboration with Queensland's James Cook University to explore whether proteins produced by hookworms could provide effective treatment for inflammatory bowel disease, by harnessing the ability of hookworms to regulate the human immune response, which enabled their survival in a human host, for the benefit of people living with Crohn's disease and ulcerative colitis.

The company said that with Janssen Australia it had extended a collaboration with the University of Queensland on a spider venom project to identify peptides as potential pain treatments.

Johnson & Johnson said it had a broad collaboration with China Pharmaceutical University on projects including a collaboration around a novel antibody-drug conjugate to treat solid tumors as well as collaborations to explore "functional foods" for improved health, the development of topical products for fast-relief of itch and pain and long-acting pain relief and a long-lasting and fast-acting nasal decongestant.

The company said it had a collaboration with Peking University to identify agonists and antagonists for G protein-coupled receptors to help develop new central nervous system medicines and a collaboration with Zhejiang University on the physiological and pathological role of human lactate receptor GPR81 in the regulation of metabolism and metabolic syndrome such as dyslipidemia, obesity, and diabetes.

Johnson & Johnson said that the Asia Pacific Innovation Centre would establish a presence in Suzhou Biobay, an incubator with more than 400 companies working in drug discovery, biotechnology, in-vitro diagnostics, medical devices and nanotechnology, as an extension of the Center to work with academics and entrepreneurs more locally.

For more information on Johnson & Johnson Innovation, go to: www.jnjinnovation.com.

PHARMAXIS

Pharmaxis says it has enrolled the first of up to 440 patients in its phase III US registration-directed trial of Bronchitol (mannitol) for adults with cystic fibrosis.

Pharmaxis said that the CF303 trial was being conducted in accordance with the requirements of the US Food and Drug Administration to gain approval for Bronchitol for cystic fibrosis and the study protocol closely followed the design of the two large scale clinical trials already completed CF 301 and CF 302.

The company said that the 26-week, randomized, double-blind parallel group investigation would administer Bronchitol twice daily and assess improvements in lung function, pulmonary exacerbations and safety.

Pharmaxis said that trial management had been outsourced to the Raleigh, North Carolina-based INC Research contract research organization which had experience running trials in the cystic fibrosis community.

The company said that more than 100 sites in 19 countries would participate in the study and recruitment was expected to take 12 months to complete.

Pharmaxis chief executive officer Gary Phillips said the phase III trial in adults had been "carefully designed with the benefit of our two previous [cystic fibrosis] CF trials where a post-hoc analysis of the subgroups of adult patients showed a significant improvement in [forced expiratory volume over one second]".

"The design of the trial also incorporates the very clear guidance provided by the FDA concerning what is required in order to gain approval for Bronchitol in the US," Mr Phillips said.

Pharmaxis said that Bronchitol was a precision spray-dried form of mannitol, delivered to the lungs by a portable inhaler.

The company said that the product was approved for patients aged over six years in Australia and for patients aged 18 years and over throughout the European Union and in Israel.

Last year, the FDA refused marketing approval for Bronchitol for cystic fibrosis, recommending an additional clinical trial (BD: Mar 19, 2013),

Pharmaxis reported the FDA complete response letter saying: "The submitted data do not provide a favorable benefit-risk balance to support the use of inhaled mannitol in patients with cystic fibrosis six years of age and older".

"The determination of efficacy based on the two clinical trials are not adequate because of the treatment-related frequent early dropouts in trial 301 for which the primary statistical analyses did not account and the lack of statistical significance in trial 302 for the primary endpoint," the FDA letter said, adding that in terms of safety, the FDA was concerned with haemoptysis, or coughing blood from the respiratory tract, particularly in children.

In January 2013, the FDA's Pulmonary-Allergy Drugs Advisory Committee voted by 11 votes to three, against whether Bronchitol was safe and demonstrated efficacy, criticized the phase III trial data and unanimously opposed marketing approval for patients aged six years and over (BD: Jan 31, 2013).

In 2011, the European Medicines Agency's Committee for Medicinal Products for Human Use overturned its previous refusal of Bronchitol for cystic fibrosis, but requiring a further trial to allow the drug for patients aged six to 18 years (BD: May 25, Jun 27, Oct 24, 2011).

In 2010, Pharmaxis second phase III trial of Bronchitol for cystic fibrosis narrowly missed its primary endpoint comparing the FEV1 improvement of Bronchitol to control over the 26 weeks ($p = 0.059$) despite showing an average 8.2 percent lung function improvement over 26 weeks (BD: Jun 22, 2010).

Pharmaxis climbed 0.9 cents or 21.4 percent to 5.1 cents.

ELLEX MEDICAL LASERS

Ellex says that advocacy group Bundesverband Auge (German Federate Eye Association) has recognized its canaloplasty as the gold standard in glaucoma surgery.
Ellex said that Cologne, Germany-based glaucoma specialist Prof Norbert Körber had been awarded the Glaukom-Forschungspreis prize for glaucoma research in recognition of his pioneering work in canaloplasty.
The company said that canaloplasty used its Itrack micro-catheter to enlarge the eye's natural drainage system, Schlemm's Canal.
Ellex said that unlike traditional trabeculectomy surgery, which created an artificial drainage channel, canaloplasty restored the function of the eye's natural outflow system to reduce the elevated intraocular pressure associated with glaucoma.
Prof Körber said that canaloplasty offered "an unprecedented level of efficacy and safety in the surgical treatment of glaucoma".
Prof Körber said that three-year trial data "demonstrated the procedure's ability to achieve a significant and sustained reduction in pressure" and confirmed the safety profile.
Ellex said that trabeculectomy had been the gold standard in glaucoma surgery and while the benefits of canaloplasty and trabeculectomy were similar, the safety profiles were "vastly different".
The company said that canaloplasty was minimally invasive and provided an improved safety profile, enabling surgeons to reduce or eliminate many post-operative complications associated with trabeculectomy, including blurred vision, bleeding in the eye and infection.
Ellex chief executive officer Tom Spurling said that the Bundesverband Auge recognition of canaloplasty's role in glaucoma treatment was "an important milestone in supporting physician uptake of the procedure".
"We are confident that canaloplasty will increasingly be recognized as the standard of care for glaucoma surgery worldwide," Mr Spurling said.
"The consumable Itrack micro-catheter adds an important recurring stream to our business revenues," Mr Spurling said.
Ellex said the glaucoma surgical device market was worth about $275 million and was expected to grow at 24 percent a year to $870 million by 2019.
The company said that glaucoma affected one in 10 Australian aged over 80 years.
Ellex was unchanged at 28 cents.

ANALYTICA

Analytica says it has completed the design of a 100-patient trial of its intra-vaginal Pericoach pelvic floor diagnostic for urinary incontinence, expected to begin this year.
Analytica said that the multi-centre, randomized, controlled study would evaluate the efficacy of the Pericoach system in females with stress urinary incontinence compared to unassisted pelvic floor exercise, as well as the degree of user satisfaction in terms of outcome, ease of use, and treatment of female sexual dysfunction.
The company said that the principal investigator would be Calvary North Adelaide Hospital urologist Dr Ailsa Wilson, a member of its clinical advisory board and the Five Corners had been selected as the contract research organization.
Analytica said that pending ethics approvals, the study would be held at up to 10 sites in Australia, with evaluations at baseline, device training and implementation, two weeks, four weeks, eight weeks, 12 weeks, 16 weeks and 20 weeks post initial use of the device.
The company said that the study was not required for regulatory approvals and was being undertaken to provide formal evidence of the system's efficacy.
Analytica was up 0.1 cents or three percent to 3.4 cents.

MESOBLAST

Mesoblast says that 70,164 shares, subject to voluntary escrow and relating to the Provasculon acquisition in 2013, will be released from escrow on November 13, 2014.
A Mesoblast executive told Biotech Daily that a further 2.9 million shares relating to the Osiris acquisition were also in voluntary escrow.
Mesoblast has 321,696,029 shares available for trading.
Mesoblast was unchanged at $4.15 with 378,856 shares traded.

VIRAX

Virax will vote to grant 40,000,000 options to managing director Dr Robert Crombie, approve the Aktivate acquisition and change the name to Prescient Therapeutics.
Virax said that on a post-consolidation basis, pending approvals, Dr Crombie would receive 2,000,000 options in four tranches of 500,000 options, vesting as the share price passed 30 cents, 60 cents, 80 cents and $1.20 for 10 of any 20 sequential trading days, equivalent to pre-consolidation prices of 1.5 cents, three cents, four cents and six cents.
In May when Dr Crombie was appointed, Virax said the options would be exercisable at the closing price on the date of approval, within four years from grant (BD: May 15, 2014).
Virax said the meeting would be asked to approve the acquisition of Aktivate shares held by “the Hopper Parties”, issue 191,666,667 shares to the Hopper Parties, the increase in Hopper Parties voting power from 3.87 percent of the company to 25.04 percent, along with 42,333,333 shares to unrelated Aktivate shareholders (BD: Oct 17, 2014).
The notice of meeting included a resolution for a 20-to-one consolidation of shares and options and said shareholders would vote on the remuneration report, the 10 percent placement capacity and the election of directors Dr Crombie, Dr De Kauwe and Mr Hopper.
Virax said that a spill resolution was in place should the remuneration report be opposed by more than 25 percent of the votes ate the meeting.
The meeting will be held at Chartered Accountants, Level 3, 600 Bourke Street, Melbourne on November 28, 2014 at 11am (AEDT).
Virax was up 0.1 cents or 12.5 percent to 0.9 cents with 16.7 million shares traded.

ISONEA

Isonea will vote to grant four directors 10,000,000 options along with 1,421,875 options to former chief executive officer Stephen Tunnell.
Isonea’s notice of meeting proposed that 4,000,000 options be granted to Leon L’Huillier, with 2,000,000 options each to David Ashmore, Dr Timothy Oldham and John Ribot-de-Bresac, “in lieu of additional cash remuneration”, and exercisable at 28 cents by February 3, 2017.
The company asked shareholders to approve the issue of 88,037 shares valued at $23,544 or 26.7 cents a share to Mr Tunnell, “for achievements under [the] company’s short term incentive plan, along with the issue of 1,421,875 options exercisable at 10 cents each by June 30, 2015 (BD: Sep 24, 2014).
The company’s notice of meeting said shareholders would vote on the remuneration report, the 10 percent placement capacity and the election of directors Mr Ashmore, Mr L’Huillier, Bruce Mathieson, Dr Oldham and Mr Ribot-de-Bresac.
The meeting will be held at Giorgios Restaurant Function Room, 1235 High Street, Armadale on November 28, 2014 at 9am (AEDT).
Isonea fell 0.6 cents or 7.1 percent to 7.9 cents.

BIOXYNE

Bioxyne will vote to grant four directors 2,600,000 options and re-elect directors Anthony Peng Ho and George Xavier Cameron-Dow.
Bioxyne said it proposed to grant 1,000,000 options to Mr Ho, 900,000 options to director Patrick Ford, 550,000 options to Mr Cameron-Dow and 150,000 options to chief financial officer Jarrod White, all exercisable at 35 percent above the five-day volume weighted average price to the annual general meeting and within three years of issue.
Bioxyne shareholders will vote on the remuneration report, the 10 percent placement capacity, the employee share option plan and the reelection of directors Mr Cameron-Dow and Mr Ho.
The meeting will be held at RMS Bird Cameron Level 12, 60 Castlereagh Street, Sydney, on November 28, 2014 at 9.30am (AEDT).
Bioxyne was untraded at 1.7 cents.

IDT AUSTRALIA

IDT has requested a voluntary suspension to follow the trading halt requested on October 28, pending an announcement “regarding a potential acquisition and an associated capital raising” (BD: Oct 28, 2014).
IDT last traded at 22.5 cents.

ADVANCED SURGICAL DESIGN AND MANUFACTURE

Advanced Surgical has requested a trading halt “pending an announcement regarding the award of significant funding”.
Trading will resume on November 3, 2014 or on an earlier announcement.
Advanced Surgical last traded at 5.5 cents.

AUSBIOTECH

Ausbiotech says Biodiem chief executive officer Julie Phillips has replaced Bionomics chief executive officer Dr Deborah Rathjen as chairman of the industry organization.
Ausbiotech said that along with Dr Rathjen retiring from the board after six years as chairman, Dr Greg Roger and Peter Turvery, were also stepping down as directors and would be replaced by Serina Cucuzza, Barry Thomas and Serg Duchini.
The industry organization said that Ms Phillips was elected a director in October 2013 and is an industry representative on the Federal Government’s Clinical Trials Advisory Committee.
Ausbiotech said that Serina Cucuzza was the Burnet Institute’s manager for commercial development and industry engagement, Mr Thomas was Cook Medical’s Asia Pacific head and Cook Australia managing director and Serg Duchini was a partner and taxation chief operating officer at Deloitte Tax Services.
Continuing Ausbiotech directors include chief executive officer Dr Anna Lavelle, Michelle Burke, Mr Lawrence Gozlan and Dr Andrea Douglas.

RESONANCE HEALTH

Resonance says that Prof Timothy St Pierre will cease to be a director of but continue in as chief scientific officer, effective immediately.

Resonance said that Prof St Pierre had been the chief scientific officer since 2003 and “an integral part of Resonance Health over the past 11 years”.

Prof St Pierre said that the company “is on a stable course with good leadership”.

“My contributions to the board are diminishing because Ferriscan is now well established and other members of the management team have built up extensive knowledge about the clinical and business environment around Ferriscan and Hepafat Scan so that my expertise in this area is no longer unique within the company,” Prof St Pierre said.

“Now is a suitable time for me to step aside,” Prof St Pierre said.

Resonance fell half a cent or 10.4 percent to 4.3 cents.