Biotech Daily

Monday November 6, 2017

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH UP: CLINUVEL UP 11%; GENETIC SIGS DOWN 19%**

*** PARADIGM 'OVERSUBSCRIBED PLACEMENT' RAISES $5.75m**

*** FDA LIFTS HOLD ON PRESCIENT PTX-200 OVARIAN CANCER TRIAL**

*** CORRECTION: REVA**

*** ANALYTICA HIRES NAVIGANT FOR LICENCING**

*** OBJ MICRO-ARRAY DOUBLES DELIVERY OF ANTI-CANCER VITAMIN B3**

*** MYLAN ARBITRATION ENDS, PHOSPHAGENICS AWAITS RESULT**

*** TPI SELLS PORTUGAL SUBSIDIARY FOR $4.3m**

*** US INCREASES IMPEDIMED L-DEX HOSPITAL REIMBURSEMENT 7%**

*** G MEDICAL REQUESTS INDIA, TAIWAN DISTRIBUTION TRADING HALT**

MARKET REPORT

The Australian stock market slipped 0.1 percent on Monday November 6, 2017 with the ASX200 down 6.1 points to 5,953.8 points. Twenty of the Biotech Daily Top 40 stocks were up, 10 fell, seven traded unchanged and three were untraded.

Clinuvel was the best, up 83 cents or 10.9 percent to $8.48 with 106,433 shares traded.

Cellmid and Medical Developments climbed five percent or more; Admedus improved 4.65 percent; Acrux, Avita and Oncosil were up more than three percent; Bionomics, Compumedics, Nanosonics and Pro Medicus rose more than two percent; Actinogen, Airxpanders, Cochlear, CSL, Ellex, ITL, Orthocell, Pharmaxis, Resmed, Sirtex and Volpara were up more than one percent; with Opthea up 0.7 percent.

Genetic Signatures led the falls, down seven cents or 18.9 percent to 30 cents with 136,238 shares traded, followed by Reva down 10 percent to 63 cents with 130,959 shares traded.

Polynovo lost 5.6 percent; Benitec, Living Cell, Mesoblast, Prana and Universal Biosensors shed more than two percent; LBT was down 1.75 percent; with Starpharma down by 0.35 percent.

PARADIGM BIOPHARMACEUTICALS

Paradigm says it has raised $5.75 million in “a significantly oversubscribed placement” at 30 cents a share, a 16.7 percent discount to the last closing price of 36 cents.
Paradigm said that chief executive officer Paul Rennie participated in the placement subject to shareholder approval and increased his holding by $100,000 as did other members of Paradigm’s management team.
The company said the funds would be used to complete the randomized, double-blind, placebo-controlled phase IIb clinical trial in 100 subjects with osteoarthritis and bone marrow odema lesions, the ongoing generation of “real world evidence” data, the expansion into other joint and pain indications; the start of a pilot phase II trial in Chikungunya virus, the generation of intellectual property and working capital.
Mr Rennie said that placement meant that the company “well-funded post the completion of our key phase II Ross River virus and osteoarthritis trials due to be completed by the end of 2018”.
Paradigm said that Baker Young Stockbrokers and Morgans Corporate were joint lead managers to the placement.
Paradigm fell half a cent or 1.4 percent to 35.5 cents.

PRESCIENT THERAPEUTICS

Prescient says the US Food and Drug Administration has lifted the clinical hold on its phase Ib trial of PTX-200 for platinum resistant ovarian cancer.
In May, Prescient said it had paused recruitment to trials of PTX-200 following the death of the last of 29 patients in its phase Ib breast cancer trial (BD: May 29, 2017).
Apart from breast cancer study, Prescient was trialling PTX-200, previously known as triciribine phosphate monohydrate (TCN-P) for breast, lung and oesophageal cancer, as well as acute myeloid leukaemia and ovarian cancer, and as recently as last month declared PTX-200 and Paclitaxel safe and had shown signs of efficacy for breast cancer (BD: Aug 26, 2015; Feb 17, Dec 8, 2016; Mar 8, Apr 6, 2017).
In September, the company said the FDA clinical hold had been lifted on its phase ib/II trial of PTX-200 for acute myeloid leukaemia (BD: Sep 4, 2017).
Today, the company said it was preparing to resume recruitment following FDA requests for an updated risk mitigation plan and changes to trial inclusion criteria and protocols.
Prescient said that the remaining clinical hold was the PTX-200 trial for metastatic and locally advanced HER2 negative breast cancer, which the company was addressing.
Prescient chief executive officer Steven Yatomi-Clarke said the company was pleased to resume the ovarian cancer trial and the team was “addressing our last remaining clinical hold and will continue to work with the FDA in a similar process until it is resolved”.
Prescient fell 0.2 cents or 2.9 percent to 6.7 cents.

CORRECTION: REVA MEDICAL

Friday night’s edition incorrectly reported that Brian Dovey was Reva’s chairman, a position he held since March last year (BD: Mar 30, 2016).
Charles Ray Larkin was appointed chairman in September (BD: Sep 20, 2017).
Reva annual and half-yearly reports pre-date Mr Larkin’s appointment and the ASX-Commsec company data continues to cite Mr Dovey as the chairman.
Biotech Daily’s back copies page had the correct information.
The mistake was made by the former Friday sub-editor.
Reva fell seven cents or 10 percent to 63 cents.

ANALYTICA

Analytica says it has selected New York investment bank Navigant Capital Advisors LLC to assist in the sale or licence off its assets.

Analytica said that Navigant would assist in the process of commercializing the intra-vaginal Pericoach pelvic floor training system for incontinence, its Autostart burette and possibly the company (BD: Jun 2, 2017).

Analytica chairman Dr Michael Monsour said it was “a credit to Analytica's management and board that the company has advanced its intellectual property to a stage where such a process can be undertaken by a leading US corporate advisor”.

Analytica chief executive officer Geoff Daly told Biotech Daily that Navigant would “help us in our strategy of a licence deal, which may or may not involve the sale of the company”.

“For the last 18 months our publicly-stated strategy has been to build the best in class, prove it works and then find a multinational partner who can take it to the world,” Mr Daly said.

Analytica was unchanged at 0.4 cents.

OBJ LIMITED

OBJ says that initial in-vivo skin penetration studies show that its new applicator delivers “almost 100 percent more nicotinamide” than standard topical delivery.

OBJ said that topical nicotinamide, or vitamin B3, was “a potent anti-skin cancer treatment for areas of the body that are consistently exposed to the sun”.

The company said that a human skin-strip trial co-ordinated by director and Perth dermatologist Dr Christopher Quirk compared a five percent nicotinamide formulation applied using the OBJ magnetic micro-array technology to normal manual application.

OBJ said the formulation was applied for 30 seconds and the formulation was left to absorb into the skin for a period of 30 minutes before analysis.

The company said that the micro-array-backed silicone brush applicator “performed well when applied to the skin with excellent coverage and minimal formulation retention”.

“A two-fold enhancement of nicotinamide penetration into target tissues is believed to set a new standard in nicotinamide delivery into local tissues,” OBJ said.

The company said the findings followed several publications on the use of nicotinamide as a means of reducing the progression of common solar keratosis to the more life-threatening melanoma forms of skin cancer and the data suggested that the use of nicotinamide might “significantly reduce the re-occurrence of melanoma in those previously successfully treated”.

Dr Quirk said that nicotinamide had been studied extensively with both systemic and topical application.

“Our aim was to develop the most effective nicotinamide delivery application with simple compliance and to avoid the first pass metabolism issues that limit the bioavailability and side effects of orally-administered nicotinamide,” Dr Quirk said.

“Our experimental delivery method indicates higher concentrations of nicotinamide delivered to the target tissues, which is expected to result in superior efficacy in those areas of clinical use,” Dr Quirk said.

“These include pigmentation, aging and prophylaxis of skin cancer and pre-cancers in patients both prone to non-melanoma skin cancer and patients who have already had a non-melanoma skin cancer previously treated,” Dr Quirk said.

OBJ said it would use the results “to attract an industry partner active in this market”.

OBJ was up 0.4 cents or 11.8 percent to 3.8 cents with 6.7 million shares traded.

PHOSPHAGENICS

Phosphagenics says the 10-day arbitration hearing with Mylan Laboratories concluded in Singapore on November 3, 2017 and it is awaiting the outcome.

In March, Phosphagenics said the dispute with Mylan was over its tocopheryl phosphate mixture (TPM) daptomycin antibiotic for complicated skin infections and staphylococcus aureus bloodstream infections, which was licenced in 2012 to India's Agila Specialties, a subsidiary of Strides Arcolab, and estimated by Biotech Daily to be worth "tens of millions" of dollars (BD: Oct 30, 2012;: Mar 3, 2017)

Phosphagenics said in its 2016 annual report that in 2013, Mylan acquired the Agila injectables business from Strides Arcolab for up to $US1.75 billion and acquired the TPM-daptomycin agreements and inherited any associated disputes.

The company said at that time that there had been no reported sales of the TPM-daptomycin and no payments despite the original branded daptomycin product Cubicin having sales of about $US1 billion a year prior to competition from generic companies entering the market in September 2016 and it was entitled to single digit royalties on sales of TPM-daptomycin.

Today, Phosphagenics said the arbitrator would consider the evidence and submissions and render an award in due course, with similar matters taking up to six months to decide, but there could be "no assurance as to the outcome".

Phosphagenics said that until the award was rendered it was possible for the parties to settle the dispute by agreement.

Phosphagenics was up 0.1 cents or 6.7 percent to 1.6 cents with 1.2 million shares traded.

TPI (TASMANIAN POPPY INDUSTRIES) ENTERPRISES

TPI says it has a binding agreement to sell its Lisbon, Portugal subsidiary for EUR2.85m ($A4.3 million), expected to close by December, this year.

TPI did not name either its Portugese subsidiary nor the purchaser

The company said that the sale was expected to result in a net gain of about $875,000 to be recognized on the closing of the transaction, along with cost savings associated with eliminating the ongoing property occupancy and administration expenses of about $200,000 on an annualized basis.

TPI said that the decision to sell the facility was made after an analysis of the active pharmaceutical ingredient production capacity of the recently acquired Norwegian opiate and finished dose facility Vistin Pharma ASA (BD: Oct 3, 2017).

The company said that since acquiring Vistin it "concluded that with modest capital investment it will be able to expand its [active pharmaceutical ingredient] capacity to meet customer demand in both {active pharmaceutical ingredient] and tableting without the need for the additional … facility in Portugal".

TPI said that the Lisbon facility had not received any investment with regard to opiate manufacturing and was sold to a non-opiate based European pharmaceutical manufacturer.

The company said that its $2 million investment in specialized Buchi laboratory equipment purchased with the support of a $1 million Federal Government grant would be assembled in Norway for the manufacture of naloxone and other high value compounds.

TPI said the sale proceeds would be used for working capital.

TPI was unchanged at $2.61.

IMPEDIMED

Impedimed says the US Centres for Medicare and Medicaid Services will increase hospital reimbursement for its L-Dex system by 7.1 percent to $US136 ($A177.74).
Impedimed said the Centres had published the new payment amounts for current procedural terminology (CPT) code 93702, effective from January 1, 2018, billed by a hospital outpatient facility from $US127 in 2017.
The company said that the physician reimbursement rate for the L-Dex system for monitoring cancer-related lymphoedema would remain unchanged at $US126.
Impedimed was unchanged at 78 cents.

G (GEVA) MEDICAL INNOVATIONS

G Medical has requested a trading halt pending an announcement in relation to agreements for distribution of its devices in India and Taiwan
The Grand Cayman Island-based G Medical has said it was commercializing its mobile telephone electronic health devices (BD: May 10, 2017).
Trading will resume on November 8, 2017 or on an earlier announcement.
G Medical last traded at 39 cents.