Biotech Daily

Thursday July 26, 2018

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: ITL UP 14%; OPTISCAN DOWN 7%**

*** POLYNOVO: PROF GREENWOOD, NOVOSORB FOR GREEK FIRE VICTIMS**

*** ORTHOCELL CELGRO 1st SALES, USE IN IRELAND**

*** OPTHEA OPT-302 FOR DME 'SAFE, WELL-TOLERATED', PHASE II BEGINS**

*** PROBIOTEC: 'UNAUDITED SALES REVENUE UP 25% TO $78m'**

*** SIRTEX CEO ANDREW MCLEAN TO US ON $852k, 12-MONTH CLAUSE**

*** CE MARK FOR REVA MOTIV PERIPHERAL ARTERY STENT**

*** US PATENT FOR PRESCIENT PTX-200 FOR OVARIAN CANCER**

*** TELIX, JFE PARTNER FOR TLX-250 JAPAN KIDNEY CANCER TRIALS**

*** INNATE NAME CHANGE TO AMPLIA, 1.4m DIRECTOR OPTIONS AGM**

MARKET REPORT

The Australian stock market slipped 0.05 percent on Thursday July 26, 2018 with the ASX200 down 3.1 points to 6,244.5 points.

Eight of the Biotech Daily Top 40 stocks were up, 23 fell, eight traded unchanged and one was untraded.

ITL was the best, up 2.5 cents or 14.3 percent to 20 cents with 28,440 shares traded.

Orthocell climbed 6.1 percent; Airxpanders and Pharmaxis improved more than four percent; Clinuvel and Pro Medicus rose more than two percent; Medical Developments was up 1.9 percent; with Cochlear, Resmed and Starpharma up less than one percent.

Optiscan led the falls, down half a cent or 7.35 percent to 6.3 cents with 2,784 shares traded.

Immutep and Reva lost more than six percent; Mesoblast fell 5.8 percent; Telix was down 4.4 percent; Compumedics and LBT were down more than three percent; Admedus, Benitec, Bionomics, Neuren, Oncosil, Prana and Universal Biosensors shed two percent or more; Actinogen, Avita, Cynata, Dimerix, Nanosonics, Opthea and Polynovo were down more than one percent; with CSL, Ellex and Sirtex down by less than one percent.

POLYNOVO

Polynovo says collaborator Prof John Greenwood will treat burns victims in Greece and the company is sending its Novosorb skin product for use on the patients.

An official of the Embassy of Greece told Biotech Daily that about 80 people had been confirmed dead in the fires near Athens, with more than 180 people attending hospitals, of which more than 20 were children.

Polynovo chief executive officer Paul Brennan told Biotech Daily that his company "had direct surgeon contact and contacted the [Greek] Ministry of Health directly to gain CE exemption for importation".

"The patients are in intensive care units and wards so surgery will probably be early next week," Mr Brennan said.

Polynovo said that Novosorb biodegradable temporizing matrix (BTM) had been offered to the surgical teams caring for patients burnt in the fires, with Royal Adelaide Hospital collaborators and burns specialists Prof Greenwood and Dr Marcus Wagstaff offering support and in direct contact with the surgical teams on the ground.

Mr Brennan said that both the South Australian Government and the Royal Adelaide Hospital would support Prof Greenwood's flight to Athens, while Dr Wagstaff covered for Prof Greenwood in Adelaide.

Mr Brennan said that the burns surgeons were experts in the use of Novosorb, a polymer invented by the Commonwealth Scientific and Industrial Research Organisation and since developed by Polynovo into several products for the treatment of major surgical wounds and burns.

The company said that Novosorb BTM acted "as a dermal tissue scaffold allowing new dermal cells, blood vessels and skin structures to develop without laying down excess scar material … [resulting in] a soft, supple and mobile regenerated dermis".

"The reduced scarring ensures improved function of the area and an improved cosmetic outcome," the company said.

Mr Brennan said that Novosorb came from the October 2002 Bali bombings in which 204 people were killed and 209 were injured, mostly from burns and shrapnel.

"That's why we invented the product," Mr Brennan said. "To treat people in mass casualty events like this."

"Australians know the impact of bush fires on human trauma," Mr Brennan said.

"We are pleased that we can offer Novosorb BTM and medical support to the patients effected by these fires so that they might have an improved outcome and assist them to rebuild their lives," Mr Brennan said.

Polynovo fell half a cent or one percent to 48 cents.

ORTHOCELL

Orthocell says its Celgro for dental bone and soft tissue repair has had its first sales and use in Ireland.

Earlier this month, Orthocell said it had appointed the Birmingham, England-based Carrera Medical as its exclusive UK distributor (BD: Jul 10, 2018).

Orthocell managing director Paul Anderson said the company was "delighted by the high level of interest and rapid uptake Celgro is receiving throughout Europe".

"Achieving first product use and sales in four key European regions demonstrates that Orthocell is successfully executing its market entry strategy," Mr Anderson said.

Orthocell has previously announced sales and use of Celgro in Poland, Italy and the UK (BD: May 22; May 31; Jul 17, 2018).

Orthocell was up two cents or 6.1 percent to 35 cents.

OPTHEA

Opthea says its nine-patient, dose escalation, phase Ib trial of OPT-302 for diabetic macular oedema (DME) has met its primary objective of acceptable safety and tolerability.
Opthea said that OPT-302 was administered by monthly intra-ocular injections in combination with aflibercept, marketed as Eylea, for three months (BD: Jan 21, 2018).
The company said that the patients, with a mean age of 61.1 years, had persistent central-involved diabetic macular oedema, despite prior sub-optimal responses to standard of care anti-vascular endothelial growth factor A (VEGF-A) therapy.
Opthea said that the patients received intra-vitreal injections, or injections into the eye, of OPT-302 at doses of 0.3 mg, 1.0mg or 2.0mg in combination with Eylea 2.0mg.
The company said that all dose levels were "well tolerated … no dose limiting toxicities were observed and the maximum tolerated dose was not reached with OPT-302".
Opthea said there were no treatment-related ocular or systemic adverse events and the few ocular events noted were mild and primarily related to the intra-vitreal injection.
The company said that there were no clinically significant changes in intraocular pressure, electro-cardiograms, blood pressure or other vital signs during the patient safety assessment period following dosing with OPT-302 combination therapy.
Opthea said that the safety data supported moving forward with OPT302 at 2mg dose in combination with Eylea in a phase IIa trial.
Opthea chief executive officer Dr Megan Baldwin said that the "favorable phase Ib safety results are an important milestone given this trial represents the first time OPT-302 has been administered in patients with DME and in combination with Eylea".
"The encouraging safety profile of a combination OPT-302 therapy in DME builds upon our growing clinical experience from completed phase I/IIa and ongoing phase IIb clinical trials in wet age-related macular degeneration patients who have received OPT-302 in combination with ranibizumab [marketed as Lucentis]," Dr Baldwin said.
Opthea said that the 108-patient, phase IIa, randomized, controlled, dose-expansion trial was open for enrolments, with 72 patients to receive OPT-302 2mg with Eylea 2mg and 36 patients to receive Eylea as a monotherapy.
The company said that the primary objectives were to evaluate the safety, tolerability and efficacy of OPT-302 as measured by the proportion of patients receiving combination OPT-302 and Eylea achieving a five-letter or better gain in visual acuity at week-12 compared to baseline.
Opthea said that secondary measures would be investigated, including changes in mean visual acuity, diabetic retinopathy severity score and anatomical parameters such as central subfield thickness and macular volume from baseline to week-12.
The company said that the phase Ib/IIa trial was being run under an investigational new drug application (IND) program with the US Food and Drug Administration at 20 US sites and six sites in Australia.
Opthea fell one cent or 1.8 percent to 55.5 cents.

PROBIOTEC

Probiotec says its unaudited sales revenue is expected to be up 24.92 percent to $75.7 million and net profit after tax to be in the order of $4.3 million to $4.6 million.
Probiotec chairman Geoff Pearce said the company was pleased to have "taken another step forward with this strong result".
"Furthermore, we are excited for the future as we build momentum, integrate new business contracts and continue to field significant sales enquiries," Mr Pearce said
Probiotec was up eight cents or 6.2 percent to $1.37.

SIRTEX MEDICAL

Takeover target Sirtex says chief executive officer Andrew McLean will move to Boston on $US634,000 ($A852,255) a year with a 12-month termination clause.
Last month, Sirtex said it had terminated a $1.56 billion scheme by Varian Medical Systems for a binding scheme deed with CDH Genetech and China Grand Pharmaceuticals to buy the company for $1.87 billion (BD: Jan 31, May 4, Jun 15, 2018).
Today, Mr McLean said his relocation, effective from August 1, 2018, made "sound strategic sense … given the Americas accounts form a significant percentage of our global dose sales, the majority of our clinician customers are based within the US, and we own and operate a manufacturing facility in close proximity to our US headquarters".
Sirtex said Mr McLean would be entitled to a short-term incentive of 50 percent of base salary, a long-term incentive of 100 percent of base salary and relocation expenses.
Sirtex said that terminating the contract required "twelve months' notice in writing from either party".
Sirtex fell two cents or 0.1 percent to $32.03 with 233,672 shares traded.

REVA MEDICAL

Reva says its Motiv drug-eluting, bio-resorbable scaffold for below the knee peripheral artery disease has received Conformité Européenne (CE) mark approval.
Reva said Motiv was made from its Tyrocore x-ray visible polymer, as were its Fantom and Fantom Encore cardiac scaffolds.
The company said it would begin to select centres to assess the performance of Motiv to inform product development activities and determine its commercial strategy in peripheral vascular applications, with the use of Motiv expected in late 2018 or early 2019.
A Reva executive told Biotech Daily that the Fantom coronary scaffolds had a "good safety and efficacy track record … [so] we were approved to move forward with no additional clinical data".
Reva chief executive officer Dr Reggie Groves said Reva "did not just achieve its own milestone with CE mark [approval] of Motiv, we achieved a therapeutic milestone for patients with critical limb ischemia".
"This is our first step beyond the coronary arteries and we look forward to bringing a new treatment option to peripheral artery disease patients and their physicians," Dr Groves said.
Reva said "drug-eluting bioresorbable scaffolds such as Motiv present a significant opportunity to improve the treatment of patients suffering from [critical limb ischemia] because of the potential to extend drug delivery and to enable retreatment without the risks associated with metal stents".
Reva fell two cents or 6.9 percent to 27 cents.

PRESCIENT THERAPEUTICS

Prescient says the US Patent and Trademark Office has allowed a patent relating to its PTX-200 for ovarian cancer.
Prescient said the patent, titled 'Effective Treatment of Ovarian Cancer Using Triciribine and Related Compounds' would provide intellectual property cover until about September 2028 and provided protection covering its compound for the treatment of ovarian cancer and a sub-population of patients with a tumor or cancer cell that overexpress the Akt tumor survival pathway.
Prescient was unchanged at 11 cents.

TELIX PHARMACEUTICALS

Telix says it has signed a definitive manufacturing agreement with Tokyo's JFE Engineering to produce TLX-250 for renal, or kidney, cancer imaging for Japan.
Last year, Telix said JFE had installed a Cyclone 18 mega-electronvolt (MeV) cyclotron at its Yokohama facility and was preparing for beam activation and the production of zirconium-89, a key isotope in the TLX-250 cancer imaging product (BD: Dec 13, 2017).
Today, Telix said that JFE had completed the installation of its cyclotron and beam line activation and was producing "commercially useful quantities of zirconium at a quality and yield suitable for investigational clinical use".
The company said the definitive manufacturing agreement superseded the previously announced technology transfer and feasibility agreement and committed the parties to an initial exclusive five-year production term sufficient to complete clinical trials for TLX250 for renal cancer imaging and to begin commercialization in Japan.
Telix fell three cents or 4.4 percent to 65 cents.

INNATE IMMUNOTHERAPEUTICS

Innate's annual general meeting will vote to change its name to Amplia Therapeutics, issue 2,330,000 options to three directors and re-elect director Dr Robert Peach.
Innate said shareholders would vote on a special resolution to change the company's name to Amplia Therapeutics, which would require 75 percent shareholder approval to pass.
The company said that if approved the ASX code would be ATX.
Innate said shareholders would vote to approve the issue of 1,370,000 options to chief executive officer chief executive officer Simon Wilkinson exercisable at 60 cents a share by March 31, 2022, with 25 percent vesting on the date of grant of August 31, 2018 for completion of the purchase of Amplia, with 25 percent on completing a $5 million capital raise, 25 percent on May 4, 2019 and May 4, 2020.
The company said shareholders would vote on the issue of 480,000 options each to directors Dr Peach and Andrew Cooke exercisable at 60 cents by August 31, 2023 vesting in equal annual tranches from August 13, 2019.
The meeting will be held at Grant Thornton, Collins Square, Tower 1, 727 Collins Street, Melbourne, on August 30, 2018 at 11.00 (AEST).
Innate was untraded at 31 cents.