Biotech Daily

Thursday November 9, 2017

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: ORTHOCELL UP 19%; AVITA DOWN 11%**

*** PRIMA: IMP321 WITH KEYTRUDA 'SAFE, TUMOR REDUCTION'**

*** EPAT HAILS 1st PAINCHEK RESIDENTIAL AGED CARE LICENCE**

*** ORTHOCELL CELGRO DENTAL SCAFFOLD WINS CE MARK**

*** IDT, VICTORIA $2m UNNAMED DRUG DEVELOPMENT DEAL**

*** ALLEGRA 2nd TRANCHE $500k TAKES TOTAL TO $1.7m**

*** MAYNE US LAUNCH OF 'FULL RANGE' OF ANTI-PSYCHOTIC CLOZAPINE**

*** ANTISENSE RECEIVES $399k FEDERAL R&D TAX INCENTIVE**

*** IMMURON COMPLETES IMM-124E FOR NASH PATIENT VISITS**

*** OBJ 58% REMUNERATION 1st STRIKE**

*** LIVING CELL REQUESTS 'NTCELL PARKINSON'S RESULTS' HALT**

*** CRESO, LGC CANNABIS COLLABORATION**

MARKET REPORT

The Australian stock market climbed 0.55 percent on Thursday November 9, 2017 with the ASX200 up 33.1 points to 6,049.4 points. Twenty-one of the Biotech Daily Top 40 stocks were up, 13 fell, four traded unchanged and two were untraded.

Orthocell was the best on CE mark approval (see below), up six cents or 19.35 percent to 37 cents with 759,118 shares traded. Psivida climbed 7.2 percent; Cyclopharm rose 6.95 percent; Dimerix and Neuren improved more than four percent; Actinogen, Medical Developments, Pharmaxis, Prima and Universal Biosensors were up three percent or more; Admedus, Osprey and Prana rose more than two percent; CSL, Ellex and LBT were up one percent or more; with Airxpanders, Nanosonics, Pro Medicus, Reva, Sirtex and Starpharma up by less than one percent.

Avita led the falls, down 0.6 cents or 10.9 percent to 4.9 cents with 6.4 million shares traded. Clinuvel fell 7.4 percent; Benitec, Cellmid and Factor Therapeutics lost five percent or more; Oncosil was down 3.6 percent; Uscom and Volpara shed more than two percent; Genetic Signatures, Impedimed and Polynovo were down more than one percent; with Cochlear, Mesoblast, Resmed and Viralytics down by less than one percent.

PRIMA BIOMED

Prima says that data from the first 12 of its 18-patient trial of IMP321 with Keytruda shows the combination is safe with tumor reduction in seven patients.

Prima said the data on the two lower dose cohorts in the phase I, multi-centre, dose-escalation trial of pembrolizumab (Keytruda) would be presented in a poster entitled 'Pushing the accelerator and releasing the brake: testing the soluble LAG-3 protein (IMP321), an antigen presenting cell activator, together with pembrolizumab in un-resectable or metastatic melanoma' at the Society for Immunotherapy of Cancer meeting in National Harbor, Maryland from November 10 to 12, 2017.

The poster, to be presented by Prima chief scientific officer Dr Frédéric Triebel, is available at: http://primabiomed.com.au/investor/presentations.php.

The poster said that patients in the 'Two active immune-therapeutics in melanoma (Tactimel) trial' would receive three cycles of pembrolizumab and those with a sub-optimal response would continue with pembrolizumab as well as eftilagimod alpha, or IMP321, injections every two weeks for six months in cohorts of 1mg, 6mg and 30mg IMP321.

The poster concluded that at the 1mg and 6mg dose the combination in advanced metastatic melanoma patients was safe and well tolerated, with anti-tumor activity, or tumor reduction, observed in seven of 12 patients.

The poster said that prior to the study all patients either had a sub-optimal response or had disease progression when treated with the pembrolizumab monotherapy.

The poster said the data supported the hypothesis that "combining an APC activator (IMP321) with a checkpoint inhibitor (pembrolizumab) results in a therapeutic synergy and a potential clinical benefit over a checkpoint inhibitor monotherapy" and further investigation of IMP321 with checkpoint inhibitors in different tumor types was warranted.

The company said the third 30mg cohort in the trial was on-going.

Dr Frédéric Triebel said that "prior to coming into this study, these patients were treated with pembrolizumab monotherapy and did not achieve a meaningful therapeutic benefit from this treatment".

Prima chief executive officer Marc Voigt said that "the positive data, taken together with the excellent safety profile of eftilagimod alpha and data from our ongoing clinical trial in metastatic breast cancer further validate the therapeutic utility of modulating the LAG-3 immune control mechanism".

Prima was up 0.1 cents or 3.6 percent to 2.9 cents with 8.5 million shares traded.

EPAT TECHNOLOGIES

Epat says it has signed the first Painchek commercial sale with an unnamed South Australian residential aged care operator.

Epat said the contract revenue was not material but the "confirmation of the … value of Painchek within the large [residential aged care] market" was material, as was the impact of partner Dementia Support Australia visiting the facility to provide care to a resident and using Painchek to help diagnose pain levels (BD : Sep 7, 2017).

The company said that following the Dementia Support Australia visit the facility operator bought a Painchek licence for pain assessment of all dementia residents on the ward.

Epat chief executive officer Philip Daffas said the sale "confirms the value proposition of Painchek in the [residential aged care] market, the value of the [Dementia Support Australia] relationship as a cost-effective channel to market and our business model".

"We now have a strong pipeline of leads across large, medium and small … providers that we are working on to convert into new commercial sales," Mr Daffas said.

Epat fell 0.2 cents or 3.6 percent to 5.3 cents with 2.5 million shares traded.

ORTHOCELL

Orthocell says it has been granted Conformité Européenne (CE) mark approval for its Celgro collagen scaffold device for dental bone and soft tissue procedures.

Orthocell managing-director Paul Anderson said the Celgro approval was “a major milestone for Orthocell as it enables commercial rollout in the lucrative dental bone and soft tissue regeneration market, where there is a significant and growing demand and market opportunity”.

“This provides a strong foundation for Orthocell to progress additional dental regulatory applications in key markets, such as the US, Japan and Australia,” Mr Anderson said.

“The CE mark also validates the potential of the entire technology platform by endorsing Celgro’s clinical performance and quality manufacturing,” Mr Anderson said.

Orthocell said that the dental product was the first product “of a diverse suite of collagen medical devices to be commercialized” with discussions underway with potential European partners to accelerate commercialization.

The company said the approval was “a strong foundation for additional dental bone and soft tissue regeneration regulatory applications in other key markets” with regulatory applications for Celgro orthopaedic, reconstructive and surgical applications to follow.

Perth, Western Australia oral and maxillofacial surgeon Dr Brent Allan said that Celgro had “clear advantages over the available alternatives”.

“I prefer to use Celgro over existing scaffolds,” Dr Allan said. “It is easy to handle and enables a high quality tissue repair.”

Orthocell said that the addressable market for Celgro dental applications was worth more than $US600 million a year, with about 1.5 million procedures using scaffolds each year.

The company said that Celgro could be used for neurological, orthopaedic and general surgery indications.

Orthocell climbed six cents or 19.35 percent to 37 cents.

IDT AUSTRALIA

IDT says it will develop an unnamed active pharmaceutical ingredient with the Government of Victoria in a contract worth more than $2,000,000.

IDT said that the details of the ingredient and the commercial terms were confidential, but the agreement extended for up to 12 months.

IDT executive chairman Graeme Kaufman said his company had significant good manufacturing practice facilities and “substantial project for the Victorian Government … enables us to build on our expertize in an exciting new field of drug development”.

IDT was up 0.6 cents or 7.8 percent to 8.3 cents.

ALLEGRA ORTHOPAEDICS

Allegra says it has raised $1.7 million in a private placement at 15 cents a share.

Allegra said that 8,000,000 shares were issued under a placement approved at the 2017 annual general meeting with 3,333,000 shares issued to Robinwood Investments Pty Ltd, an entity related to director Anthony Hartnell, under the second tranche of the placement (BD: Sep 8, 2017).

The company said that the funds would be used for ongoing working capital to commercialize its Sr-HT-Gahnite bone project, the establishment of a pilot manufacturing facility, regulatory process submissions and the manufacture of a three-dimensional spinal cage for the first product application of its technology.

Allegra was unchanged at 15 cents.

MAYNE PHARMA GROUP

Mayne Pharma says it has launched “the full range” of anti-psychotic clozapine tablets in 25mg, 50mg, 100mg and 200mg doses in the US.
Mayne said that clozapine was a generic alternative to the Novartis drug Clozaril.
Mayne chief executive officer Scott Richards said the launch of the full range of clozapine tablets was the company’s sixth product launch in 2017.
Mr Richards said the product was manufactured by Teva Pharmaceuticals but would be manufactured at Mayne’s facility in Greenville, North Carolina, expected to open in early 2018 and quadruple the company’s manufacturing capacity more than one billion doses and introduce new capacity to manufacture high potent compounds and modified-release bead and pellet products.
The company said US sales of clozapine tablets was $US125 million for the year to August 31, 2017.
Mayne was up two cents or 3.2 percent to 64 cents with 10.9 million shares traded.

ANTISENSE

Antisense says it has received $399,374 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.
Antisense said the rebate related to research and development expenditure for the year to June 30, 2017.
Antisense was up 0.1 cents or 2.9 percent to 3.5 cents.

IMMURON

Immuron says the last patient visit has been completed in its 133-patient, phase II trial of IMM-124E for non-alcoholic steato-hepatitis, or fatty liver disease.
Immuron started the trial in 2011, filed its investigational new drug application to the US Food and Drug Administration at the end of 2011 but was not cleared to start the trial until 2013, finally beginning the trial in 2015, following several changes to board and management (BD: May 24, Nov 7, 2011; Nov 8, 2013; Jan 18, 2015).
Today, the company said it expected results by April 2018.
Immuron said that the last patient had the final scheduled visit on October 9, with the close-out visit on October 18, concluding dosing and research at all study sites.
Immuron said the data and safety monitoring board reported that IMM-124 “demonstrated a statistically significant reduction” in alanine transaminase (ALT) an enzyme most commonly found in the liver when the two treatment doses were compared to placebo.
In July, the company said all three groups, IMM-124E 1200mg and 600mg and placebo, demonstrated a significant change in ALT levels at 24 weeks compared to baseline ($p = 0.0038$, $p = 0.016$ and $p = 0.0337$), but “no statistical difference was noted between the groups” (BD: Jul 10, 2017).
The company said at that time that there were significant differences when comparing the statistical analyses of “the area under the curve” for all ALT values.
Today, Immuron said the preliminary results suggested “a reduction in liver injury … over the duration of treatment compared to the placebo”.
Immuron chief executive officer Dr Jerry Kanellos said the completion of the patient studies “marks a pivotal inflection point for Immuron, as we now look forward to analysing and reporting the data results”.
Immuron fell 2.5 cents or 12.2 percent to 18 cents.

OBJ

OBJ has earned a remuneration report first strike with the annual general meeting defeating the resolution 245,735,133 votes (57.95%) to 178,311,588 votes (42.05%).
Under the Corporations Amendment (Improving Accountability on Director and Executive Remuneration) Act 2011 any company sustaining a vote of 25 percent or more against the remuneration report in two successive annual meetings is required to vote on a board spill and at the later meeting, and if passed by more than 50 percent of votes, the directors must stand for re-election at a subsequent meeting within 90 days.
OBJ's most recent Appendix 3B new issue announcement said that the company had 1,778,795,969 shares on issue, meaning that the votes against the remuneration report amounted to 13.8 percent of the company, sufficient to requisition extraordinary general meetings.
The OBJ meeting narrowly passed the employee incentive scheme, with the ratification of previous securities issues, the 10 percent placement capacity and election of director Steven Schapera passed by wider margins.
Last year, the placement capacity faced 34.4 percent dissent with the remuneration report passed easily (BD: Oct 28, 2016).
OBJ fell 0.1 cents or 2.5 percent to 3.9 cents with 2.9 million shares traded.

LIVING CELL TECHNOLOGIES

Living Cell has requested a trading halt "pending the NTCell Parkinson's disease clinical trial results announcement to the ASX, expected on Friday, November 10, 2017".
Trading will resume on November 13, 2017 or on an earlier announcement.
Living Cell last traded at 20.5 cents.

CRESO PHARMA

Creso says it expects to sign a collaboration agreement with the Montreal, Quebec-based LGC Capital for an integrated cannabis operation by the end of this year.
Creso said that LGC had agreements for investments in private cannabis operations in South Africa, Australia and Canada and had "potential access to the highest quality, competitive supply of cannabis from southern Africa, a global logistics footprint and capability to introduce Creso's innovative products to key markets of Canada and Africa and other regions".
The company said that with LGC it would develop, produce and market human and animal health cannabis and hemp-derived products for therapeutic, cosmetic, food additive and lifestyle markets.
Creso said the alliance was "designed to result in better access to high quality cannabis-based consumer products".
LGC founder and co-chair David Lenigas said that Creso operated "under the highest [good manufacturing practice] Swiss standards and all of its products are manufactured, quality controlled and certified in Switzerland".
"Creso's team consists of globally-recognized pharma professionals and this alliance between Creso and LGC is a terrific development for both companies," Mr Lenigas said.
Creso climbed 8.5 cents or 13.3 percent to 72.5 cents with two million shares traded.