Biotech Daily

Thursday July 7, 2016

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH EVEN: OSPREY UP 14%, POLYNOVO DOWN 7%**

*** J&J OPENS APPLICATIONS FOR $665k QUICKFIRE CHALLENGE**

*** WEHI CANCER DNA TEST TO REDUCE COLORECTAL CHEMOTHERAPY**

*** ADALTA IPO TO RAISE $10m FOR AD-114 FOR FIBROSIS**

*** BIOPHARMACEUTICALS AUSTRALIA $250k ZZ MANUFACTURING GRANT**

*** ATCOR ADDS UNNAMED 35m LIVES INSURER FOR US COVER**

*** OSPREY CLAIMS RECORD JUNE QUARTER SALES**

*** UNNAMED IVF COMPANY ADOPTS BLUECHIIP TRACKING TECHNOLOGY**

*** RESAPP 'SCHULTZ' TO ASX 35% FALL QUERY; UNIQUEST BELOW 5%**

*** SINGAPORE GRANTS NUSEP'S PRIME BIOLOGICS ALBUMIN GMP**

MARKET REPORT

The Australian stock market was up 0.58 percent on Thursday July 7, 2016 with the ASX200 up 30.4 points to 5,227.9 points. Fifteen of the Biotech Daily Top 40 stocks were up, 14 fell, 10 traded unchanged and one was untraded.

Osprey was the best, up three cents or 13.6 percent to 25 cents, with 485,997 shares traded.

Admedus and Factor Therapeutics climbed more than eight percent; Clinuvel was up 7.95 percent; Genetic Technologies improved 5.6 percent; Compumedics and Prana were up four percent or more; Oncosil and Universal Biosensors were up more than three percent; Actinogen, Pharmaxis and Reva rose two percent or more; Impedimed and Starpharma were up more than one percent; with Cochlear, CSL and Sirtex up less than one percent.

Polynovo led the falls, down two cents or seven percent to 26.5 cents, with 953,204 shares traded.

Living Cell fell 4.6 percent; Bionomics, Ellex and Orthocell lost three percent or more; Benitec, IDT, Mesoblast, Nanosonics, Pro Medicus, Uscom and Viralytics shed more than two percent; Medical Developments was down 1.45 percent; with Acrux and Resmed down by less than one percent.

JOHNSON & JOHNSON INNOVATION, JANSSEN RESEARCH & DEVELOPMENT

Johnson & Johnson Innovation says that applications have opened for its 2016 $US500,000 ($A665,212) World Without Disease Quickfire challenge.

Johnson & Johnson Innovation said that with subsidiary Janssen Research & Development the competition was “the largest and most ambitious Quickfire challenge to date” to find entrepreneurs, researchers or start-up companies “advancing potentially game-changing, early stage innovations that have the potential to cross traditional boundaries of the pharmaceutical, device or consumer health sectors”.

Johnson & Johnson said it would consider global applicants with products across the pharmaceutical, medical device and consumer sectors.

The company said that apart from the grant money the recipient would receive entrance to a Johnson & Johnson Innovation, J-Labs community.

Johnson & Johnson pharmaceuticals chairman and chief scientific officer Dr Paul Stoffels said his company was “passionate about finding and deploying comprehensive, integrated healthcare solutions that take into account the world in which we live today, which is why this challenge is focused on innovations that address disease along the entire spectrum of health, including prevention and interception”.

The company said the product could originate from anywhere and from one or more individuals, teams or companies.

To apply, go to http://jlabs.jnjinnovation.com/quickfire-challenges.

Johnson & Johnson said the deadline for applications was August 31, 2016, with the award recipients to be announced by the end of 2016.

THE WALTER AND ELIZA HALL INSTITUTE OF MEDICAL RESEARCH

The Walter and Eliza Hall Institute says that fragments of colorectal cancer-related DNA in blood can determine whether surgery should be followed by chemotherapy.

The Institute said that its scientists with partners from the Ludwig Cancer Research and Johns Hopkins Kimmel Cancer Centre had designed a blood-based screening test to determine a patient’s risk of colon cancer recurrence after surgery.

WEHI said that accurate testing of the risk factor could end chemotherapy following surgical tumor removal by identifying patients who did not need the extra treatment.

The research, entitled ‘Circulating tumor DNA analysis detects minimal residual disease and predicts recurrence in patients with stage II colon cancer’ was published in the journal Science Translational Medicine, and an abstract is available at: http://stm.sciencemag.org/content/8/346/346ra92.

WEHI said that cancer cells often shed DNA into the blood when they died and new technology allowed researchers to capture and profile the fragments of DNA and understand whether chemotherapy would be beneficial.

The Institute said the research followed 230 stage 2 colon cancer patients in 13 hospitals in Australia over four years.

The lead author Dr Jeanne Tie said that most patients with stage 2 colon cancers would be cured of the disease after surgery alone.

Dr Tie said that stage 2 tumors generally invaded through the bowel wall but did not spread to other organs and the majority of these cancers were cured by surgery alone.

“Because current methods of predicting recurrence are imprecise, doctors tend to err on the side of caution,” Dr Tie said.

“Up to 40 per cent of these patients undergo the ordeal of chemotherapy even though we know only a small fraction of them are likely to experience a cancer relapse,” Dr Tie said.

ADALTA

Adalta hopes to raise up to $10 million in an initial public offering at 25 cents a share to list on the ASX to develop lead compound AD-114 for lung and eye fibrosis.

Adalta said that cornerstone investors including Yuuwa Capital had agreed to subscribe for $7 million in the offer.

Adalta chief executive officer Sam Cobb told Biotech Daily that the company expected to lodge its prospectus with the Australian Securities and Investments Commission tomorrow, July 8, 2016.

Ms Cobb said that the company had developed its novel technology platform from proteins that mimicked the shape of shark antibodies.

“We identified the shape of the shark single domain antibody, searched human databases and found a human protein that was the same shape as the shark antibody,” Ms Cobb said.

“That human protein was from a family of molecules called I’set and we modified it to invent a library of compounds and selected 114 for fibrosis,” Ms Cobb said.

Ms Cobb said that the initial indication would be lung fibrosis but the company also had data for fibrosis of the eye.

I-set molecules are one of four groups – the intermediate group - of immunoglobulin or immunoglobulin-like domains.

Ms Cobb said that Adalta developed the novel protein and called it I-body.

In a media release, Adalta said the I-body platform would be used to develop a pipeline of drugs called I-bodies, with an initial focus on treating fibrotic diseases, with lead compound AD-114 for the treatment of idiopathic pulmonary fibrosis.

The company said it was founded nine years ago, based on discoveries by scientists in the Co-operative Research Centre for Diagnostics, including the Commonwealth Scientific and Industrial Research Organisation and La Trobe University.

Adalta said that investors included Leon Serry and Yuuwa directors Dr James Williams and Liddy McCall, with IDT chief executive officer Paul MacLeman as chairman and Dr John Chiplin as a director.

The media release said that prior to Adalta, Ms Cobb led business development at the Co-operative Research Centre for Diagnostics and previously worked for medical technology companies and the University of Queensland’s technology commercialisation businesses Uniquest and IMBcom.

“Proceeds from the offer will be deployed to expedite our first candidate into phase I human clinical trials and extend the technology into other diseases,” Ms Cobb said.

“Our strategy is to licence this drug candidate on completion of the planned phase I clinical studies proposed in the offer,” Ms Cobb said.

“We also plan to expand our own internal development pipeline of novel proprietary I-body drug candidates generating sustainable future licensing opportunities,” Ms Cobb said.

“In addition, Adalta intends to licence or partner the I-body technology platform for drug discovery with pharmaceutical and biotechnology companies, with the objective of earning up front, milestone payments and licencing revenues,” Ms Cobb said.

Adalta said that AD-114 had shown anti-fibrotic activity as well as anti-inflammatory activity in pre-clinical studies, which were important for preventing the disease and for the treatment of idiopathic pulmonary fibrosis.

Adalta said that its proposed ASX code would be AAB and more information about the company was available at: www.adalta.com.au.

BIOPHARMACEUTICALS AUSTRALIA

Biopharmaceuticals Australia says it has granted ZZ Biotech $250,000 to support development of 3K3A-APC for ischemic stroke and diabetic foot ulcers.

Biopharmaceuticals Australia said that the Houston, Texas-based ZZ drug was manufactured at the Durham North Carolina-based Patheon's contract manufacturing facility in Brisbane and would be used in animal studies and phase II clinical trials.

Biopharmaceuticals Australia chief executive officer David Hughes told Biotech Daily that his Queensland Government-owned company had supported the state-of-the-art contract manufacturing facility in order to encourage the growth of the Australian bio-pharmaceuticals industry.

"We are very happy to assist ZZ Biotech establish its clinical development capability in Queensland," Mr Hughes said in a media release.

"Valuable export income is being earned for Australia, not only from the supply contract with Patheon, but also with other local clinical trials services companies," MR Hughes said.

"This deal-flow creates and maintains high quality jobs in advanced manufacturing and other cutting edge disciplines," Mr Hughes said.

The media release said that ischemic stroke was the third leading cause of death and the most common cause of disability in industrialized nations with healthcare costs in the billions of dollars.

Biopharmaceuticals Australia said that ZZ Biotech's modified active protein c (APC) had anti-inflammatory, anti-apoptotic and regenerative activities which aimed to reduce the impact of stroke and ZZ had shown the product to be safe in a phase I trial.

ZZ chief executive officer Kent Pryor said that "the manufacturing campaign at Patheon's Brisbane facility has been successful and will enable ZZ Biotech to complete our phase II stroke study and to commence the pre-clinical animal studies that are a prerequisite for the planned multi-centre human wound-healing studies in Australia and US".

Biopharmaceuticals Australia said that the chronic wound market of diabetic foot ulcers, venous leg ulcers, pressure sores and orthopaedic wounds affected about 1.5 percent of the general population and in the US more than 6.5 million people had lower leg ulcers, with annual treatment cost of more than $25 billion.

ATCOR MEDICAL

Atcor says "a large US national health insurance plan provider" with more than 35 million lives covered will reimburse its Sphygmocor central blood pressure test.

Atcor said that adding the unnamed insurer meant the company had more than 126 million people in the US covered for test reimbursement.

Atcor chief executive officer Duncan Ross said the company was "very pleased with the rate at which health plans are supporting reimbursement for the Sphygmocor test".

"Reimbursement is now provided for doctors covering over 40percent of US insured lives," Mr Ross said.

"This enables tens of millions of patients to benefit from non-invasive central arterial pressure waveform analysis, and supports our commercial launch," Mr Ross said.

Atcor said it was targeting four major metropolitan areas through its specialist sales force supported by a telemarketing campaign.

Atcor was unchanged at 13.5 cents.

OSPREY MEDICAL

Osprey says it had record sales of its Dyevert and Avert x-ray dye reduction systems in the three months to June 30, 2016, but did not quantify the sales.
Osprey said that sales for the three months were up 45 percent compared to the three months to March 31, 2016.
The company said the first sales territory in San Antonio, Texas was profitable or cash-flow breakeven in June 2016, with more than 65 percent of San Antonio hospitals buying from Osprey, equating to 40 percent penetration of chronic kidney disease patients.
Osprey said that the average selling price of Dyevert was $US355 ($A474).
Osprey chief executive officer Mike McCormick said “the continued increases in hospital purchases of the new Dyevert system and encouraging market share growth highlight the strong commercial prospects of Osprey’s products”.
Osprey was up three cents or 13.6 percent to 25 cents.

BLUECHIIP

Bluechiip says an unnamed Australian in-vitro fertilization partner has included its tracking technology in its assistive reproductive technologies storage cassette.
Bluechiip said that the tracking technology was launched at the European Society of Human Reproductive Embryology trade show in Helsinki, Finland.
The company said it was “the first time one of our OEM partners has included Bluechiip’s technology in a tradeshow exhibition”.
Bluechiip chief executive officer Andrew McLellan said the display was “a significant milestone” in its partner strategy.
“The value to the company of our technology being shown in our OEM partners’ products cannot be underestimated,” Mr McLellan said.
“We expect that the underlying products will launch in the market early in calendar year 2017,” Mr McLellan said.
Bluechiip said it had filed a provisional patent, describing the use of Bluechiip tags in systems used to transport biological samples, entitled ‘A system, method and device for transporting, handling and monitoring samples in a temperature-controlled storage environment’.
The company said that the provisional patent strengthened its position and protected the technology that tracked identity and measured temperature at the sample level.
Bluechiip said that the new patent added an additional family of patents to its library of 24 granted and six pending patents across nine patent families.
Bluechiip fell 0.2 cents or 8.3 percent to 2.2 cents.

RESAPP

Resapp has told the ASX that it is not aware of any information it has not announced which, if known, could explain recent trading in its securities.
The ASX said the company’s share price fell 13.5 cents or 35.1 percent from 38.5 cents on July 1, to 25 cents today July 7, 2016, and noted an increase in trading volume.
Resapp said that it previously announced the release of 55,312,500 vendor shares from escrow on July 2, and it was “aware that a significant number of these … shares … have been sold on-market”.
Separately, Uniquest filed a ceasing substantial shareholder notice saying it had sold 17,390,536 shares for $5,523,089 or 31.8 cents share.
Resapp closed up half a cent or 1.7 percent at 29.5 cents with 71.4 million shares traded.

PRIME BIOLOGICS, MEMPHASYS (FORMERLY NUSEP)

Prime Biologics says Singapore's Health Sciences Authority has approved good manufacturing practice certification for the production of albumin from plasma.

The then Nusep, now Memphasys, began the spin-out of Prime in 2012, with some of the original Nusep executive and board moving with Prime to Singapore, followed by issues between the two companies (BD: Oct 15, 2012; Jun 30, 2015; May 17, 2016).

Prime said that the certificate was valid for three years and validated its technology "as a viable pharmaceutical process for the production of plasma products for human use".

The company said that the facility was the first new plasma production process approved by a regulator since the introduction of chromatography in the early 1980s. Prime said that it was "the first plasma product manufactured without any upstream processing of plasma including ethanol precipitation or cryo-precipitation" and the first plasma fractionation facility in South East Asia.

The company said that it aimed to manufacture other plasma based therapeutic proteins and would apply for subsequent regulatory approval for each of these.

Memphasys chair Alison Coutts told Biotech Daily that her company owned "about half the shares in Prime, but they are all non-voting B shares".