Biotech Daily

Tuesday May 19, 2020

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: AMPLIA UP 87%; MESOBLAST DOWN 9%**

*** US COURT DENIES COCHLEAR PATENT APPEAL, TO PAY $429m**

*** AMPLIA: AMP945 WINS FDA ORPHAN STATUS FOR IPF**

*** IMAGION NANOPARTICLES FOR HIV TREATMENT**

*** BTC INFUSION KIT ORDERS FOLLOW ELECTIVE SURGERY RULES**

*** ADMEDUS STARTS ADAPT ANTI-CALCIFICATION RAT TRIAL**

*** M&G REDUCES TO 12.5% OF MESOBLAST**

*** ONEVENTURES APPOINTS DR JOHN WESTWATER, KELLY CONSTABLE**

*** JUSTYN STEDWELL REPLACES LIFESPOT DIRECTOR ANDREAS EMPL**

*** IMPRESSION APPOINTS RUGBY'S JAMES GRAHAM TBI ADVISOR**

*** NOXOPHARM: 'FDA PRE-IND NOX66 FOR COVID-19 TRIAL SUBMISSION'**

MARKET REPORT

The Australian stock market was up 1.81 percent on Tuesday May 19, 2020, with the ASX200 up 99.0 points to 5,559.5 points.

Twenty-one of the Biotech Daily Top 40 stocks were up, eight fell, 10 traded unchanged and one was untraded. All three Big Caps fell.

Amplia was the best, up 7.2 cents or 86.75 percent to 15.5 cents with 3.7 million shares traded. Imugene climbed 13.3 percent; Paradigm was up 7.3 percent; Actinogen improved 5.6 percent; Pharmaxis was up 4.8 percent; Ellex, Immutep, Medical Developments, Pro Medicus and Resonance were up more than three percent; Genetic Signatures, Neuren, Opthea, Prescient, Telix and Uscom rose more than two percent; Clinuvel, Kazia, Orthocell and Proteomics were up more than one percent; with Volpara up 0.4 percent.

Yesterday's 14.25 percent best, Mesoblast, led the falls, down 36 cents or 8.6 percent to $3.81 with 10.7 million shares traded. Patrys lost 7.1 percent; Avita, Cochlear and Compumedics fell three percent or more; CSL, Next Science and Polynovo shed more than one percent; with Cynata, Nanosonics and Resmed down by less than one percent.

COCHLEAR

Cochlear says the US Court of Appeals for the Federal Circuit in Washington, DC has denied its petition for a rehearing of patent infringements appeal.

In March, Cochlear said the Court of Appeals affirmed the US District Court decision in the lawsuit of the Alfred E Mann Foundation for Scientific Research and Advanced Bionics LLC against Cochlear and its US subsidiary Cochlear Americas, ruling that Cochlear must pay $US268 million in patent infringement damages (BD: Mar 17, 2020).

Today, the company said the judgment would be final on May 26, 2020 and was remanded to the District Court for payment of about $US280 million ($A429 million) for the judgment amount and post judgment interest.

Cochlear it expected to make the payment by July 2020 and had bank loans to fund the judgment.

The company said a decision in the US District Court was still pending on the Alfred E Mann Foundation and Advanced Bionics' application for prejudgment interest of $US123 million and attorney's fees of $US15 million, and it opposed both applications and the calculation methodology.

Cochlear said there was significant uncertainty on whether pre-judgment interest and/or costs would be awarded, and/or the amount of any award and therefore the exposure would be treated as a contingent liability.

Cochlear said the patent had expired and the judgment would not disrupt its US business.

Cochlear fell $5.67 or three percent to $183.34 with 297,345 shares traded.

AMPLIA THERAPEUTICS

Amplia says the US Food and Drug Administration has awarded orphan drug designation for AMP945 for idiopathic pulmonary fibrosis (IPF).

Amplia said the designation was the second FDA orphan drug designation for the AMP945 focal adhesion kinase inhibitor, following the March orphan drug designation approval of AMP945 for pancreatic cancer (BD: Mar 25, 2020).

Today, Amplia said the designation meant it would qualify for waived FDA fees, clinical trial protocol assistance and other incentives, along with seven years' market exclusivity, should AMP945 receive US regulatory approval for idiopathic pulmonary fibrosis.

The company said that idiopathic pulmonary fibrosis was caused by the build-up of fibrotic tissue in patients' lungs and affected more than three million people worldwide, including more than 130,000 people in the US.

Amplia said that the two drugs approved for the treatment of idiopathic pulmonary fibrosis, pirfenidone and nintedanib, were able to slow progression of the disease by up to 50 percent, but were not able to treat it.

Amplia said that pre-clinical studies showed that AMP945 was able to both reduce and reverse the formation of fibrotic tissue in the lungs.

The company said it intended to start a phase I clinical trial of AMP945 later this year to confirm that, like other focal adhesion kinase inhibitors, it was well-tolerated, and the trial would provide safety, pharmacokinetic and exploratory pharmacodynamic data to enable phase II trials in cancer and idiopathic pulmonary fibrosis patients in 2021.

Amplia chief executive officer Dr John Lambert said the orphan drug designation "further highlights the extensive opportunities provided by Amplia's pipeline".

"This orphan drug designation for the use of AMP945 to treat patients with [idiopathic pulmonary fibrosis] provides further validation of the pipeline of opportunities we are putting in place for our proprietary [focal adhesion kinase] inhibitors," Dr Lambert said.

Amplia was up 7.2 cents or 86.75 percent to 15.5 cents with 3.7 million shares traded.

IMAGION BIOSYSTEMS

Imagion says researchers at the Weill Cornell Medical College are trialling the use of its nanoparticles for an HIV treatment.

Imagion said that an article, titled 'Neutralizing Antibody Induction by HIV-1 Envelope Glycoprotein SOSIP Trimers on Iron Oxide Nanoparticles May Be Impaired by Mannose Binding Lectin' published in the Journal of Virology showed how iron oxide nanoparticles "could be used in conjunction with viral specific agents to form 'a particulate immunogen' that stimulates the body's immune response through neutralizing antibody induction:.

The full article is available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7158715/.

Imagion executive chairman Bob Proulx said that company was "happy to see new biomedical applications being developed from the commercial sale of our Precision-MRX brand of nanoparticles".

Mr Proulx said that nanoparticles might provide a role in the development of effective treatments for viruses.

"While we remain focused on our goal of developing the nanoparticles for the detection of cancer through our Magsense programs, it is clear there are many potential clinical applications in which our nanoparticles can be applied, and we are keen to identify prospective partners in these areas," Mr Proulx said.

Imagion fell 0.1 cents or 4.35 percent to 2.2 cents with 55.3 million shares traded.

BTC HEALTH (FORMERLY BIOTECH CAPITAL)

BTC says that demand for its speciality health products for hospitals has resumed following the Australian National Cabinet decision to allow elective surgeries.

BTC said that demand for its hospital infusion kit business, acquired from Admedus last year, fell in April following the Covid-19 pandemic shutdown and cancellation of elective surgery (BD: May 31, 2019; Mar 26, 2020).

The company said that the May 15 National Cabinet decision to resume elective surgeries had led to an increase in demand for its products during May and its sales representatives were working with hospitals to support the staged increase in elective surgery.

BTC said there had been no disruptions to its national or internationally supply and distribution of products.

BTC was up 0.6 cents or 8.1 percent to eight cents.

ADMEDUS

Admedus says it has begun a study of 48 rats to compare the anti-calcification properties of its Adapt tissue treatment for cow and pig heart valve substitutes.

Admedus said the study would be conducted at an unnamed facility in Minneapolis, Minnesota and would compare the anti- calcification properties of Adapt to other bovine and porcine tissues that were used in commercially available surgical and transcatheter aortic valve replacement products.

The company said calcification played "a significant role in the failure of bioprosthetic and other tissue heart valve substitutes".

Admedus said that it would implant Adapt and other tissues in 48 rats, which would be processed for histological and calcium or phosphorus analysis after four months.

Admedus chief executive officer Wayne Paterson said that "collecting and building data proving superiority of Adapt tissue against current treatments in the [transcatheter aortic valve replacement] market is an important step towards ultimate commercialization".

Admedus fell 23 cents or 3.1 percent to $7.10.

MESOBLAST

M&G Plc and its subsidiaries say they have reduced their substantial holding in Mesoblast from 73,009,156 shares (13.6%) to 72,470,118 (12.48%).
The London-based M&G said that between December 4, 2019 and May 15, 2020 it bought and sold share with the single largest sale on January 23, 2020 of 334,394 shares for $1,000,104 or $2.99 a share and the single largest purchase on May 15, 2020 of 1,187,500 shares for $3,800,000 or $3.20 a share.
Earlier this month, Mesoblast said it had raised $US90 million ($A138.9 million) in a placement to institutional investors at $3.20 a share (BD: May 13, 2020).
Mesoblast fell 36 cents or 8.6 percent to $3.81 with 10.7 million shares traded.

ONEVENTURES

Oneventures says it has appointed Dr John Westwater as a principal and Kelly Constable as a venture partner and director of investee company Prota Therapeutics.
Oneventures said Ms Constable had more than 20 years' experience in the healthcare sector, was currently the chief executive officer of Aulus Partners and chief strategy officer for oncology clinical trials platform, Omico, as well as a director of Australian National Digital Health and an advisor to New South Wales Health committees.
The company said Dr Westwater had almost 20 years' experience in operational, venture capital and investment roles in the life sciences sector and was previously the chief financial officer of Elastagen.
Onventures said Dr Westwater held a Doctor of Philosophy from Edinburgh's Heriot Watt University.
The company said its healthcare portfolio included the $170 million Healthcare Fund III, which was a licencee of the Australian Government Biomedical Translation Fund.
Oneventures said the fund was investing $10 million to $20 million in companies commercializing medical devices, drugs in clinical development or diagnostics.

LIFESPOT HEALTH

Lifespot says it has appointed company secretary Justyn Stedwell as an interim director, replacing director Andrea Empl.
Lifespot said Mr Empl had resigned from the company.
Lifespot was unchanged at three cents.

IMPRESSION HEALTHCARE

Impression says it has appointed rugby player James Graham to its advisory board to assist with the commercialization of IHL-216A for concussion and traumatic brain injury.
Impression said Mr Graham would advise the company on the development of "real world" aspects of the clinical program for the marijuana-based IHL-216A, to build a relationship and with the Rugby League Players Association, and to develop an arrangement with the National Rugby League for the use of IHL-216A in the competition season.
The company said Mr Graham played for the St George Illawarra Dragons in the National Rugby League, and for England and Great Britain at the international level.
Impression was unchanged at 4.9 cents.

NOXOPHARM

Noxopharm says the US Food and Drug Administration has allowed it to lodge a pre-investigational new drug submission for trial of Veyonda or NOX66 in Covid-19 patients.

Noxopharm said the conversion of a pre-investigational new drug submission into a full investigational new drug application submission was “a new option offered to high priority Covid-19 submissions to reduces the time and complexity of the FDA review process significantly”.

The company previously said that idronoxil, the active ingredient in Veyonda, or NOX66, inhibited “a key inflammatory pathway involved in a process known as a cytokine storm (BD: Apr 1, 21, 2020).

Noxopharm was up one cent or 4.55 percent to 23 cents with 6.4 million shares traded.