Biotech Daily

Thursday March 21, 2019

Daily news on ASX-listed biotechnology companies

*** ASX FLAT, BIOTECH DOWN: AVITA UP 15%; CYNATA DOWN 29%**

*** CYNATA FALLS 43% ON FUJIFILM OPTION EXTENSION**

*** J&J, MONASH WORK ON INHALED OXYTOCIN**

*** COMPUMEDICS $1.4m US ADVENTIST MONITOR DEAL**

*** ALCIDION $1m PATIENTRACK DEAL WITH UK HOSPITALS**

*** BIOCELECT, 60 DEGREES KODATEF FOR MALARIA IN AUSTRALIA**

*** TELIX, CYCLOTEK COMPLETE VISACT MANUFACTURE**

*** PRESCIENT REQUESTS CAPITAL RAISING TRADING HALT**

*** MEDIBIO REVIEWS HEART-MENTAL ILLNESS FDA SUBMISSION**

*** SPILL CALL SHAREHOLDERS TAKE 19.97% OF FACTOR**

*** FMR BELOW 5% OF RESMED**

*** INVICTUS APPOINTS PROF ED GANE ADVISOR**

MARKET REPORT

The Australian stock market edged up 0.03 percent on Thursday March 21, 2019, with the ASX200 up 1.9 points to 6,167.2 points. Fourteen of the Biotech Daily Top 40 stocks were up, 17 fell, six traded unchanged and three were untraded.

Avita was the best, up three cents or 15.4 percent to 22.5 cents, with 28.6 million shares traded. Compumedics climbed 10.6 percent; Immutep improved 6.25 percent; LBT was up 5.1 percent; Actinogen, Airxpanders, Ellex, Genetic Signatures and Oncosil were up more than three percent; Clinuvel and Kazia rose more than two percent; Nanosonics and Polynovo were up more than one percent; with Mesoblast and Resmed up by less than one percent.

Cynata led the falls (see below), closing down 52 cents or 29.4 percent at $1.25, with 3.1 million shares traded. Patrys lost 11.5 percent; Imugene was down 9.5 percent; Paradigm and Proteomics retreated more than seven percent; Impedimed, Osprey and Volpara fell more than four percent; Benitec, Orthocell, Pro Medicus and Uscom were down more than three percent; Antisense and Optiscan shed more than two percent; with Cochlear, CSL, Medical Developments, Neuren and Opthea down by less than one percent.

CYNATA THERAPEUTICS

Cynata fell as much as 43 percent on news that its licence with Fujifilm for CYP-001 for graft-versus-host disease (GvHD) has been extended to September 19, 2019.
In 2016, Cynata signed a $60 million agreement with Fujifilm for CYP-001 for graft-versus-host disease and its Cymerus stem cell technology (BD: Jan 22, 2017).
In December, Cynata said Fujifilm had 90 days to exercise the licence option that was today extended (BD: Dec 18, 2018).
Cynata chief executive officer Dr Ross Macdonald said "the purpose of this extension is to enable the parties to seek to accommodate certain requests made by Fujifilm in relation to structural aspects of the GvHD licence agreement".
"We note that Fujifilm has not raised any material issues in respect of the financial, clinical or technical aspects of CYP-001 or Cynata's core Cymerus technology generally," Dr Macdonald said.
Dr Macdonald told Biotech Daily that the company was "not negotiating any changes to those material terms and no changes have been agreed".
Cynata fell as much as 76 cents or 42.9 percent to $1.01, before closing down 52 cents or 29.4 percent at $1.25, with 3.1 million shares traded.

JOHNSON & JOHNSON, MONASH INSTITUTE OF PHARMACEUTICAL SCIENCES

Johnson & Johnson says it is working with Melbourne's Monash University to develop an inhaled version of oxytocin to prevent and manage complications of pregnancy.
Johnson & Johnson said subsidiary Janssen Pharmaceutica was working on the oxytocin for post-partum haemorrhage with the Monash Institute of Pharmaceutical Sciences.
The company said post-partum haemorrhage or excessive blood loss after birth, was the leading cause of maternal mortality, causing an estimated 60,000 deaths a year, especially in third-world countries.
Johnson & Johnson said that most deaths from post-partum haemorrhage "could be avoided if access to suitable medical innovation were available … [and was] effectively managed in developed countries using the gold standard therapy, oxytocin, a manufactured form of a natural hormone" but was only available in an injectable form requiring refrigeration.
Johnson & Johnson said the agreement built on a 2014 MIPS' collaboration with Glaxosmithkline to formulate the dry powder, inhaled oxytocin and eliminate the need for refrigerated storage conditions.
Johnson & Johnson Innovation Australia and New Zealand new ventures director Kathy Connell said the agreement "builds on our legacy of innovative academic-industry collaborations in Australia focused on developing life-saving treatments for the highest unmet needs".

COMPUMEDICS

Compumedics says it will supply brain monitoring equipment to the Roseville, California-based Adventist Health System with an initial $1.4 million order.
Compumedics said it would supply its sleep, neurological and brain monitoring systems to Adventist's 48 hospital campuses in 10 US states.
The company said the initial $1.4 million order was from an Adventist affiliated hospital in Tampa, Florida for its systems including the Grael product platform, Nexus360 and Neuvo systems and it had shipped and installed 19 epilepsy-monitoring systems hospital.
Compumedics was up 3.5 cents or 10.6 percent to 36.5 cents.

ALCIDION GROUP

Alcidion says it has a five-year contract to supply its Patientrack technology to England's Brighton and Sussex University Hospitals National Health Service Trust.
Alcidion said it would implement Patientrack to improve patient care and safety in the GDP574,000 ($A1.03 million) deal.
The company said the Trust had four hospitals, was a major trauma centre for south east England and delivered specialist and tertiary services.
Alcidion fell 0.3 cents or five percent to 5.7 cents with 7.7 million shares traded.

BIOCELECT

Biocelect says the Washington, DC-based 60 Degrees Pharmaceuticals' tafenoquine succinate, or Kodatef, for the prevention of malaria is available to customers in Australia.
Last year, Biocelect said the Australian Therapeutic Goods Administration approved tafenoquine as a prophylaxis for malaria (BD: Sep 20, 2018).
The company said 60 Degrees developed the drug with the US Walter Reed Army Institute of Research and was partnering with Biocelect to provide Kodatef in Australia.
Today, Biocelect said the first shipments of Kodatef had arrived in Australia and would be the launched in the US under a different name in the summer of 2019.
The company said one dose of Kodatef was required prior to travel, weekly while travelling in malaria affected areas and one final dose on return.
Biocelect is a private company.

TELIX PHARMACEUTICALS

Telix says that Melbourne's Cyclotek has completed manufacturing Visact, its immune-positron emission tomography imaging tracer for tumors.
Telix said that Visact, or 18-fluorine-9-beta-D-arabinofuranosyl-guanine, or 18-F-AraG, was suitable for clinical use and could "take a snapshot of how the immune system is responding to therapy".
The company said it would use Visact "to image immune response and determine when best to cycle between therapies" and said there were "multiple collaborative clinical trials" showing the potential of the technology in immune-oncology.
Telix chief executive officer Dr Christian Behrenbruch said the company was "keen to take a licence to Visact because of our kidney cancer glioblastoma brain cancer therapy programs".
"A vitally important part of the treatment response mechanism of targeted radiation relates to the mobilization of the immune system," D Behrenbruch said.
"In particular, Telix's TLX250 program will be further developed as a combination therapy with checkpoint inhibitor drugs such as Bristol-Myers Squibb's Opdivo [anti-programmed cell death-1 antibody] so we need to know when the immune system is properly primed to give the best combined treatment effect," Dr Behrenbruch said.
Telix was unchanged at 65.5 cents.

PRESCIENT THERAPEUTICS

Prescient has requested a trading halt "pending an announcement by the company to the market regarding a proposed material capital raising".
Trading will resume on March 25, 2019 or on an earlier announcement.
Prescient last traded at 5.6 cents.

MEDIBIO

Medibio says that a de novo submission to the US Food and Drug Administration for its heart rhythm test for mental illnesses “has shortcomings” and is under review.
Medibio said the de novo submission was being reviewed, the company was “assessing the most appropriate way forward” and the FDA was helping guide it through the process.
The company said its regulatory focus continued to be on one or more 510(k) submissions to the FDA, with clearance expected by July 2019, leading to a US commercialization strategy by the end of 2019, and initial commercialization would be based “primarily around physician prescribed inpatient sleep studies”.
The company said it was finalizing the details of a sponsored research agreement with a European university and/or hospital system, with an announcement “expected soon”.
Medibio was up 0.2 cents or 13.3 percent to 1.7 cents.

FACTOR THERAPEUTICS

The shareholders who called for a Factor board spill say they have increased their shareholding from 202,683,121 shares (19.44%) to 208,183,121 shares (19.97%).
Last month, the shareholders requested a board spill to replace chair Dr Cherrell Hirst and directors Tim Hughes and John Michailidis with Bruce Lane and David Sanders, with the meeting due to be held on March 29, 2019 (BD: Feb 5, Feb 22, 2019).
Today’s notice said that David Neesham, Pamela Christine Neesham, and Alitime Nominees bought 2,000,000 shares each at 0.4 cents a share and Perth’s Pura Vida Energy NL said it acquired 1,500,000 shares at 0.4 cents a share.
Factor was unchanged at 0.4 cents with 1.45 million shares traded.

RESMED

Fidelity Management & Research (FMR) says it has ceased to be a substantial shareholder in Resmed, from 8,552,087 shares (6.03%) to 7,031,701 shares (4.91%).
The Boston-based FMR said it bought 3,098,148 shares and sold 4,665,953 shares in more than 50 pages of trades between November 16, 2017 and March 18, 2019.
Resmed was up three cents or 0.2 percent to $13.91 with 2.3 million shares traded.

INVICTUS BIOPHARMA

Invictus says it has appointed hepatologist Prof Ed Gane to its scientific advisory board.
Invictus said Prof Gane would help guide the development of the protocols for the pending phase II study for non-alcoholic fatty liver disease and non-alcoholic steatohepatitis”.
The company said Prof Gane was a professor of medicine at the University of Auckland, New Zealand and the Auckland City Hospital liver unit deputy director.
Invictus said that Dr Gane was an investigator on many clinical trials, had published more than 300 peer-reviewed papers in journals including The Lancet and the New England Journal of Medicine and held a Doctor of Philosophy from King’s College London.
Invictus is a public unlisted company.