Biotech Daily

Wednesday October 10, 2018

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH EVEN: PARADIGM UP 6%; REVA DOWN 12%**

*** COCHLEAR INVESTIGATES 'FULLY IMPLANTABLE' HEARING AID**

*** CLINUVEL UK NICE SCENESSE EPP DECISION 'REMITTED'**

*** TELIX, GENESISCARE TLX101 GLIOBLASTOMA COMPASSIONATE USE**

*** CHILDRENS HOSPITAL FOUNDATION $10m FOR BRAIN CANCER**

*** MTP CONNECT $690k FOR THREE PROJECTS**

*** ACTINOGEN RECEIVES $3.2m FEDERAL R&D TAX INCENTIVE**

*** KAZIA COMPLETES CANTRIXIL OVARIAN CANCER DOSE ESCALATION**

*** IMPEDIMED STARTS US SOZO HEART FAILURE TRIAL**

*** ZELDA BEGINS US MARIJUANA AUTISM TRIAL**

*** QUEENSLAND BAUXITE'S MEDCAN WINS MARIJUANA LICENCES**

*** IMMURON 437k DIRECTOR SHARES, 2m OPTIONS, 43% FEE POOL AGM**

*** CORRECTION: MGC**

*** LGC DILUTED BELOW 5% IN BLUECHIIP**

*** MEDADVISOR APPOINTS JAMES ROTSART, LUCAS MERROW ADVISORS**

MARKET REPORT

The Australian stock market recovered 0.14 percent on Wednesday October 10, 2018 with the ASX200 up 8.7 points to 6,049.8 points. Fourteen of the Biotech Daily Top 40 stocks were up, 15 fell, six traded unchanged and five were untraded.

Paradigm was the best, up 4.5 cents or 6.1 percent to 78 cents with 22,929 shares traded. Both Imugene and Osprey climbed 4.8 percent; Cochlear, Cynata, Telix and Uscom were up more than three percent; Orthocell and Prescient rose more than two percent; Clinuvel, CSL, Mesoblast, Nanosonics and Polynovo were up more than one percent; with Opthea and Volpara up by less than one percent.

Reva led the falls for the second day in a row, down three cents or 12.0 percent to 22 cents, with 50,000 shares traded. Impedimed and Pharmaxis lost more than six percent; Medical Developments was down 5.2 percent; both Avita and Universal Biosensors fell 4.2 percent; Dimerix was down 3.1 percent; Actinogen, Factor, Immutep and Oncosil shed two percent or more; Resmed and Starpharma were down one percent or more; with Genetic Signatures, Neuren and Pro Medicus down by less than one percent.

COCHLEAR

Cochlear says it has renewed research and development of a “totally implantable cochlear implant” and has started an 11-patient Australian feasibility study.

Cochlear said the development of totally implantable cochlear implant technology was complex and a commercially available product was not expected for years, but it was one of the company’s long-term development goals.

The company said that a further, single-site, feasibility study had begun to evaluate the totally implantable technology and would collect safety and performance data of a fully implantable cochlear device to be used with and without an externally-worn sound processor to provide people with 24-hour hearing.

Cochlear said that in 2005 it conducted initial clinical research on three patients with the first-generation investigational device.

A 2008 research article, titled ‘Initial clinical experience with a totally implantable cochlear implant research device’ co-authored by the Royal Victorian Eye and Ear Hospital’s Prof Robert Briggs was published in Otology and Neurotology.

An abstract is available at: https://www.ncbi.nlm.nih.gov/pubmed/17898671 .

The 2005 study of three patients concluded that “the challenges in developing a safe and effective [totally implantable cochlear implant] can be overcome”.

The study concluded that all three subjects “reported benefit from routine use … [and] for each subject, hearing outcomes using invisible hearing mode were not as good as when using the external Esprit 3G [behind-the-ear] sound processor in the conventional mode”.

Today, Cochlear said the new study would obtain preliminary efficacy evidence, collect additional safety data and compare clinical outcomes before and after an intervention.

The company said the study technology differed from existing devices and included an implanted microphone, an implanted rechargeable battery, and an implanted processor.

Cochlear said that patients could choose between using an external sound processor, or taking it off and relying on the implanted microphone and internal sound processor, while still maintaining hearing function.

The company said the study’s principal investigators were Prof Briggs, leading the surgical team, and the Hearing Co-operative Research Centre’s Prof Robert Cowan, leading the non-surgical team.

“A long-term goal of research in this area is to provide totally implantable cochlear implant technology that will enable people to hear with and without any externally worn components, helping them to have useful hearing 24 hours a day,” Prof Briggs said.

Cochlear said that, to date, it was “the only company that has reported studies of totally implantable cochlear implant technology” and following the acquisition of implantable microphone technology in 2012, it was able to further develop the technology.

Cochlear chief technology officer Jan Janssen said the company “leads the industry in investing in research and development to innovate and transform the lives of those living with hearing loss”.

“Totally implantable cochlear implant technology is an exciting area of product development for Cochlear,” Mr Janssen said. “However, we remain in the very early stages, and given the remaining technical, clinical and regulatory requirements, the technology is not expected to be commercially available for years.”

“Cochlear implants provide significant benefit for people with severe to profound hearing loss,” Prof Briggs said. “Anyone with hearing loss who is considering a cochlear implant today should not delay accessing treatment now … [because] hearing loss is linked with greater unemployment, increased risk of poor health, depression and increased risk of other conditions including dementia.”

Cochlear climbed $6.24 or 3.25 percent to $198.12 with 255,272 shares traded.

CLINUVEL PHARMACEUTICALS

Clinuvel says a UK appeal panel has called for a review of the final decision not to reimburse Scenesse, or afamelanotide 16mg, for erythropoietic protoporphyria.

Clinuvel said that on July 30, 2018, an independent panel heard its appeal against the National Institute of Health and Care Excellence (NICE) highly specialized technology (HST) committee's final decision in May not to recommend Scenesse for use by the English National Health Service for adult patients with the rare metabolic disorder erythropoietic protoporphyria (EPP) (BD: May 23, 2018).

The company said its appeal claimed that when NICE decided not to recommend Scenesse for reimbursement for EPP patients it failed to act fairly, exceeded its powers and made an unreasonable decision in light of the evidence.

The company said the appeal panel decided that the May 22 decision by NICE was to be "remitted" to the HST Committee, or to be set aside pending a review.

Clinuvel said the appeal panel decided that the HST Committee "must now take all reasonable steps to address": its failure to include an International Porphyria Patient Network representative from the second HST Committee meeting; its failure to demonstrate adequate consideration of the legal duties and obligations placed on it under the Equality Act (2010); and "the appeal panel's conclusion that it was unreasonable for the Committee to state that the trial results show small benefits with Scenesse".

The company said the appeal panel considered it likely the Committee should include consideration of "whether the methodology used to evaluate of Scenesse discriminates against patients with EPP and if so what reasonable adjustments should be made".

Clinuvel said it made its appeal with three other organizations representing erythropoietic protoporphyria patients and expert physicians, and while there was no further avenue for appeal through the NICE process, consultees had up to three months to apply to the UK High Court for judicial review.

Clinuvel European general-manager Lachlan Hay said the appeal was "the first step to make Scenesse available to British EPP patients and … we are now keen to understand how the committee will engage with the remit it has been provided by the appeal panel".

"The findings of the appeal panel show that the NICE HST Committee failed to discharge some of its functions properly in evaluating Scenesse and to use an adequate methodology in the case of this disease entity," Mr Hay said.

Clinuvel was up 23 cents or 1.2 percent to $19.73 with 123,851 shares traded.

TELIX PHARMACEUTICALS

Telix says it has a strategic collaboration agreement with Genesiscare Pty Ltd for oncology services in Australia and Europe.

Telix said that the Sydney-based Genesiscare was "the largest private provider of oncology services in Australia and Europe" and the two entities had established "a preferred clinical provider relationship" for radiation oncology studies in Australia for the inclusion of patients into its multi-centre trials in neuro-oncology and urologic oncology.

Telix said it would partner with Genesicare for compassionate use access to its TLX101 glioblastoma program and the companies would explore the commercial potential of Telix's products in China.

Telix chief executive officer Dr Christian Behrenbruch said that Genesiscare had "both patient access and geographic reach in radiation oncology".

Genesiscare chief executive officer Dan Collins said collaborations could advance clinical trials, make treatments available more quickly and improve outcomes for patients.

Telix was up three cents or 3.9 percent to 80 cents.

FEDERAL GOVERNMENT

The Federal Government says that the Children's Hospital Foundation Queensland has committed $10 million to a children's brain cancer research centre.
A media release from the Federal Minister for Health Greg Hunt said the Children's Hospital Foundation's commitment brought the total invested in the Federal Government's Australian Brain Cancer Mission to $105 million.
Minister Hunt's office said $55 million came from the Federal Government's Medical Research Future Fund, $20 million from the Cure Brain Cancer Foundation, $10 million from the Minderoo Foundation's Eliminate Cancer Initiative, $5 million from Carrie's Beanies For Brain Cancer and $3 million from the Mark Hughes Foundation.
The Government said the Brain Cancer Mission was coordinated by Cancer Australia and aimed to "double survival rates and improve the quality of life of people living with brain cancer over the next 10 years, with the longer-term aim of defeating brain cancer".
Mr Hunt said that an objective of the Brain Cancer Mission was to ensure every adult and child patient had the opportunity to participate in clinical trials.
The media release said that this would be achieved by "investing in more clinical trials, ground-breaking research, further international collaborations, expanding research platforms and fostering the talents of researchers".

MTP CONNECT

MTP Connect says $690,000 has been awarded to three life science projects to support researchers, improve industry collaboration and open market opportunities.
MTP Connect chief executive officer Dr Dan Grant said the funding had been awarded to the Industry Mentoring Network in Science, technology, engineering and mathematics (IMNIS), the Medical Device Partnering Program (MDPP) and Asialink Business.
A media release from the Federal Government-funded MTP Connect said that IMNIS was a project that linked doctoral students with industry experts to narrow the cultural gap between business and academia.
MTP Connect said MDPP at Adelaide's Flinders University had developed new medical devices, "streamlining the … process of bringing new products to market and creating new commercial opportunities for traditional and local manufacturers in South Australia".
The media release said Asialink Business would assist Australian medical technology and pharmaceutical companies realize commercial opportunities in Asia.
MTP Connect said Asialink Business would develop two guides: 'Digital Health in Indonesia' and 'Frugal Innovation in Medical Devices and Technologies in India' and would also develop a report on "the current levels of Asia-capability of boards and senior executives of ASX-listed health care equipment and services companies".
Dr Grant said that "each of these projects, IMNIS, MDPP and Asialink Business, is characterized by increased collaboration between research and industry, a focus on achieving commercial outcomes and building the capacity of Australia's health tech community to take its ideas and products to the world".

ACTINOGEN MEDICAL

Actinogen says it has received $3,158,000 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.
Actinogen said the rebate related to research and development expenditure for the year to June 30, 2018.
Actinogen fell 0.1 cents or two percent to 4.9 cents.

KAZIA THERAPEUTICS

Kazia says it has completed the dose-escalation stage of its 14-patient phase I study of Cantrixil for ovarian cancer.
Kazia said that 11 of the 14 patients in the trial were well enough to receive treatment and it determined a maximum tolerated dose of 5.0mg/kg.
The company said the second stage of the trial would recruit a further 12 patients to find preliminary evidence of efficacy, expected to conclude in 2019.
Kazia said the most common side effects were abdominal pain, fatigue, and vomiting.
Kazia was unchanged at 45 cents.

IMPEDIMED

Impedimed says it has enrolled the first of 200 patients for its US, multi-site, at-home trial of Sozo bio-impedance spectroscopy for heart failure.
Impedimed said the study would investigate how changes in Sozo measurements pre-empt patient-reported symptoms of acute heart failure leading to hospital readmission in the 45 days after discharge from a heart failure related hospital admission.
Impedimed chief executive officer Richard Carreon said the company was “very pleased to have begun enrollment in this clinical trial, which will further build on the data already being generated in various independent trials of Sozo in heart failure”.
The company said Sozo had US Food and Drug Administration clearance and Conformité Européenne (CE) mark approval for use in heart failure patient monitoring and the data from the trial would be used to support marketing efforts.
Impedimed fell three cents or 6.4 percent to 44 cents.

ZELDA THERAPEUTICS

Zelda says it has begun recruitment for its about 100-patient US trial of marijuana-based compounds for paediatric autism.
Zelda said that the “observational trial” was being conducted at Pennsylvania’s Children’s Hospital of Philadelphia and sought to understand the efficacy of medical cannabis treatment in existing autism patients.
The company said that 15 patients had been enrolled and preliminary results were expected by July 2019.
Zelda said that the study would “lay the groundwork for a possible future clinical trial to generate high quality, robust and acceptable data to validate the existing anecdotal data amongst patient populations”.
The company said that “the ultimate goal is to identify cannabinoid-based compounds that may demonstrate efficacy in the treatment of paediatric autism”.
Zelda was unchanged at 6.8 cents.

QUEENSLAND BAUXITE

Queensland Bauxite says its “soon to be wholly owned subsidiary” Medcan Australia has won an Australian Office of Drug Control medical cannabis manufacture licence.
Queensland Bauxite said the licence would allow Medcan to manufacture its marijuana products and it had also secured a Queensland Health licence allowing for the storage of Schedule 9 substances including cannabis seeds and a Federal Department of Agriculture and Water Resources permit allowing for the importation of cannabis seeds.
Queensland Bauxite was in a suspension and last traded at 3.7 cents.

IMMURON

Immuron investors will vote to issue 437,500 shares to Grandlodge, 2,000,000 options to director Richard Berman and increase the directors fee pool by 42.9 percent.
Immuron said it proposed to grant 473,500 shares to related party Grandlodge "for the provision of management, sales, logistics, warehouse and marketing services".
The company said that Grandlodge Pty Ltd was associated with executive vice-chairman Peter Anastasiou and director Stephen Anastasiou.
The company said it proposed to issue 2,000,000 options to Mr Berman exercisable at 50 cents or 56 percent above the share price on the date of issue, expiring on June 30, 2020.
Immuron's notice of meeting said it would also seek shareholder approval to increase the directors' annual fee pool from $350,000 to $500,000 to "provide the board with the ability to appoint additional directors … [and] ensure the company maintains the ability to pay non-executive directors' remuneration at levels commensurate with market rates".
The meeting will be held at Level 2, 62 Lygon Street, Carlton, Melbourne, on November 19, 2018 at 3:30pm (AEDT).
Immuron was unchanged at 29.5 cents.

CORRECTION: MGC (MEDICAL GRADE CANNABIS) PHARMACEUTICALS

Last night's edition carried the headline: MGC requests 'Canada marijuana deal' trading halt, which should have been 'MGC requests TGA marijuana application' trading halt.
The mistake was made by the Cannabis Corner sub-editor who has been sent to Headline Writing Rehab.
MGC last traded at 5.1 cents.

BLUECHIIP

LGC Superannuation Fund says its 24,371,369 share-holding in Bluechiip has been diluted below the five percent substantial threshold.
Last week, Bluechiip said it had raised $1.95 million in a share plan, adding to the September $5.5 million placement (BD: Sep 10, Oct 3, 2018).
In a substantial shareholder notice issued today, LGC director Laurence G Cox said it did not purchase any shares in the placement.
Bluechiip was up 0.2 cents or 3.45 percent to six cents.

MEDADVISOR

Medadvisor says it has appointed James Rotsart and Lucas Merrow as advisors for its expansion into the US market.
Medadvisor said Mr Rotsart was Adheris head of sales and marketing for its "direct-to-patient medication adherence program" and was previously an executive with US pharmacy chains D S Revco and Brooks Drugs.
The company said that Mr Merrow was Eliza Corporation chief executive officer and chief technology officer, and was a cofounder of Adheris.
Medadvisor was up 0.1 cents or 2.7 percent to 3.8 cents.