Biotech Daily

Tuesday May 2, 2017

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: DIMERIX UP 17%, LIVING CELL DOWN 8%**

*** VICTORIA BUDGET: $34m FOR RESEARCH, WEHI DRUG DISCOVERY**

*** ADMEDUS PRODUCES CARDIOCEL 3D CARDIAC PATCH**

*** 'IRRATIONAL' NICE DECISION DELAYS CLINUVEL SCENESSE 16 MONTHS**

*** BIOTRON: 'NATURE ARTICLE BACKS MACROPHAGE APPROACH'**

*** USPTO REVIEWS ACRUX COMPETITOR ANTIFUNGAL PATENT**

*** ISO ACCREDITATION FOR ITL'S MYHEALTHTEST**

*** CRESO PARTNER HEALTH HOUSE IMPORTS 1st MEDICAL MARIJUANA**

*** MGC, RMIT COLLABORATE ON MARIJUANA GENETICS, CULTIVATION**

*** PANCANN TO BACK MMJ MARIJUANA GROWING EXPANSION**

*** NOXOPHARM: '6 NEW CANCER TRIALS IN 6 MONTHS'**

*** BIOCURATE APPOINTS DR GLENN BEGLEY CEO**

MARKET REPORT

The Australian stock market slipped 0.1 percent on Tuesday May 2, 2017 with the ASX200 down 6.1 points to 5,950.4 points. Nine of the Biotech Daily Top 40 stocks were up, 22 fell, eight traded unchanged and one was untraded.

Dimerix was the best, up 0.1 cents or 16.7 percent to 0.7 cents, with one million shares traded. Admedus and Benitec climbed more than five percent; Starpharma rose 2.8 percent; Atcor, Medical Developments and Mesoblast improved more than one percent; with Clinuvel, Cochlear, CSL and Nanosonics up by less than one percent.

Living Cell led the falls, down one cent or 7.7 percent to 12 cents with one million shares traded. Factor Therapeutics and Prana lost five percent or more; Actinogen, Oncosil and Universal Biosensors fell four percent or more; Airxpanders, Cellmid, Prima and Reva were down more than three percent; Genetic Signatures and Orthocell shed more than two percent; Avita, Compumedics, Neuren, Opthea, Osprey, Pharmaxis and Viralytics were down more than one percent; with Ellex, Impedimed, Pro Medicus and Resmed down by less than one percent.

VICTORIA GOVERNMENT

The Victoria Government Budget announced by Treasurer Tim Pallas included just two measures directly affecting the biotechnology and innovation sectors.

According to a spokesperson for the Minister for Health Jill Hennessy and Budget Paper No. 3, the Government allocated $34.2 million over four years to the Operational Infrastructure Support program to provide “support to medical research institutes to cover the operational costs of research”.

“This will provide greater certainty to the medical research sector, leverage grant opportunities, and ensure the future growth of health and medical research in Victoria,” the Budget Paper said.

The State Budget said that the Walter and Eliza Hall Institute would be funded for one year “to explore expansion opportunities in Victoria and nationally for a National Drug Discovery Centre, which will accelerate the translation of research into new drugs”.

A spokesman for the Minister for Small Business, Innovation and Trade Philip Dalidakis told Biotech Daily that there was “no new money … announced for the biotech and innovation sectors in today's budget as the Victorian Government focused on other pressing priorities”.

“The Victorian Government remains committed to helping the State's world leading medical technologies, biotechnologies and pharmaceuticals sector to grow and driving innovation through the Future Industries Fund, Launchvic - the Government's $60 million start-up initiative – [and other] programs,” the spokesman said.

“The Victorian Government is continuing to support the sector with the implementation of the Medical Technologies and Pharmaceuticals Sector Strategy, already investing in major initiatives including Biocurate and the Medicines Manufacturing Innovation Centre,” the spokesman said.

ADMEDUS

Admedus says it has US Food and Drug Administration 510(k) clearance to market Cardiocel 3D in the US, effective immediately.

Admedus said there were “virtually no flat surfaces in the vascular or cardiac structure” and the 60-degree-shaped collagen product targeted complex neo-natal arch and pulmonary artery repair, intended to optimize suturing of central and extra-cardiac shunts.

The company said its dimensions and specifications were designed to join the triple plane anatomy found in neonatal arch and pulmonary artery repairs.

Admedus chief executive officer Wayne Paterson said that the approval was “an important accomplishment for Admedus as we expand our Adapt tissue engineering portfolio”.

The company said that Cardiocel 3D was designed for surgeons and patients who required more than a single dimension patch material to optimize cardiac and vascular repair.

Mr Paterson said that Cardiocel 3D was “a high need product which meets an unaddressed demand … [and] is the first product of its kind in a market where there are presently no off-the-shelf competing solutions”.

“This is a major development in our strategy to increase Admedus’ market share in the strategically important congenital heart surgery and valve repair segments,” he said.

Admedus said that the first human use of the product was expected in June 2017 with a planned US launch between July and the end of 2017.

The company said that the first Cardiocel 3D units were being manufactured at its Perth, Western Australia facility, with plans to scale-up production.

Admedus was up two cents or 5.5 percent to 38.5 cents with 3.7 million shares traded.

CLINUVEL PHARMACEUTICALS

Clinuvel says the UK Department of Health has re-designated Scenesse for regulatory approval, costing patients and the company at least 16 months of access to the drug.
Clinuvel said that the re-classification of Scenesse, or afamelanotide 16mg, for erythropoietic protoporphyria (EPP) to be evaluated as a "highly specialised technology" acknowledged that the UK National Institute for Health and Care Excellence (NICE) "committed an error in its earlier assessment of Scenesse as only eligible for review under a single technology appraisal, a mainstream appraisal pathway".
The company said the highly specialised technology referral had been accepted by the UK Secretary of State for Health for adult patients with EPP and NICE's timelines for the start of the drug's formal review would be released shortly.
Clinuvel said that should NICE recommend Scenesse at the end of the highly specialised technology appraisal it would then be made available for adult EPP patients under the National Health Service in England.
The company said that the Institute originally recommended that Scenesse be evaluated under its usual mainstream evaluation pathway, rather than as a highly specialised technology, with the review finalised in May 2018 at the earliest, but the company "strongly and repetitively challenged NICE's decision … [saying that] NICE's erroneous conclusions had been based on incorrect underlying assumptions".
The company said that NICE had admitted its error and Scenesse would be evaluated under the highly specialised pathway, with a second submission to be made by July 2017.
Clinuvel chief executive officer Dr Philippe Wolgen said that "unfortunately the complexity of the proposed therapy in a poorly understood genetic disease led to a less than expected rigour in the review processes by NICE".
"The case in the UK has shown once again that our teams will challenge unsubstantiated and irrational decisions in any jurisdiction," Dr Wolgen said.
Dr Wolgen said British patients and Clinuvel had lost a minimum of 16 months of access.
Clinuvel was up five cents or 0.7 percent to $6.85.

BIOTRON

Biotron says that an article published in Nature Medicine supports its approach of targeting HIV cells in macrophage reservoirs with BIT225.
Biotron said the paper "validates Biotron's approach" with the independent study reporting that humanized mice infected with HIV-1 established persistent infection of virus in tissue macrophages despite treatment with anti-retroviral therapy.
The study, entitled 'HIV persistence in tissue macrophages of humanized myeloid-only mice during antiretroviral therapy' was published in Nature Medicine, with an abstract available at: https://www.nature.com/nm/journal/vaop/ncurrent/full/nm.4319.html.
Biotron quoted the study saying that "one major barrier to eradication [of HIV-1] is that the virus infects multiple cell types that may individually contribute to HIV persistence [and] tissue macrophages are critical contributors to HIV pathogenesis".
Biotron managing-director Dr Michelle Miller said that the study "upholds Biotron's approach to treatment of HIV-1 infection".
"BIT225 specifically targets HIV-1 in macrophages," Dr Miller said. "This … study clearly demonstrates the need for new drugs to eradicate virus in this persistent reservoir."
Biotron said it was conducting a phase II trial of BIT225 with anti-retroviral therapy targeting HIV-1 in macrophage reservoirs expected to be completed by October 2017 with preliminary results "shortly thereafter".
Biotron was unchanged at 3.5 cents.

ACRUX

Acrux says the US Patent and Trademark Office is reviewing a patent owned by Kaken Pharmaceutical and licenced to Valeant on anti-fungal compounds for onychomycosis.
Last year, Acrux filed its own patent application entitled 'Topical Antifungal composition and Method for treatment of Fungal Infections' covering ACR-065 which it said was an improved formulation of Jublia, containing the anti-fungal agent efinaconazole for fungal infection of the nail bed in toes and fingers, or onychomycosis; and the next day filed a petition to institute an inter partes review of US patent number 7,214,506, entitled 'Method for treating onychomycosis' owned by Kaken (BD: Nov 2, 3, 2016).
The company said at that time that the alleged Kaken invention covered the use of various anti-fungal compounds, including efinaconazole, for the treatment of onychomycosis.
Today, Acrux said that the USPTO had instituted an inter partes review proceeding it filed against US patent 7,214,506 owned by the Tokyo, Japan-based Kaken Pharmaceutical Co and licenced to the Laval, Quebec-based Valeant Pharmaceuticals International.
Acrux said that with the review initiated, the USPTO would issue a scheduling order which was expected to result in a final written decision within 12 to 18 months.
Last year, the company said that an inter partes review was a procedure for challenging the validity of a granted US patent and if the review was instituted, the process provided a relatively cost effective and short duration option to invalidate a granted patent in the US.
Acrux said that lodging the petition was an "important step in Acrux' patent strategy to enter the onychomycosis space".
Acrux was unchanged at 27 cents.

ITL HEALTH GROUP

ITL says its Myhealthtest division has International Standards Organisation accreditation for its direct to consumer pathology testing laboratory.
ITL said the Myhealthtest division had been accredited to the ISO15189 and National Pathology Accreditation Advisory Council standards by the National Association of Testing Authorities and the Royal College of Pathologists of Australasia.
The company said that accreditation was required by July 1, 2017 for test laboratories to be compliant with a new medical devices regulatory regime for in-vitro diagnostics administered by Australia's Therapeutic Goods Administration, and accreditation would enhance partners ability to market the test and enable Australian Medicare rebates.
The company said that along with the existing HbAc1blood glucose test it was working on test panels for prostate, thyroid and cardiac disease (BD: Apr 29, Jul 14, 2015).
ITL was untraded at 60 cents.

CRESO PHARMA

Creso says that Australian partner Health House International has imported its first medicinal cannabis products.
Creso said that the import was a range of three cannabis oils for human health from Canadian medical cannabis group, Cannimed.
The company said that the oils would be used for a variety of conditions as approved by prescribing physicians under Australian Federal and State laws and regulations.
Creso chairman Boaz Wachtel said the first import of medicinal cannabis was "an unprecedented achievement for both Creso Pharma and Health House International, and a ground-breaking moment for patients and the medicinal cannabis industry in Australia".
Creso fell 3.5 cents or 5.6 percent to 59 cents with 2.5 million shares traded.

MGC (MEDICAL GRADE CANNABIS) PHARMACEUTICALS

MGC says it will work with the Royal Melbourne Institute of Technology to research marijuana, initially centred on genetics and cultivation.
MGC said the joint medicinal cannabis research programs would include establishment of a world first International Library of Cannabis Medicine detailing the genetics of a variety of cannabinoid strains, development of genetics and breeding programs for specific diseases and development of medical grade cannabis products for future clinical studies.
The company said it would apply for licence for cultivation and research at the RMIT facilities and the collaboration would fast-track its path to clinical trials in Australia.
MGC company said the binding memorandum “substantially strengthens [its] research credentials and its leadership position in the Australian medicinal cannabis market”.
MGC managing-director Nativ Segev said the memorandum was “a substantial and landmark research agreement”.
RMIT head of Science Engineering and Health Prof Peter Coloe said the initiative “presents a significant long-term commercial opportunity for the company, as the research could guide the development of future proprietary medical grade cannabis products”.
“It will be a world first to create the International Library of Cannabis Medicine and we look forward to working together MGC Pharmaceuticals to build it,” Prof Coloe said.
MGC fell 0.3 cents or 4.8 percent to 5.9 cents with 18.1 million shares traded.

MMJ PHYTOTECH

MMJ says 60 percent subsidiary Harvest One Cannabis has agreements with Pancann Streaming to finance the Lucky Lake production facility and a new production facility.
MMJ said the agreements with Pancann were through Harvest One’s United Greeneries subsidiaries and consideration would be in shares and “a production yield allocation”.
The company said that if funded, United Greeneries could scale-up capacity for medicinal and recreational cannabis without additional capital outlay or shareholder dilution.
MMJ said that the Lucky Lake facility would have at least 60,000 square feet (5,574 square metres or 1.4 acres) of cultivation space, with the new additional facility designed to accommodate a similar area and United Greeneries had an existing agreement with Cowichan Tribes for a 13 acre (5.3 hectare) land package adjacent to its Duncan facility.
MMJ fell 10.5 cents or 17.8 percent to 48.5 cents with 15 million shares traded.

NOXOPHARM

Noxopharm says cancer patients are currently receiving NOX66 with chemotherapy and it expects to start “six additional clinical trials … within [the] next six months”.
Noxopharm said that NOX66 was “a first-in-class sensitizer of chemotherapy and radiotherapy [with] the potential to bring fundamental change to the treatment of many forms of cancer”.
The company said the trials would test safety and the ability of NOX66 to provide meaningful responses such as tumor shrinkage to chemotherapy or radiotherapy or both in patients with late-stage cancers who had no remaining standard treatment options and whose cancers would not normally be expected to respond to therapy.
Noxopharm said it would initiate seven proof-of-principle clinical trials in 2017, expected to conclude by October 2018 and it proposed to present early data from September 2017 and hold public briefings in Melbourne on May 30, Sydney on June 2 and the Gold Coast in Queensland on June 6, 2017.
Noxopharm fell half a cent or 1.3 percent to 38.5 cents.

BIOCURATE PTY LTD

Biocurate says it has appointed of Dr Glenn Begley as its inaugural chief executive officer to manage the $80 million fund, effective from May 22, 2017.

Biocurate said it was a venture launched in 2016 by Monash University and the University of Melbourne and supported by the Victorian Government, with former Victoria Treasurer and Premier John Brumby as its chair.

The company said that Dr Begley previously held academic positions in Australia, and had worked in small biotechnology and large pharmaceutical companies.

Biocurate said that most recently Dr Begley was the Thousand oaks, California-based Akriveia Therapeutics chief scientific officer.

Mr Brumby said that Dr Begley brought “an extraordinary combination of commercial, academic and clinical insight to this significant venture”.

Mr Brumby said the Biocurate ambition was “to unlock the exceptional research capabilities of the University of Melbourne and Monash University and their partners in hospitals, medical institutes and industry, enabling significant new discoveries to be translated more rapidly into new medicines”.

Biocurate said that Dr Begley was a clinical haematologist and medical oncologist.

Dr Begley’s Linkedin page said that he held a Bachelor of Surgery, Bachelor of Medicine and Doctorate of Philosophy from the University of Melbourne.