Biotech Daily

Tuesday July 4, 2017

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH EVEN: ADMEDUS UP 6%, DIMERIX DOWN 9%**

*** INDUSTRY WELCOMES FEDERAL BACK-DOWN ON SKILLED VISAS**

*** EPAT CLAIMS APP CORRELATES 88% FOR PAIN DETECTION**

*** STARPHARMA VIVAGEL BACTERIAL VAGINOSIS RESULTS DELAY**

*** RACE: 'US NCI TO PROVIDE BISANTRENE DATA PACK'**

*** CORRECTION: CELLMID**

*** US ASSOCIATION BACKS IMPEDIMED L-DEX FOR LYMPHOEDEMA**

*** NOVOGEN RAISES NASDAQ ADR RATIO TO 100:1**

*** SUDA REQUESTS 'LICENCE AGREEMENT' TRADING HALT**

*** AUSTRALIAN ETHICAL TAKES 7% OF CYCLOPHARM**

*** DIRECTOR ANDREW KROGER TAKES 34% OF CRYOSITE**

*** MEDIBIO APPOINTS EX US MHR PATRICK KENNEDY DIRECTOR**

*** CLARITY HIRES DR KATHLEEN MILLER FOR BUSINESS DEVELOPMENT**

MARKET REPORT

The Australian stock market climbed 1.75 percent on Tuesday July 4, 2017 with the ASX200 up 99.3 points to 5,783.8 points. Thirteen of the Biotech Daily Top 40 stocks were up, 13 fell, eight traded unchanged and six were untraded. All three Big Caps rose.

Admedus was the best, up 1.5 cents or 5.6 percent to 28.5 cents with 631,628 shares traded. Living Cell and Opthea climbed five percent or more; Acrux, Bionomics and Medical Developments rose more than two percent; LBT, Oncosil and Sirtex were up more than one percent; with Cochlear, Compumedics, CSL, Ellex, Nanosonics, Resmed and Starpharma up by less than one percent.

Dimerix led the falls, down 0.1 cent or 9.1 percent to one cent with 4.9 million shares traded. Cellmid fell 7.4 percent; Pharmaxis lost 3.85 percent; Clinuvel and Pro Medicus shed more than two percent; with Factor Therapeutics, Impedimed, Mesoblast, Neuren, Osprey, Prana, Universal Biosensors and Viralytics down more than one percent.

FEDERAL GOVERNMENT

Six life sciences industry organizations have welcomed the Federal Government's back-down on axing life sciences skilled visas.

In April, Research Australia said that the new "temporary skill shortage visa" announced by Prime Minister Malcolm Turnbull included the abolition of six life science categories, effective from March 2018 (BD: Apr 19, 2017).

Research Australia said in April that occupations removed from the 457 visa class included biochemists, biotechnologists, life scientist (general), life scientist (not elsewhere classified), nurse researcher and research and development manager.

Today, Ausbiotech, Research Australia, Medicines Australia, the Bio-Melbourne Network, the Medical Technology Association of Australia and the Association of Australian Medical Research Institutes welcomed "the restoration of key occupations for the medical technology, biotechnology, research and pharmaceutical sector to the skilled migration visa list".

In a joint media release, the combined peak body group said it was "pleased the Government has addressed concerns that were widely shared across the medical technologies, biotechnologies and pharmaceuticals industry sector and the health and medical research sector".

"The revised list of occupations is an important step for which there is significant acknowledgment and relief that the attraction of highly-skilled individuals will not be thwarted and demonstrates continued support for Australia's competitive advantage in life sciences innovation," the group said.

EPAT TECHNOLOGIES

Epat says its mobile application for pain detection has shown an 88 percent correlation when comparing observations in dementia patients with the existing Abbey pain scale.

Epat said that 353 paired observations in 40 people with moderate to severe dementia, aged 60 to 98 years were used to compared its electronic pain assessment tool (Epat) with the Abbey pain scale which requires a nurse or carer to grades people who are unable to verbalize a pain scale, on the six measures of vocalization, facial expression, body language, behavior, physiological change and physical changes.

"The results showed a strong positive correlation between the two tools," Epat said, but did not provide specific data.

Epat said that the study, entitled 'Pain assessment in dementia: Evaluation of a point-of-care technological solution' had been accepted for publication in the Journal of Alzheimer's Disease and confirmed "the validity and reliability of the electronic pain assessment tool in people with moderate to severe dementia".

The Perth, Western Australia-based Curtin University's Prof Jeff Hughes, a co-author on the research paper, said the results were "important given the potential for point-of-care pain detection systems to deliver better health outcomes for patients".

"Pain is very common among people with dementia but as the disease progresses they often lose their ability to communicate verbally, so the pain goes undetected," Prof Hughes said. "Being able to show the validity and reliability of an app used on a smartphone is an important step toward the adoption of more convenient technologies to derive accurate pain assessments."

Epat chief executive officer Phillip Daffas said the study was "another important milestone in showing the effectiveness of the Epat technology".

Epat fell 0.1 cents or 3.85 percent to 2.5 cents.

STARPHARMA HOLDINGS
Starpharma says top-line results from its pivotal two phase III studies of Vivagel BV for the prevention of recurrent bacterial vaginosis (BV) have been delayed by about one month.
Starpharma previously said the double-blind, randomized, placebo-controlled trials would compare the rate of bacterial vaginosis recurrence in women using Vivagel BV to the rate of recurrence in women using a placebo gel during a 16-week treatment period with the primary endpoint measured as patients completed the treatment period with results expected by June 30, 2017 (BD: Mar 30, 2017).
Today, Starpharma said results were expected in late July or early August 2017.
The company said the change in timing “allowed for additional confirmation from the [US Food and Drug Administration] on the statistical analysis plan to ensure consistency of the trial data analyses with [its] special protocol agreement, prior to un-blinding and analysis of the data”.
Starpharma said that the special protocol agreement granted by the FDA provided binding agreement on the phase III trial design including the primary endpoint.
The company said that the statistical analysis plan and bio-statistical programming were being finalized, prior to the unblinding of the data.
Starpharma said it was “well-advanced” in its preparation of the new drug application for Vivagel for the treatment and symptomatic relief of bacterial vaginosis (BV).
The company said it had appointed an unnamed “healthcare investment bank” to support negotiating commercial terms with potential partners for Vivagel BV.
Starpharma was up half a cent or 0.7 percent to 73.5 cents.

RACE ONCOLOGY
Race says the US National Cancer Institute has granted it the right to use NCI data and filings on Bisantrene for its regulatory pathway.
Race said the agreement provided the data and filings “for the purpose of developing, preparing and otherwise supporting Race’s own investigational new drug application for Bisantrene, as well as all other regulatory filings necessary to obtain approval for Bisantrene”.
The company said that the data package included all pre-clinical and clinical data on Bisantrene that were developed or used as part of the NCI’s original investigational new drug (IND) application, which was active between 1981 and 1991 and was the basis for numerous trials conducted or sponsored by the NCI, including detailed clinical safety and efficacy data on the use of Bisantrene in hundreds of patients.
Race said the agreement was “an important development, because to date, it has had to rely on published data and summary-level reports from the NCI”.
Race chief executive officer Peter Molloy said the NCI data package was “a valuable asset for Race”.
“We now can incorporate all the NCI data and should expect that this will lead to an earlier IND filing and faster regulatory review,” Mr Molloy said.
“Moreover, it should strengthen and further de-risk our 505(b)(2) approval pathway for Bisantrene,” Mr Molloy said.
The company said that following a pre-investigational new drug application meeting with the US Food and Drug Administration earlier this year, it had announced that Bisantrene qualified for expedited approval under the FDA’s 505(b)(2) pathway and intended to file an IND application aimed at supporting a pivotal study on Bisantrene in relapsed and refractory acute myeloid leukaemia.
Race was up 1.5 cents or 6.7 percent to 24 cents.

CELLMID

Last night's edition provided a link to Cellmid's Spanish mouse study which showed that midkine was "a crucial agent in the promotion of melanoma metastasis".
Biotech Daily incorrectly reported the link was to the full article but it was, in fact, to the abstract: https://www.nature.com/nature/journal/v546/n7660/full/nature22977.html.
Biotech Daily apologizes unreservedly for the mistake, which was made by a sub-editor unfamiliar with scientific journal articles and has been seconded to Murine Cancer Monthly for re-training.
Cellmid fell 0.2 cents or 7.4 percent to 2.5 cents with three million shares traded.

IMPEDIMED

Impedimed says the American Physical Therapy Association clinical practice guideline for lymphoedema diagnosis and management recommends its L-Dex diagnostic .
Impedimed said that Association's oncology section commissioned the writing of evidence-based guidelines for secondary lymphoedema in cancer survivors.
The company said the clinical practice guideline recommended L-Dex for patients at risk of, or with early stage, lymphoedema of the arm for both detection and ongoing management.
Impedimed chief executive officer Richard Carreon said the "scientific and independent review that lead to the recommendation of L-Dex for the early detection and management of secondary lymphoedema is significant".
"We see these guidelines as a major step forward in our journey to make L-Dex the standard of care for cancer survivors at risk of developing lymphoedema," Mr Carreon said.
Impedimed fell 1.5 cents or 1.9 percent to 78 cents with two million shares traded.

NOVOGEN

Novogen says it will increase the ratio between its Australian shares and American depository receipts from 25-to-one to 100-to-one, effective from July 14, 2017.
Last month, Novogen said that the Nasdaq had again issued a notice to comply with the $US1.00 share bid price rule (BD: Jul 23, 2010; Jul 26, 2011; Jun 1, 2017).
Novogen said the May 31, 2017 Nasdaq letter said that for the last 30 consecutive business days the bid price of the company's common stock closed below the minimum $US1.00 per share requirement for continued inclusion on the Nasdaq market.
The company said that to regain compliance, shares of its common stock must maintain a minimum bid closing price of at least $US1.00 per share for a minimum of 10 consecutive business days during the grace period.
Today, Novogen said that about 37 percent of the company's shares were held in ADRs and the change in ratio would have no effect on the number of outstanding shares on issue or the listing of its shares on the ASX.
Novogen chairman Iain Ross said the ratio change and increase in the market price ADRs "will bring our ADR shares back into compliance with Nasdaq's $US1.00 minimum bid price requirement".
"We believe that continued listing on both the ASX and Nasdaq provides important liquidity and compliance on two major exchanges for our shareholders," Mr Ross said.
Last night on the Nasdaq, Novogen closed unchanged at 90 US cents ($A1.183) with 4,451 shares traded.
On the ASX, Novogen was unchanged at 4.9 cents.

SUDA

Suda has requested a trading halt "pending the release of an announcement regarding a licence agreement".
Trading will resume on July 6, 2017 or on an earlier announcement.
Suda last traded at 1.9 cents.

CYCLOPHARM

Australian Ethical Investment says it has increased its substantial shareholding in Cyclopharm from 3,372,381 shares (5.65%) to 4,802,443 shares (7.00%).
Australian Ethical said it bought shares between February 6 and June 30, 2017, for an average price of 80.3 cents a share.
Cyclopharm was untraded at 82 cents.

CRYOSITE

Cryosite director Andrew Kroger says he has increased his substantial shareholding from 14,616,906 shares (31.19%) to 16,016,906 shares (34.18%).
Mr Kroger said the shares were bought off-market on June 30, 2017, with 1,327,500 shares acquired for 19 cents each and a further 72,500 shares bought for 16 cents each.
Mr Kroger said that the shares were held directly and through Austen Bay Pty Ltd acting for the Andrew Kroger superannuation fund, SHR Pty Ltd and Process Wastewater Technologies Pty Ltd.
Cryosite was untraded at 16 cents.

MEDIBIO

Medibio says it has appointed Patrick Kennedy as a director.
Medibio said that Mr Kennedy was a former US Democrat Member of the House of Representatives for the state of Rhode Island "and the nation's leading political voice on mental illness, addiction, and other brain diseases".
The company said that in the 16 years he representing Rhode Island, Mr Kennedy "fought a national battle to end medical and societal discrimination against these illnesses, highlighted by his lead sponsorship of the Mental Health Parity and Addiction Equity Act of 2008" and was recently appointed to President Donald Trump's Commission on Combating Drug Addiction and the Opioid Crisis.
Medibio said that Mr Kennedy's "political career and his brave openness about his own health challenges provide unique expertise" for the company.
"Medibio's technology is truly ground-breaking and has the potential to fundamentally change the mental health system for the better," Mr Kennedy said.
Medibio chief executive officer Jack Cosentino said that Mr Kennedy's "wealth of experience gained from serving in the US Congress along with his advocacy for mental health will open doors and heighten awareness for Medibio's technology".
The company said that Mr Kennedy was a co-founder of One Mind for Research, which sought to increase resources and collaboration in brain research, and was the founder of the Kennedy Forum to transform mental health and addiction care.
Medibio was up half a cent or 1.4 percent to 36 cents with four million shares traded.

CLARITY PHARMACEUTICALS

Clarity says it has appointed Dr Kathleen Miller as a business development executive, effective immediately.

Clarity said that Dr Miller had more than 25 years' experience in the pharmaceutical, medical imaging and medical device industries, most recently as Mallinckrodt Pharmaceuticals' director of business development.

The company said that Dr Miller began her pharmaceutical career in research and development at Mallinckrodt, "successfully leading the development of a radiopharmaceutical orphan drug … in commercial use today" and had experience marketing interventional and radio-therapeutic devices.

Clarity said that Dr Miller held a Bachelor of Science from the University of Illinois in Champaign-Urbana, a Doctorate of Philosophy from the University of California Los Angeles and a Masters of Business Administration from Washington University in St Louis.

Clarity is a public unlisted company.