Biotech Daily

Monday May 30, 2016

Daily news on ASX-listed biotechnology companies

*** ASX EVEN, BIOTECH UP: PSIVIDA UP 27.5%, BENITEC DOWN 5%**

*** ELLEX INTERIM REVIEW SHOWS 2RT SAFE, POSSIBLE EFFICACY**

*** UK GUIDELINES RECOMMEND RESONANCE FERRISCAN**

*** IMPEDIMED, MAYO CLINIC 5-YEAR INDICATIONS TRIAL DEAL**

*** TBG SUPPLIES HLA TYPING KITS TO MD ANDERSON CANCER CENTRE**

*** PRIMA FILES US SEC 'SHELF REGISTRATION' TO RAISE UP TO $84m**

*** NOVARTIS, MEDADVISOR 12-MONTH ENGAGEMENT TRIAL**

*** MEDIBIO CLAIMS PILOT STUDY 'SUCCESS'**

*** IMUGENE FILES HER-VAXX GASTRIC CANCER TRIAL ETHICS REQUESTS**

*** CANADA APPROVES MGC CANNABIS-BASED COSMETICS**

*** HUNTER HALL BELOW 5% OF MEDICAL DEVELOPMENTS**

*** POLYNOVO REQUESTS 'NON-CLINICAL TRIAL FUNDING' TRADING HALT**

*** BIOMEDVIC, AUSBIOTECH HOST INNOVATION CONNECT**

MARKET REPORT

The Australian stock market edged up 0.04 percent on Monday May 30, 2016 with the ASX200 up 2.1 points to 5,408.0 points. Seventeen of the Biotech Daily Top 40 stocks were up, 11 fell, eight traded unchanged and four were untraded. All Big Caps were up.

Psivida was the best, up $1.10 or 27.5 percent to $5.10 with 8,216 shares traded. Nanosonics climbed 8.9 percent; Pharmaxis and Pro Medicus were up more than five percent; Avita and Ellex were up more than four percent; Cellmid and IDT were up more than three percent; Acrux and Mesoblast rose more than two percent; Actinogen, Impedimed, Opthea, Prana, Resmed and Starpharma were up more than one percent; with Cochlear, CSL, Reva and Sirtex up by less than one percent.

Benitec led the falls, down half a cent or 4.8 percent to 10 cents, with 7,000 shares traded. Admedus, Neuren and Prima fell more than four percent; Clinuvel, Compumedics and Uscom shed more than two percent; Bionomics, Biotron and Living Cell were down more than one percent; with Medical Developments down 0.6 percent.

ELLEX MEDICAL LASERS

Ellex says an interim review of 150 of 292 patients has approved continuation of the trial of its retinal rejuvenation therapy (2RT) for age-related macular degeneration.

Ellex began recruitment in 2012 for the multi-centre trial to validate the efficacy of its retinal rejuvenation therapy for early age-related macular degeneration, conducted by the Centre for Eye Research Australia at the Royal Victoria Eye and Ear Hospital, and led by the Centre's head of macular research Prof Robyn Guymer (BD: Nov 23, 2012).

Today the company said that the interim review of patients at 18 months follow-up was conducted without unmasking to maintain on-going trial integrity and the trial would continue its full course to at least April 2018.

Ellex said that there was a meaningful difference between the two study groups in that one of the two groups demonstrated a reduction in drusen load and an improvement in retinal sensitivity.

The company said that to maintain the statistical integrity of the trial, the interim review did not disclose whether the sham or the laser treatment group showed better retinal sensitivity or lower drusen volume or area.

Ellex said that the usual consequence of drusen regression was the development of geographic atrophy, but this did not seem to be the case in this trial, as drusen load reduction was not accompanied by loss of retinal sensitivity.

The company said that it did not expect to see a statistical difference in the number of participants that reached end-stage AMD at the interim review stage of the trial, but hoped to see a difference when the trial was completed.

Ellex said that there was "no meaningful difference in the incidence of neovascularization … between groups, giving reassurance that the 2RT laser was not leading to an early increase in neovascularization as had appeared to be the case in previous thermal laser trials".

The company said that there was "no meaningful difference in the incidence of geographic atrophy … between groups, thereby giving reassurance that the 2RT laser was not dramatically increasing the rate" of geographic atrophy.

Ellex said that the number of geographic atrophy cases did not differ between groups, reinforcing the safety aspect of the treatment.

The company said that both Prof Guymer and the independent review board recommended that the trial continue without modification.

Ellex chief executive officer Tom Spurling said that the company was "very pleased to report that the trial has passed this important milestone and will continue".

"This milestone was achieved based on the recommendation from the lead investigator on the trial," Mr Spurling said.

"The analysis reported a meaningful difference in drusen progression and retinal sensitivity between the two groups, one of which received sham treatment and the other 2RT treatment," Mr Spurling said. "It also demonstrated a good safety profile."

The company said that the randomized participants received treatment as a standardised series of 12 laser spots applied to the macula region of the treatment or study eye, a conservative dose designed to minimise the possibility of harm to patients and each patient was reviewed at six-monthly intervals for 36 months.

Ellex said that the 36-month review for the last patient was expected to be completed in April 2018.

The company said that the interim analysis showed that randomization produced two groups which were very well matched in terms of AMD characteristics and potential variables, such as smoking status, that might influence the outcome of the disease.

Ellex climbed 4.5 cents or 4.8 percent to 98 cents.

RESONANCE HEALTH

Resonance says that UK Forum on Haemoglobin Disorders and the UK Thalassaemia Society has named its Ferriscan as the preferred measure of iron overload.
Resonance said that the Forum and Society launched a new set of guidelines the 'UK Standards of Care for Thalassaemia'.
The company said that the recommendations stated: "Liver iron concentration should be assessed using a validated and standardised [magnetic resonance imaging] technique" and the Ferriscan system was preferable to competitors "because the methodology is more robustly standardized and has been licenced for use in routine clinical practice".
Resonance said that Ferriscan was suitable for paediatric patients as it did not require a breath-hold.
Resonance chief scientific officer Prof Tim St Pierre said that "the continual clinical education and proactive stakeholder work we undertake to profile data on the accuracy of Ferriscan is vital to obtain inclusion in Guidelines such as this".
"Ferriscan has become the gold standard for measurement of liver iron concentration in haemoglobin disorders," Prof St Pierre said.
"The UK Standards of Care further substantiate the position of Ferriscan as the only method that offers the standardization that is a prerequisite for reliable measurements on which to base patient treatment decisions," Prof St Pierre said.
Resonance UK marketing director Melanie Baxter said the recognition of Ferriscan as the preferred technique would increase uptake by clinicians in the UK, improve National Health Service funding and assist reimbursement in other regions.
Resonance said that more than 30,000 patient Ferriscans had been performed in more than 30 countries.
Resonance was up 0.8 cents or 53.3 percent to 2.3 cents with 4.3 million shares traded.

IMPEDIMED

Impedimed says it has a five-year clinical trial agreement with the Mayo Clinic to explore additional indications for its bio-impedance spectroscopy technology.
Impedimed currently uses the bio-impedance spectroscopy in its US Food and Drug Administration approved L-Dex system to assist diagnosis of post-breast cancer lymphoedema and has raised funds in part to develop a congestive heart failure test using the fluid status and body composition monitoring technology (BD: Feb 9, 2016).
Today, Impedimed said that its bio-impedance spectroscopy sent 256 unique frequencies through the body to assess both intracellular and extracellular fluid and that the detection of small amounts of fluid changes could help health care providers better detect and manage chronic diseases and give individuals information to better manage their health.
The company said that the technology was approved in Australia and the US for the early assessment of post-operative lymphoedema in arms and legs.
Impedimed said the Rochester, Minnesota-based Mayo Clinic would conduct clinical trials and would explore indications potentially including cardiology and nephrology.
The Mayo Clinic's department of cardiovascular medicine vice-chair and remote monitoring medical director Dr Paul Friedman said that changes in body fluid "give an early indication that an intervention may be necessary, especially when caring for patients with heart failure".
Impedimed chief executive officer Richard Carreon said the agreement "expands our opportunity to scientifically explore applications for our … technology, and its potential impact on reducing healthcare costs and improving quality of care and outcomes".
Impedimed was up 1.5 cents or 1.6 percent to 95 cents with 1.4 million shares traded.

TBG DIAGNOSTICS (FORMERLY PROGEN PHARMACEUTICALS)

TBG says that it has begun the supply of its human leukocyte antigen typing kits to the Houston-based University of Texas MD Anderson Cancer Centre.

TBG said the typing kits would be used for histo-compatibility testing services applied to whole organ, tissue, or stem cell transplants where compatibility of gene groups, or human leukocyte antigens (HLA), was imperative for transplant tissue acceptance.

The company said that apart from histo-compatibility testing services, the MD Anderson laboratory was also involved in the study of population genetics of the HLA system, the definition of epitopes, the part of the antigen recognized by the immune system, in the HLA molecular and the selection of peptides by different HLA molecules.

TBG chief operating officer Eugene Cheng said that the MD Anderson contract “endorses the high quality and leading edge product that we develop at TBG Diagnostics”.

“We are very proud that our products are employed at the forefront of medical services at varied diagnostic and healthcare centres around the world,” Mr Cheng said.

TBG was up two cents or 9.1 percent to 24 cents.

PRIMA BIOMED

Prima says it has filed “a shelf registration form” with the US Securities and Exchange Commission to raise up to $US 60 million ($A83.8 million) over three years.

Prima said that the shelf registration to issue American depository shares (ADSs) was a common practice in the US allowing a company to complete the SEC review process prior to the issuing of any securities and then have up to three years within which to use the prospectus.

The company said that any offer of securities would be made through an SEC-approved prospectus, with the terms and price of any offer to be established at that time.

Prima said that its ADSs trade on the Nasdaq under the code PBMD, with one ADS equivalent to 30 Australian shares.

Prima fell 0.2 cents or 4.2 percent to 4.6 cents with 2.5 million shares traded.

MEDADVISOR

Medadvisor says it has a 12-month agreement for Novartis Pharmaceuticals to use its adherence system for a patient engagement program for three oncology drugs.

Medadvisor said that it would work with the Basel, Switzerland-based Novartis in Australia “to help communicate important educational information about the pharmaceutical manufacturer’s products to patients using the Medadvisor platform”.

The company said that the program was expected to begin in June 2016 and deliver educational messages through a mobile telephone, tablet computer tablet or internet browser, with patients able to register for Medadvisor’s free mobile telephone application.

Medadvisor said that the patient’s profile would be updated with information on their medication usage and Novartis would be able to send a series of messages to patients prescribed its medications.

Medadvisor chief executive officer Robert Read said that the partnership with Novartis would which “help Medadvisor users to get important and timely product information, direct from the manufacturer, in a format that is easy to understand”.

Medadvisor was up 0.2 cents or 6.45 percent to 3.3 cents with 5.4 million shares traded.

MEDIBIO

Medibio claims that it has “successfully completed the first commercial pilot study of its workplace stress product”.

Medibio said the 66-participant study was conducted by the Perth, Western Australia-based Vital Conversations, which it described as its “corporate wellness partner” and said the study “independently validated the commercial and technical aspects of the product”.

In 2014, Medibio back-door listed into Bioprospect to develop a circadian heart rhythm test for depression and last year announced the partnership with Vita Conversations for its cardiac corporate stress product (BD: Oct 27, 2014; Sep 25, 2015).

Today, Medibio said that Vital ran the pilot trial with an unnamed corporate client with more than 5,000 employees in Australia, with the five-week study dividing the 66 employees into three categories of mild or low-risk, moderate and severe or at-risk stress.

Medibio said that Vital used its stress test, along with traditional psychological workplace assessments that included self-report questionnaires screening for depression, anxiety and stress, sleep quality, resilience and coping styles.

Medibio said that the normal to mild categories comprised about 63 percent of the pilot population and the results showed an 86 percent agreement between the Medibio stress test and traditional self-report stress measures “at this low risk end of the wellness continuum, where self-report bias is not generally an issue”.

“At the high risk end, this pilot successfully demonstrated one of the core competencies of Medibio’s objective workplace stress test … the ability to identify at-risk employees where the traditional subjective measures often fail due to misleading self-reports”.

The company said that “a number of participants were accurately identified to be in the severe, or at-risk category, which was on one occasion in conflict with their self–report”.

Medibio said that during a follow-up interview a participant who received a severe result but was categorized as normal by the conventional self-report screening, disclosed they had under-reported their symptoms and the employee was “able to gain psychological support for a longstanding serious stress-related problem”.

Medibio was up eight cents or 32 percent to 33 cents with 1.9 million shares traded.

IMUGENE

Imugene says it has filed all eight ethics committee submissions for its phase Ib/II study of HER-Vaxx immuno-oncology therapy for gastric cancer.

Imugene said that completing the filings with the Novotech contract research organization, was a “major milestone” for the two part trial, in which the phase Ib part trial would enrol up to 18 patients to be treated with HER-Vaxx at three dose levels in combination with chemotherapy to provide safety and immunogenicity data, evaluate the booster schedule and determine the optimal dose to take into the phase II study.

Imugene said that the phase II study would recruit about 68 patients randomized into two arms of either HER-Vaxx plus standard-of-care or standard-of-care alone.

Imugene chief operating officer Leslie Chong said the filings were a significant achievement in the clinical development of HER-Vaxx.

“Within my experience of developing numerous world class oncology medicines it is truly remarkable to have all our sites ethics committee review applications completed and submitted within seven weeks of finalizing the study protocol,” Ms Chong said.

“Reaching this major milestone so efficiently demonstrates the calibre of Imugene’s clinical development team and strategically places us well for a successful re-entry of HER-Vaxx into the clinic in 2016,” Ms Chong said.

Imugene was unchanged at one cent with 1.9 million shares traded.

MGC (MEDICAL GRADE CANNABIS) PHARMACEUTICALS

MGC says that Health Canada has approved its MGC Derma Anti-Aging line of cannabidiol-based cosmetics.
MGC said the Canadian cosmetic market was worth $US1.9 billion and the approval followed US and European approvals (BD: May 11, 25, 2016).
MGC was up 0.6 cents or 10.9 percent to 6.1 cents with 33.7 million shares traded.

MEDICAL DEVELOPMENTS INTERNATIONAL

Hunter Hall Investment Management says it has ceased its Medical Developments substantial holding reducing from 2,932,737 shares (5.07%) to 2,889,312 shares (4.99%).
Hunter Hall said it sold 43,425 shares for $276,098 or $6.36 a share on May 26, 2016.
In February, Hunter Hall became substantial Medical Developments with 2,932,737 shares or 5.07 percent, buying shares between February 5 and 18, 2016 with the largest purchase 852,689 shares for $3,341,660 or $3.92 a share (BD: Feb 22, 2016).
Medical Developments fell four cents or 0.6 percent to $6.18.

POLYNOVO

Polynovo has requested a trading halt “pending the release of an announcement of a contract to fund a non-clinical trial”.
Trading will resume on June 1, 2016 or on an earlier announcement.
Polynovo last traded at 26.25 cents.

BIOMEDICAL RESEARCH VICTORIA, AUSBIOTECH

Biomedical Research Victoria and Ausbiotech say that Innovation Connect will facilitate discussion, collaboration and engagement between industry and researchers.
Biomedical Research Victoria, or Biomedvic, chief executive officer Prof Jan Tennent said that there was a strong desire for increased collaboration between the research sector and industry but often there was little understanding of how it could be achieved.
“Researchers are encouraged by governments, their own institutions and funding bodies to increasingly interact with industry and to think about potential commercialisation of their research, yet no one provides the researchers with a playbook on how to make this happen,” Prof Tennent said.
“Conversely, it can often be hard for industry to know how to infiltrate the research sector to find those projects worth commercialising,” Prof Tennent said.
“Innovation Connect aims to make these connections easier to form and grow,” Prof Tennent said.
The industry organizations said that the first event, entitled ‘Accelerating Innovation: Browse, Connect and Engage with Victoria’s World-Class Research Infrastructure’, would focus on the Victorian Platform Technologies Network and the ways that the resource could be used by industry.
Biomedvic said that the event would be held on June 21, 2016, from 4pm to 6pm at the Monash Conference Centre, 30 Collins Street, Melbourne.
For more details go to: http://www.platformtechnologies.org or ’phone +613 8344 2802.