Biotech Daily

Wednesday June 14, 2017

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: GENETIC SIGNATURES UP 11%, CYCLOPHARM DOWN 6.4%**

*** STARPHARMA SELLS AGRICULTURAL BUSINESS TO AGRIUM FOR $35m**

*** AUSCANN WELCOMES GREENS MARIJUANA BAN DISALLOWANCE**

*** PSIVIDA 2nd PHASE III TRIAL BACKS DURASERT FOR POSTERIOR UVEITIS**

*** DORSAVI SIGNS KIESER FOR VIMOVE2 FOR BACK PAIN**

*** REDHILL TO PROMOTE DONNATAL, ENTERAGAM IN THE US**

*** RESONANCE A.I. FOR LOW-COST LIVER IRON TEST**

*** WEHI, PETER MAC LUNG CANCER BIOMARKER DIRECTS TREATMENT**

*** IMPEDIMED: MACQUARIE STARTS SOZO LYMPHOEDEMA TRIAL**

*** ITL EXPECTS REVENUE UP 12.5% TO $35m**

*** CCS APPOINTS PARENT LBT AS APAS DISTRIBUTOR**

*** MICHAEL ABOLAKIAN, HISHENK TAKE 5% OF NOVOGEN**

*** BIOXYNE CEO NAM HOAT CHUA TAKES 15%**

*** NAOS TAKES 8% OF BIOTECH CAPITAL**

*** LISA DEA REPLACES MMJ CFO KWONG CHOO**

MARKET REPORT

The Australian stock market climbed 1.06 percent on Wednesday June 14, 2017 with the ASX200 up 61.1 points to 5,833.9 points. Sixteen of the Biotech Daily Top 40 stocks were up, 12 fell, 10 traded unchanged and two were untraded. All three Big Caps were up.

Genetic Signatures was the best, up four cents or 11.1 percent to 40 cents with 32,809 shares traded. Compumedics and Osprey climbed more than eight percent; Dimerix rose 6.7 percent; Starpharma improved 5.7 percent; Sirtex was up four percent; Clinuvel, CSL and Nanosonics were up more than three percent; Avita, Oncosil, Resmed and Viralytics rose more than two percent; Actinogen, Airxpanders, ITL, Medical Developments and Mesoblast were up one percent or more; with Cochlear up 0.6 percent.

Cyclopharm led the falls, down 5.5 cents or 6.4 percent to 80 cents with 9,102 shares traded, followed by Prana down six percent to 4.7 cents with 139,375 shares traded. Polynovo lost 5.3 percent; Living Cell and Uscom fell more than four percent; Benitec was down 3.45 percent; Atcor, Ellex, Impedimed, LBT and Opthea shed two percent or more; with Pro Medicus down 1.55 percent.

STARPHARMA

Starpharma says it has sold its agricultural chemicals and Priostar business to the Calgary Alberta, Canada-based Agrium for $35 million in cash.

Starpharma said that the chemicals and Priostar business, Starpharma Agrochemicals, would be operated by Agrium subsidiary, Loveland Products Inc.

The company said that Starpharma Agrochemicals was “comprised of key patents and technical know-how as well as a small number of staff dedicated solely to Priostar dendrimers and agrochemicals operations” and was independent of its dendrimer enhanced product (DEP) and Vivagel products and related intellectual property portfolios.

Starpharma chief executive officer Dr Jackie Fairley told Biotech Daily the agriculture business had a book value of $7.5 million and the sale would provide a profit of $20 million to $25 million for the company.

Dr Fairley said Starpharma acquired the core intellectual property from Dow Chemical and Central Michigan University and developed their scientific observations on dendrimer technology “to improve the performance of agricultural chemicals”.

Dr Fairley said the technology showed greater adhesion of pesticides and herbicides to plant leaves and was water soluble, thereby eliminating solvents, while improving efficacy.

She said the dendrimers had shown improved efficacy when used with glyphosate, marketed as Roundup, and 24D.

In 2011, Starpharma said that Priostar dendrimer studies showed improvements including the ability to increase the effectiveness of agricultural chemicals such as glyphosate, and it had explored a number of off-patent agents in combination with its dendrimer technology including the insecticide imidacloprid and the herbicide trifluralin (BD: Mar 3, Jul 12, 2011).

Dr Fairley said in 2011 that “reformulating known generic agents with its proprietary dendrimers … [offered] the potential for reduced frequency and amount of application, with the potential to reduce the chemicals’ environmental impact”.

The company said fertilizers, chemicals and their application were a significant cost for farmers and that more effective formulations could reduce expenses and reapplications.

Today, Dr Fairley said that the small number of staff involved in the division would continue their employment with Agrium and Starpharma would rent space to Agrium for its Australian operations.

Dr Fairley said the sale left Starpharma free to focus on its pharmaceutical business including Vivagel for condoms and bacterial vaginosis, as well the dendrimer-enhanced cancer therapies being developed with Astrazeneca and internally.

In a media release, Starpharma said it intended to use the funds to accelerate the development and commercialization of its higher value pharmaceutical dendrimer-based products and to explore other opportunities in this area.

Starpharma said that with the net proceeds from the transaction it would have more than $60 million at June 30, 2017.

Dr Fairley said the sale was “an exciting milestone for the company and the culmination of our strategy to maximize the value of the Priostar technology”.

“We achieved this outcome through the development of a range of value-added formulations utilising Priostar to a stage where those products had high attraction value as differentiated products for a market-facing third party such as Agrium,” Dr Fairley said.

Starpharma said that the transaction involved the sale of its wholly-owned US subsidiary Dendritic Nanotechnologies Inc and a newly created Australian subsidiary containing all Priostar and agricultural chemical intellectual property and business assets.

The company said that the sale followed a process conducted with its financial adviser, Macquarie Capital (Australia).

Starpharma was up four cents or 5.7 percent to 74 cents.

AUSCANN GROUP

Auscann says it welcomes a Greens Senate disallowance motion that removes marijuana from a prohibited substances list.

Auscann said that the changes “increase the ability of Australian medical practitioners to prescribe cannabinoid medicines to critically ill patients”.

The Senate Journal said that the motion was passed by 40 votes to 30 votes with the Greens and Labor voting in favor, along with Senators Derryn Hinch, Jacqui Lambie, David Leyonhjelm, Pauline Hanson and Malcolm Roberts, while those voting against were the Liberal-National Coalition and the Xenophon and Family First senators.

In May, when a similar motion failed to be passed in the Senate, Health Minister Greg Hunt claimed in a media release that “Bill Shorten joined with the Greens to vote in favor of opening the floodgates for dangerous, unregulated drugs to come to Australia”.

“It would have opened the way for personal importation through our airports of hashish and other products that are unsafe, unregulated and even deadly,” Mr Hunt said.

“People have died overseas from unsafe medicinal cannabis products and Labor voted to make that a real possibility in Australia,” Mr Hunt said.

Despite requests for evidence of people dying from marijuana use, Mr Hunt’s office was unable to provide details other than the claim that “there have been a number of cases overseas of people dying from unsafe cannabis”.

Mr Shorten is a Member of the House of Representatives, not the Senate.

Today, Auscann said that the Therapeutic Goods Administration had two access pathways for doctors to prescribe unregistered cannabinoid medicines: the authorized prescriber scheme and the special access scheme category B.

Auscann said that both required the doctor to apply for and wait for approval from the TGA prior to being able to prescribe, while special access scheme category A did not require prior approval, with the doctor notifying the TGA that they had prescribed the medicines.

The company said that prior to Greens leader Senator Richard Di Natale’s disallowance motion, any unregistered therapeutic goods could be supplied through the special access scheme category A process, except for prohibited substances in schedule 9 of the Poisons Standard and medicinal cannabis products.

Auscann said that Senator Di Natale’s disallowance motion changed the Therapeutic Goods and Other Legislation Amendment (Narcotic Drugs) Regulation 2016 to enable terminally ill patients to access medicinal cannabis products through the TGA special access scheme category A process.

Auscann managing-director Elaine Darby said that “excluding cannabinoid medicines from this pathway was not necessary given the safety evidence in respect to cannabinoids that has come out of pre-clinical and clinical studies”.

“We are pleased terminally ill patients will now be able to access cannabinoid medicines through the TGA’s special access scheme category A,” Ms Darby said.

Auscann said that category A patients were defined as “persons who are seriously ill with a condition from which death is reasonably likely to occur within a matter of months, or from which premature death is reasonably likely to occur in the absence of early treatment”.

The company said that the doctor completed the relevant category A form and sent it to the supplier of the product and a copy to the TGA, providing a supplier, such as Auscann, with the legal authority to supply the product.

The company said that in respect to other patient groups the TGA access schemes provided the necessary checks and balances for the approval of doctors to prescribe unregistered cannabinoid medicines.

Auscann was up one cent or 2.9 percent to 35.5 cents with 2.1 million shares traded.

PSIVIDA

Psivida says its 153-patient, second phase III trial of Durasert for posterior segment uveitis achieved its primary endpoint of prevention of recurrence at six months.

Psivida said that the study involved patients being followed for 36 months and the Durasert three-year insert “demonstrated a significant reduction in the recurrence of posterior segment uveitis through six months”.

The company said that 21.8 percent of Durasert-treated patients had a recurrence compared to 53.8 percent of patients in the sham group ($p < 0.001$).

Last month, Psivida said that its first 129-patient, phase III trial of Medidur for posterior uveitis met its primary endpoint of prevention of recurrence of disease with a high statistical significance at 12 months follow-up (BD: Jul 28, 2016; May 9, 2017).

Psivida previously referred to the technology as Medidur and had described the delivery system Durasert and recently adopted the name Durasert for the tehnology.

Today, Psivida chief executive officer Nancy Lurker said the data from the second phase III trial “confirms previous clinical research demonstrating our three-year Durasert insert for posterior segment uveitis may significantly help patients suffering from this devastating disease, the third leading cause of blindness”.

Ms Lurker said the company expected to file its European market authorization application by the end of June and a new drug application to the US Food and Drug Administration by the end of 2017.

Psivida said that intraocular pressure (IOP) elevation, which could lead to glaucoma, was 2.4mmHg and 1.3mmHg at six months compared to baseline for Durasert and control, respectively with 41.6 percent of Durasert patients requiring IOP-lowering therapy during the first six months compared to 34.6 percent for control patients, with no patients requiring IOP surgery during the first six months of follow-up.

The company said that for patients with a natural, or phakic, lens at baseline, 4.9 percent in the Durasert group required cataract surgery in the six months compared to 8.6 percent in the sham group.

Psivida said that posterior segment uveitis was a chronic, non-infectious inflammatory disease affecting the posterior segment of the eye, often involving the retina, which was a leading cause of blindness in the developed and developing countries and in the US affected up to 100,000 people.

Psivida was untraded at $3.00.

DORSAVI

Dorsavi says Kieser Australia has signed a three-year deal worth more than $150,000 to roll-out the Vimove2 wearable sensor system at its Melbourne and Sydney centres.

Dorsavi said that Kieser was a network of integrated physiotherapy, rehabilitation and strength training centres established in 2006 with a core principle of ‘Strength for Health’.

The company said that Kieser had eight centres in Melbourne and opened its first Sydney centre last year, with back pain management one of the largest parts of its business and all back pain clients to have movement analysis with Vimove2 as part of their program.

Kieser managing-director Tony Smith said that “the quality of data captured by Vimove2 allows for highly patient specific treatment plans and ultimately better and more sustainable results”.

“The decision to move our clinics to Vimove2 was incredibly simple,” Mr Smith said.

“We took it out of the box and could use it immediately with no training,” Mr Smith said.

Dorsavi was up 1.5 cents or 4.7 percent to 33.5 cents.

REDHILL BIOPHARMA

Redhill says it has begun promotion of two gastrointestinal specialty products, Donnatal and Enteragam in the US.

Redhill said that its US commercial operations were headquartered in Raleigh, North Carolina and included a gastrointestinal-focused sales force of more than 30 staff.

Redhill chief business officer Guy Goldberg said that promotion of Donnatal and Enteragam marked the company's transition to a revenue-generating, gastro-intestinal-focused, specialty pharmaceutical company in the US.

Mr Goldberg said that the US commercial operations were an integral part of Redhill's plan to commercialize the gastrointestinal products Bekinda, or RHB-102, for gastroenteritis and irritable bowel syndrome, RHB-105 for Helicobacter pylori infection and RHB-104 for Crohn's disease in the US, if approved by the FDA.

In 2010, Israel's Redhill bought Myoconda (RHB-104), Heliconda (RHB-105) and Picoconda (RHB-106) from Sydney's Giaconda (BD: Aug 17, 2010).

On the Nasdaq, Redhill was up 16 US cents or 1.72 percent to $US9.47 ($A12.55) with 26,751 shares traded.

RESONANCE HEALTH

Resonance says it has developed a machine-learned artificial intelligence prototype for a low-cost test to measure liver iron concentration.

Resonance said that a recent study showed a need for an affordable product to measure liver iron concentration in developing nations, where a widely-available but unvalidated magnetic resonance imaging transverse relaxation time technique known as T2* was potentially endangering patients' lives.

The company said a study to be presented at the European Haematology Association meeting raised "concerns regarding patients' safety when assessed using a widely available [liver iron concentration] assessment technique, the Iron Health T2* method".

Resonance said the study compared the T2* test against the validated reference standard, its Ferriscan test, and the T2* failed to identify about 30 percent of patients confirmed by Ferriscan to be at greatly increased risk of cardiac disease and early death.

The company said patients were at risk of not receiving potentially life-saving treatments.

Resonance said the study concluded "the data indicate that the T2* R2* method of measurement of [liver iron concentration] is not safe for routine clinical measurement … [and] could result in inappropriate clinical decision making".

The company said that the artificial intelligence test would enable iron overload management at a significantly lower price than the Ferriscan test.

Resonance said that the technology allowed penetration of the substantial markets of iron overloaded patients in these emerging growth markets and positioned it "at the cutting edge of [artificial intelligence] in healthcare".

The company said its prototype had increased automation and throughput and "demonstrated a significant correlation with the true [liver iron concentration] value as measured by Ferriscan" with superior performance compared to the unvalidated T2* technique.

Resonance said further testing had begun on larger datasets to prove the robustness of the prototype for clinical application.

Resonance chairman Martin Blake said his company was "one of the first organizations worldwide to successfully apply state-of-the-art artificial intelligence techniques to a quantitative assessment of medical images".

Resonance was up 0.8 cents or 44.4 percent to 2.6 cents with 15.2 million shares traded.

THE WALTER AND ELIZA HALL INSTITUTE OF MEDICAL RESEARCH

The Walter and Eliza Hall Institute says its researchers have identified a biomarker that improves the selection of lung squamous cell carcinoma patients for treatment.
WEHI said that the researchers showed a better way to recruit the right participants for fibroblast growth factor receptor (FGFR) inhibitors, which were being investigated for treating lung squamous cell carcinoma.
The Institute said that its researchers Dr Marie-Liesse Asselin-Labat, Dr Clare Weeden and Dr Aliaksei Holik worked with Peter MacCallum Cancer Centre oncologist Prof Ben Solomon and Richard Young and found that high levels of the anti-cancer drug's target FGFR1 in a patient's tumor RNA were a better predictor of a potential response to the FGFR inhibitors than current tests.
WEHI said that the researchers showed that combining the targeted FGFR inhibitors with chemotherapy had the potential to improve treatment outcomes.
Prof Solomon said the finding could improve the design of future clinical trials by selecting the right patients to participate.
"Fewer than 10 percent of new cancer drugs make it past phase I clinical trials," Prof Solomon said.
"In many cases this isn't because of the drug itself, but because of a limitation in clinical trial design," Prof Solomon said.
"Understanding which patients are most likely to respond to certain drugs in clinical trials is crucial both for patients to receive the best treatment, and for new drugs to make it to the clinic," Prof Solomon said.
"Hopefully these data will help to improve trial outcomes by recruiting patients who otherwise might not have been matched to the right trial for them," Prof Solomon said.
Dr Weeden said that as well as identifying which patients would respond to the targeted therapy, the study found that FGFR inhibitors could be improved when combined with chemotherapy.
"FGFR inhibitors stop cancer cells from growing and adding in chemotherapy kills the cancer," Dr Weedon said.
"Our research shows combining FGFR inhibitors with chemotherapy should be looked at in future clinical trials," Dr Weedon said.
"Our laboratory models, known as patient-derived xenografts, are the most accurate representation of real patient tumors that can be used for testing," Dr Weeden said.
"These models, using samples donated to the biobank by people with lung cancer, were crucial to define which tumors responded best to FGFR inhibitors," Dr Weedon said.

IMPEDIMED

Impedimed says that Sydney's Macquarie University Hospital has begun enrolment in the first clinical study of Sozo units for lymphoedema.
Impedimed said that the study aim was to determine the best practices for at home lymphoedema monitoring and would be led by Macquarie University Hospital Lymphoedema Education, Research and Treatment program manager Louise Koelmeyer.
Impedimed said that the program aimed to optimize positive outcomes for people living with lymphoedema.
Impedimed chief executive officer Richard Carreon said the Macquarie University Hospital team was "a leading advocate for the use of L-Dex to monitor cancer patients for lymphoedema".
Impedimed fell 1.5 cents or 2.4 percent to 60.5 cents.

ITL HEALTH GROUP

ITL says it expects revenue for the year to June 30, 2017 to be up 12.5 percent to $35 million with profit before tax up 11-fold to up to $3.8 million from $300,000.
ITL said it expected the six months to June 30, 2017 results to show “a significant improvement over the corresponding period” and followed the 11 percent revenue increase to $17.5 million in the six months to December 31, 2016.
The company said that the improved results were driven by continued growth in the operating divisions, ITL Biomedical and ITL Healthcare.
ITL executive chairman Bill Mobbs said the financial year was “a step change for ITL”.
“Our strategy to pursue high margin opportunities in emerging healthcare growth markets and accelerate development of innovative patented products for the global healthcare markets has been a success,” Mr Mobbs said.
ITL was up one cent or 1.8 percent to 56 cents.

LBT INNOVATIONS

LBT says it has been appointed by 50 percent joint-venture Clever Culture Systems to distribute the APAS Independence in Australia and New Zealand.
LBT said the LBT-developed automated plate assessment system (APAS) Independence would be launched in Australia and trialled in microbiology centres.
LBT fell half a cent or two percent to 24.5 cents.

NOVOGEN

Michael Abolakian and Hishenk Pty Ltd say they have become substantial shareholders in Novogen with 26,188,670 shares or 5.4 percent of the company.
The Artarmon, Sydney-based Mr Abolakian said the shares were held by Hishenk Pty Ltd and Hishenk Super Fund.
Mr Abolakian said he acquired the shares between March 3 and June 13 for $794,581 or 3.03 cents a share.
According to Commsec data the lowest price Novogen has traded in that period was 3.8 cents on June 6, 2017.
Novogen fell 0.3 cents or 5.4 percent to 5.3 cents.

BIOXYNE

Bioxyne chief executive officer Nam Hoat Chua says he has 76,549,342 shares in the company or 15.08 percent.
The Petaling Jaya, Selangor, Malaysia-based Mr Chua said the shares were held with his spouse Peng-Hyang Ng and he acquired 12,500,000 shares on April 19, 2017 at 1.9 cents of which 6,000,000 were consideration for selling a business to Bioxyne and 4,500,000 for signing on as the company’s chief executive officer.
Mr Chua said he acquired 64,049,342 shares at one cent each on April 30, 2017 in the rights issue to acquire companies to which he was related (BD: Apr 19, 2017).
Bioxyne fell 0.1 cents or five percent to 1.9 cents.

BIOTECH CAPITAL

Naos Asset Management has increased its substantial shareholding in Biotech Capital from 8,754,085 shares (7.19%) to 10,565,022 shares (8.31%).
The Martin Place, Sydney-based, Naos said it was acting as investment manager for "various trustee companies" and the registered holder was Australian Executor Trustees, but again failed to cite the cost of the 1,810,937 shares acquired on-market, as required under the Corporations Act 2001 (BD: Feb 24, 2017).
The substantial shareholder notice was signed by director Sebastian Evans.
Biotech Capital was up half a cent or 3.6 percent to 14.5 cents.

MMJ PHYTOTECH

MMJ says it has appointed Lisa Dea as chief financial officer, replacing Kwong Choo, effective immediately.
MMJ said that Ms Dea had been appointed chief financial officer of Harvest One Cannabis and Mr Choo had been appointed the head of finance at Harvest One.
The company said that Ms Dea had more than 20 years' experience in finance, securities and accounting fields, including with Australian and Canadian stock market listed companies.
MMJ said that Ms Dea was responsible for corporate strategy, all aspects of finance and legal, debt and capital market activities, internal and external public reporting, financial controls, processes and corporate governance.
The company said that Ms Dea previously worked for Deloitte and Touche LLP for 11 years.
MMJ said that Ms Dea held a Bachelor of commerce from the University of British Columbia.
MMJ was up half a cent or 1.5 percent to 34 cents with 1.1 million shares traded.