Biotech Daily

Monday November 23, 2015

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: COMPUMEDICS UP 10%; OPTISCAN DOWN 12.5%**

*** D3 HELPS ALIOS RSV TRIAL, J&J $2.4b ACQUISITION**

*** VICTORIA BACKS MRCF $9m FOR PEANUT ALLERGY, CARDIAC DRUG**

*** TISSUE THERAPIES TO RAISE $15m FOR US BIOLOGIC PATHWAY**

*** STUDY BACKS NANOSONICS TROPHON EPR FOR HPV DISINFECTION**

*** GENETIC TECHNOLOGIES BREVAGENPLUS VALIDATION STUDY**

*** ANALYTICA PERICOACH INCONTINENCE TOOL 'IMPROVES SEX'**

*** PARADIGM ZILOSUL BME PILOT TRIAL ETHICS APPROVAL**

*** REVA OCTOBER OPTIONS RAISE $13m, SIX SUBSTANTIALS DILUTED**

*** INNATE DIRECTOR CHRISTOPHER COLLINS TAKES 17%**

*** DORSAVI TO RELEASE 72m ESCROW SHARES**

*** MEDICAL AUSTRALIA TO RELEASE 18m ESCROW SHARES**

*** POLYNOVO REQUESTS 'CAPITAL RAISING TRADING HALT**

*** SUN REQUESTS 'BOARD CHANGES' TRADING HALT**

*** PRIMA HIRES TROUT GROUP, LOSES STUART ROBERTS**

MARKET REPORT

The Australian stock market climbed 0.39 percent on Monday November 23, 2015 with the ASX200 up 20.3 points to 5,276.4 points. Thirteen of the Biotech Daily Top 40 stocks were up, 18 fell, seven traded unchanged and two were untraded. All three Big Caps were up.

Compumedics was the best, up three cents or 10 percent to 33 cents with 362,393 shares traded. Nanosonics climbed six percent; Tissue Therapies was up five percent; Actinogen improved four percent; Oncosil was up 3.1 percent; Clinuvel, Prima and Pro Medicus rose more than two percent; Bionomics, Cochlear, Neuren, Psivida, Resmed and Starpharma were up more than one percent; with CSL and Mesoblast up by less than one percent.

Optiscan led the falls, down half a cent or 12.5 percent to 3.5 cents with 42,954 shares traded. Living Cell fell 9.3 percent; Orthocell lost 8.1 percent; Antisense was down 7.4 percent; Avita and Biotron were down six percent or more; Admedus and Benitec lost more than five percent; Atcor fell 4.9 percent; Cellmid and IDT were down more than three percent; Ellex, Osprey and Reva shed more than two percent; Anteo, Impedimed and Universal Biosensors were down more than one percent; with Acrux down 0.65 percent.

D3 MEDICINE

D3 says it worked with Alios Biopharma on the phase IIa trial of ALS-008176 for respiratory syncytial virus contributing to its $US1.75 billion ($A2.44 billion) acquisition.

D3 chief executive officer Dr Craig Rayner told Biotech Daily that the privately-owned, Melbourne-based D3 began working with the San Francisco, California-based Alios in 2013, advising on the clinical program and devising an innovative study design, expediting the clinical development pathway.

Dr Rayner said that by using an adaptive design and undertaking a complex analysis of each cohort before dosing the next, the company saved about six months and $US13 million.

Dr Rayner said the study enrolled 62 healthy adults to develop the anti-viral drug for use with children and immune-compromised adult patients, especially those post-transplant.

Dr Rayner said that the trial was a “value-driver” for the Johnson & Johnson acquisition of Alios concluded on September 30, 2015.

Dr Rayner said that healthy volunteers in the study were infected with an attenuated strain of respiratory syncytial virus and then inoculated with ALS-008176.

He said that Alios and D3 investigated virus shedding as well as blood markers.

The trial results, co-authored by D3 chief scientific officer Dr Patrick Smith, concluded that “more rapid respiratory syncytial virus clearance and a greater reduction of viral load, with accompanying improvements in the severity of clinical disease, were observed in the groups treated with ALS-008176 than in the placebo group”.

The article, entitled ‘Activity of Oral ALS-008176 in a Respiratory Syncytial Virus Challenge Study’ was published in the New England Journal of medicine and an abstract is at: http://www.nejm.org/doi/full/10.1056/NEJMoa1413275.

Dr Smith said that respiratory syncytial virus (RSV) was “the primary etiological agent associated with the majority of serious lower respiratory tract infections and hospital visits during infancy and childhood”.

“Despite RSV being the most common cause of bronchiolitis and pneumonia in children under one year of age, there is currently no effective therapy for the treatment of this debilitating disease,” Dr Smith said.

Dr Smith said that D3 and Alios collaborated with investigators from the University of Tennessee Health Sciences Center and London’s Retroscreen Virology.

“The results of this study demonstrated proof of antiviral activity for ALS-008176, and using an adaptive design approach the team was able to interrogate the exposure-response relationship to establish dosing recommendations for future development in both adults and paediatrics using population pharmacokinetic and viral kinetic modelling,” Dr Smith said.

“These results were utlilized by the team to establish doses of ALS-008176 for use in infants which represent the highest unmet medical need population,” Dr Smith said.

“The adult challenge study results demonstrate that innovative trial design including pharmacometric analyses between cohorts can result in significant cost and timeline savings, reducing the required sample size by maximizing information content of the collected data,” Dr Smith said.

“The data presented in the NEJM paper represents an important first step for a promising drug, and additional clinical development to demonstrate benefit in patients is in progress,” Dr Smith said. “The study also demonstrates how innovative trial design incorporating quantitative pharmacology can provide the scientific basis to make informed decisions to initiate treatment of infants earlier in new drug development programs,” Dr Smith said.

Dr Rayner said that as part of Johnson & Johnson, Alios was conducting a phase IIb trial of ALS-008176 for respiratory syncytial virus.

VICTORIA GOVERNMENT, MEDICAL RESEARCH COMMERCIALISATION FUND

The Victoria Government says $9 million in Medical Research Commercialisation Fund grants reinforce the State's "strength as Australia's medtech and research hub".

A media release from the Minister for Small Business, Innovation and Trade Philip Dalidakis said that two Victorian startups would receive funding from the Brandon Capital Partners managed third Medical Research Commercialisation Fund.

Aravax director Dr Chris Smith told Biotech Daily that his company, formed from research into peanut allergies at Monash University and the Alfred Hospital would receive $4.85 million from the $200 million Medical Research Commercialisation Fund.

Dr Smith said that Cardiora, a drug trial being conducted by the Baker IDI Heart and Diabetes Institute at the Alfred Hospital to treat patients with heart failure would receive $4.15 million from the MRCF for a drug to allow patients to take their medication in tablet form at home, potentially reducing the need for them to be admitted to hospital.

The Victoria Government media release said that the Fund supported early-stage biotechnology companies and was backed by "four of the nation's largest industry superannuation funds … [and is] Australia's largest ever life science-focused venture fund".

The media release said that Victoria's medical technologies and pharmaceuticals industry was "a key growth sector in the … Government's 'Back to Work Plan' to boost local high-skill jobs".

"The sector now employs more than 20,000 people and generates more than $10 billion for the state," the media release said.

Mr Dalidakis said that the funding of the two projects was "a significant vote of confidence for Victoria's medtech sector".

Brandon Capital managing director Dr Chris Nave said his company was "pleased that the Victorian Government recognises the importance of access to early stage investment capital and hands-on investment expertise to guide the development and commercialization of these medical technologies".

"Biotechnology is one of the few manufacturing industries that can continue to pay Australia's high salaries and remain internationally competitive, offering an opportunity for Australian manufacturing to move its capability up the value chain," Dr Nave said.

TISSUE THERAPIES

Tissue Therapies says it hopes to raise $15 million to complete a US Vitrogro wound treatment phase II program and for phase III manufacturing process development.

Tissue Therapies said that it had made "significant and measurable progress in its transition from a device to a biopharmaceutical (biologic) regulatory pathway" and had formally engaged with the US Food and Drug Administration and received clear guidance on how to proceed with phase II clinical development.

The company said that the bio-pharmaceutical pathway created "a far larger commercial opportunity for the company".

Tissue Therapies said that it had developed "a pipeline and commercial strategy that will maximise the value of the company's considerable intellectual property portfolio in the field of targeted growth factors for wound care".

Tissue Therapies said that a presentation attached to today's 'Investor Update' was part of the process of "articulating the company's go-forward strategy over the coming months".

The company said that several matters in the presentation would be discussed during the annual general meeting to be held on November 25, 2015.

Tissue Therapies was up 0.2 cents or five percent to 4.2 cents.

NANOSONICS

Nanosonics says a study shows that its Trophon EPR is the only high level disinfection system for ultrasound probes proven to kill high-risk, human papillomavirus.

Nanosonics said the article, 'Susceptibility of HPV16 and 18 to high level disinfectants indicated for semi-critical ultrasound probes' was published in the Journal of Medical Virology with an abstract at: http://onlinelibrary.wiley.com/doi/10.1002/jmv.24421/abstract.

The article, co-authored by the Hershey, Pennsylvania-based Penn State College of Medicine professor of microbiology and immunology Prof Craig Meyers, said that human papillomavirus (HPV) was "highly resistant to [ortho-phthalaldehyde, but] sonicated hydrogen peroxide offers an effective disinfection solution for ultrasound probes".

"Disinfection methods that are effective against HPV should be adopted where possible," the abstract said.

The abstract said that the study compared two leading ultrasound probe high level disinfection methods, liquid ortho-phthalaldehyde, Cidex OPA, and Trophon EPR using sonicated hydrogen peroxide, against HPV16 and HPV18 in a hard-surface carrier test.

Nanosonics said the study showed that the Trophon EPR was "the only high level disinfection system proven to kill natural, infectious, high-risk cancer causing strains of human papillomavirus".

The company said that high-risk HPV accounted for five percent of all cancers, was responsible for most cases of cervical cancer and was a leading cause of oral, throat, anal and genital cancers.

Nanosonics said published studies had shown there was a risk of cross contamination between patients examined with ultrasound probes, with up to seven percent of probes remaining contaminated despite the use of probe covers and disinfection.

"We were the first ever to grow papillomavirus in culture," Prof Meyers said.

"In our original study we chose, specifically, glutaraldehyde and ortho-phthalaldehyde to test because these are disinfectants that hospitals believe are sterilants that kill everything, including papillomavirus," Prof Meyers said.

Nanosonics said the original 2014 study showed that both glutaraldehyde and ortho-phthalaldehyde "completely failed to inactivate natural, infectious, high-risk HPV16, even after 24 hours of contact time" and this study showed that the Trophon EPR was the only disinfectant to completely inactivate HPV.

"Our first study showed that commonly used disinfectants are not effective, while this latest study found that Trophon EPR was completely effective," Prof Meyers said.

"The concern is that these other liquid chemical disinfectants are commonly used in medical and healthcare facilities," Prof Meyers said. "Where this is happening, HPV is not being killed, posing a risk for transmission."

Nanosonics chief executive officer Michael Kavanagh said that the study "clearly demonstrates the unique effectiveness of Trophon EPR in inactivating high-risk, cancer-causing HPV".

Mr Kavanagh said the Trophon technology used a disinfectant with a high concentration of hydrogen peroxide, sonically activated to form a sub-micron particle mist, generating "a high number of free radicals with superoxidative properties that destroy the virus".

"Publication of the study is very timely given the current increased scrutiny of disinfection practices, Mr Kavanagh said. "An alert issued in the US by the Centers for Disease Control and the FDA in September stipulates that reusable medical devices, such as ultrasound probes, must be properly maintained, cleaned and disinfected/sterilized and urged healthcare facilities to immediately review current reprocessing practices to protect patients."

Nanosonics was up nine cents or six percent to $1.595.

GENETIC TECHNOLOGIES

Genetic Technologies says a validation study backs its Brevagenplus breast cancer risk test's applicability to African-American and Hispanic women.

Genetic Technologies launched the original Brevagen in 2011, confirming in 2014 that it was only applicable for Caucasian women and said that it was developing Brevagen 2.0, now named Brevagenplus, to diagnose African-American and Hispanic women (BD: Jun 20, 2011; Mar 18, 2014).

Today, Genetic Technologies said that a study, entitled 'SNPs and breast cancer risk prediction for African American and Hispanic women' published in the journal Breast Cancer Research & Treatment was co-authored by the company's scientific director Dr Richard Allman.

The company said that the study investigated the impact of 75 single nucleotide polymorphisms (SNPs) on the predictive accuracy of the Gail breast cancer risk assessment tool and the IBIS Tyrer-Cuzick breast cancer risk assessment models.

Genetic Technologies said that the study of 7,539 African-American and 3,363 Hispanic women showed that including information from the SNPs associated with breast cancer risk "improves the discriminatory accuracy" of assessments for both African-American and Hispanic women.

An abstract is available at http://link.springer.com/article/10.1007/s10549-015-3641-7.

Genetic Technologies said the SNPs in the study were predominantly identified by studies in Caucasian women and the resultant risk scores were likely to improve further as more detailed genetic mapping studies were conducted across populations.

Genetic Technologies chief executive officer Eutillio Buccilli said that African-American and Hispanic women were "a very large and under-served population in the context of healthcare in the US and I'm extremely pleased that we are able to offer the Brevagenplus test to as many of these women as possible".

"Today's announcement is indicative of our commitment to reinvigorate the pathway to peer-reviewed publications," Mr Buccilli said.

The company's said that its first generation Brevagen initially comprised seven single nucleotide polymorphisms combined with the US National Cancer Institute breast cancer risk assessment tool, in an easy-to-use predictive risk test for Caucasian women at risk of developing sporadic, or non-hereditary breast cancer.

Genetic Technologies said that as more SNPs were discovered, the genetic component of the Brevagenplus test was increased 10-fold and its applicability expanded to include African-American and Hispanic women.

The company said that the present study provided scientific supporting evidence that the addition of SNP information also improves the predictive accuracy of two commonly used breast cancer risk assessment models for both African-American and Hispanic women.

Genetic Technologies said that the study results were "important to physicians in that it allows them to better target and develop individualised breast cancer prevention and screening strategies for more of their patients".

The company said that the next step was "to confirm those potential health improvements in clinical studies" with the scheduled to begin by the end of 2015 with completion expected by July 2016, with two longer-term clinical trials expected to begin by July 2016 and designed to run for up to two years.

Genetic Technologies said that one study would be prospective looking at patient outcomes, with the other being retrospective, assessing the impact of the test on magnetic resonance imaging screening rates.

Genetic Technologies was unchanged at 2.4 cents with 1.9 million shares traded.

ANALYTICA

Analytica says that its intra-vaginal pelvic floor strengthening system increases sexual satisfaction after use to treat urinary incontinence.

Analytica said that in a survey of 124 customers, 80 reported that that they had poor to average sexual satisfaction before using the Pericoach and more than a third reported an improvement in their sexual satisfaction as a result of using the device.

The company said that a lack of sexual satisfaction was a condition with significant unmet medical need, with 60.5 percent of Australian women reporting at least one sexual problem within the preceding year.

Analytica said that a lack of interest in having sex was reported by 54.8 percent of Australian women while 28.6 percent of respondents were unable to orgasm and 27.3 percent were not finding sex pleasurable.

Newcastle University's Prof Pauline Chiarelli said that "many women with urinary incontinence face low levels of sexual satisfaction as they may be frightened of leaking or concerned about odor during sex which then affects their mood, libido and levels of satisfaction and arousal".

"Using the Pericoach is probably making these women more confident given it is improving their incontinence and therefore makes them more confident sexually, allowing them to enjoy sex more and become more aroused," Prof Chiarelli said.

Analytica chairman Dr Michael Monsour said that Analytica was undertaking a post-approval, randomized, controlled clinical trial which would provide independent clinical data on the use of Pericoach for female sexual dysfunction.

"In the trial, we will be monitoring, for the first time, the improvement of strength in pelvic floor muscles and their role in sexual function," Dr Monsour said.

"This is potentially a much safer option than current treatments on the market as improvement in pelvic floor strength does not have the risk of side effect associated with drugs," Dr Monsour said.

Analytica fell 0.05 cents or 8.3 percent to 0.55 cents with 1.6 million shares traded.

PARADIGM BIOPHARMACEUTICALS

Paradigm says it has ethics approval for a 40-patient, open-label, pilot trial of the safety and tolerability of Zilosul, for bone marrow oedema.

Paradigm said that the trial of the Geretsried, Germany-based Bene Pharmachem GmbH's Zilosul, an injectable form of pentosan polysulphate, would be conducted at Adelaide's Southern Orthopaedics and Melbourne's Southern Orthopaedics.

The company said that Zilosul would be administered twice weekly for three weeks in patients with exhibiting a bone marrow oedema lesion identified by magnetic resonance imaging in association with bone pain and reduced joint function following an anterior cruciate ligament (ACL) injury.

Paradigm chief executive officer Paul Rennie said that unresolved traumatic bone marrow oedema lesions might be the harbinger of post-traumatic osteoarthritis and there was no registered pharmaceutical agent approved to treat the unmet medical need.

The company said the primary objectives was to evaluate the safety and tolerability of intra-muscular Zilosul in subjects with bone marrow lesions following an ACL injury, with secondary objectives to evaluate the effect of Zilosul on bone marrow lesions as assessed by magnetic resonance imaging and the effect of Zilosul on functional knee joint capacity, as well as its effect on pain and on biomarkers of inflammation, bone and tissue remodelling.

Paradigm was up one cent or three percent to 34 cents.

REVA MEDICAL

Reva says that six major investors have been diluted following an October exercise of options which raised $US9,505,781 ($13,238,979).
In October, the Hong Kong-based Senrigan said it had become substantial in Reva with a holding including 4,375,000 US shares, equivalent to 43,7500,000 Chess depository instruments but did not disclose the cost of the shares (BD: Oct 6, 2015).
At that time, Reva published an announcement to the ASX, entitled 'Appendix 3B' and not flagged as market sensitive, saying that it had issued those shares as a result of the exercise of options in conjunction with a 2014 convertible, saying it had raised $US9,505,781 (BD: Sep 26, 2015).
Today, Reva said that Domain Partners, Elliott Associates, Saints Capital Everest, Brookside Capital, Cerberus and Medtronic had been diluted by between 1.1 percent and 1.5 percent.
Reva fell two cents or 2.4 percent to 82 cents.

INNATE IMMUNOTHERAPEUTICS

Innate director Christopher Collins says he has increased his shareholding in the company from 25,899,139 shares (16.02%) to 33,899,139 shares (17.26%).
Mr Collins said that the 8,000,000 shares were acquired for $1,360,000 or 17 cents a share in the recent placement (BD: Nov 20, 2015).
Innate was up one cent or five percent to 21 cents.

DORSAVI

Dorsavi says it will release 53,385,500 ASX escrow and 18,835,119 voluntary escrow shares on December 11, 2015.
Dorsavi said that following the release there would be no further shares held in escrow and 149,914,616 shares would be available for trading.
Dorsavi was up half a cent or 1.2 percent to 41.5 cents.

MEDICAL AUSTRALIA

Medical Australia says it will release 18,333,334 shares from voluntary escrow on December 7, 2015.
Medical Australia said that the shares were issued as part consideration for the acquisition of Medivet Pty Ltd.
Medical Australia chief financial officer Michael Andrews told Biotech Daily that following the release from escrow, the company would have 136,766,031 shares available for trading.
Medical Australia was untraded at 5.4 cents.

POLYNOVO

Polynovo has requested a trading halt "pending an announcement regarding a capital raising".
Trading will resume on November 26, 2015 or on an earlier announcement.
Polynovo last traded at 18 cents.

SUN BIOMEDICAL

Sun Biomedical has requested a trading halt “pending an announcement regarding board changes”.
Trading will resume on November 25, 2015 or on an earlier announcement.
Sun Biomedical has an annual general meeting scheduled for November 26, 2015, with resolutions to change its name to Dimerix and re-elect executive chairman Howard Digby.
Sun last traded at 0.7 cents.

PRIMA BIOMED

Prima says that it will hire the New York-based investor relations firm Trout Group and its head of investor relations Stuart Roberts will resign.
Prima said that “as a result and in light of our expanded US shareholder base, it is important that we have someone on the ground in New York City and in the same time zone”.
The company said that Mr Roberts was employed following the acquisition of Immutep “to help explain the benefits of our LAG-3 based immuno-oncology assets, primarily to the Australian investment community” (BD: Jan 20, 2015).
“We thank him for his contribution to our investor relations efforts and wish him well,” Prima said.
Prima was up 0.1 cents or two percent to five cents with 3.4 million shares traded.