Biotech Daily

Thursday December 15, 2016

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: GENETIC SIGNATURES UP 7.5%, MESOBLAST DOWN 6%**

*** TGA APPROVES SIENNA'S ADJUNCT BLADDER CANCER TEST**

*** ELLEX TRAINS CHINESE SURGEONS IN ITRACK FOR GLAUCOMA**

*** RESONANCE: 'INDEPENDENT DATA BACKS FERRISCAN'**

*** DSMB OKAYS REDHILL PHASE III RHB-104 (MYOCONDA) CROHN'S TRIAL**

*** I'ROM PAYS IDT $10m FOR 61% of ADELAIDE CMAX**

*** SIRTEX TELLS ASX AWARE QUERY: 'WE COMPLIED WITH THE RULES'**

*** PROTEOMICS: 'PROMARKERD PREDICTS DIABETIC KIDNEY DISEASE'**

*** ROYAL ADELAIDE APPROVES CYNATA CYP-001 PHASE I GVHD TRIAL**

*** MMJ WELCOMES CANADA RECREATIONAL MARIJUANA REVIEW**

*** OVENTUS SIGNS UNNAMED DENTAL GROUP FOR SNORING, APNOEA**

*** PHOSPHAGENICS CHICKEN FEED STUDY BACKS TPM FOR GROWTH**

*** RESPIRI DEVELOPS SONOSENTRY NIGHT ASTHMA MONITOR**

*** BIO-MELBOURNE '2017 TRENDS' FEBRUARY BRIEFING**

MARKET REPORT

The Australian stock market fell 0.82 percent on Thursday December 15, 2016 with the ASX200 down 46.0 points to 5,538.6 points. Eleven of the Biotech Daily Top 40 stocks were up, 22 fell and seven traded unchanged. All three Big Caps were up.

Genetic Signatures was the best, up three cents or 7.5 percent to 43 cents with 339,082 shares traded. Opthea climbed 5.8 percent; Orthocell improved 4.9 percent; Actinogen and Universal Biosensors were up more than three percent; Anteo, Psivida and Uscom rose more than two percent; Neuren and Polynovo were up more than one percent; with Airxpanders, Cochlear, CSL and Resmed up by less than one percent.

Mesoblast led the falls, down nine cents or six percent to $1.41 with 597,181 shares traded. Avita, Compumedics and Cyclopharm lost more than three percent; Factor Therapeutics, IDT, Impedimed, Living Cell, Osprey, Sirtex and Starpharma shed more than two percent; Acrux, Admedus, Atcor, Benitec, Medical Developments, Pharmaxis, Prana, Pro Medicus and Reva were down more than one percent; with Clinuvel and Ellex down by less than one percent.

SIENNA CANCER DIAGNOSTICS

Sienna says that following US and European approvals, the Australian Therapeutic Goods Administration has approved its adjunct diagnostic for bladder cancer.
Sienna said the TGA had approved the telomerase-based adjunct in-vitro diagnostic, initially for bladder cancer, as a class 2 in-vitro diagnostic as its first Australian approval.
Earlier this week the test was approved by the European Medicines and Healthcare Products Regulatory Agency and it was approved by the US Food and Drug Administration last month (BD: Nov 15, Dec 12, 2016).
Sienna chief operating officer, Matthew Hoskin said the company was “thrilled to launch this technology to the Australian market”.
Sienna is a public unlisted company.

ELLEX MEDICAL LASERS

Ellex says it has begun training Chinese physicians in the use of its Itrack minimally invasive glaucoma surgery device, the only such device approved in China.
Ellex said that the training program was the first program for the ab-interno canaloplasty technique which used its Itrack micro-catheter to open up all components of the eye’s outflow system to reduce intra-ocular pressure and medication burden (BD: May 6, 2016).
The company said the training program was being conducted at hospitals and teaching institutions in Shanghai and Beijing from December 12 to 17, 2016.
Ellex chief executive officer Tom Spurling said sales in China had been “limited because only the more complex ab-externo canaloplasty surgery technique has been marketed”.
“Our program in China to relaunch Ellex Itrack for the simpler, faster [ab-interno canaloplasty] technique is expected to be well received,” Mr Spurling said.
Ellex said the training program followed the November presentation of Itrack at the inaugural minimally invasive glaucoma surgery symposium in Changsha, China.
Ellex fell half a cent or 0.4 percent to $1.325.

RESONANCE HEALTH

Resonance says that multiple studies demonstrate broadening acceptance of its Ferriscan iron monitoring and management technology.
Resonance said that results from the multicentre US ‘Transcranial Doppler (TCD) with Transfusions Changing to Hydroxyurea’ or Twitch study and from China’s Guangxi Medical University were presented at the American Society of Hematology meeting in San Diego, California from December 3 to 6, 2016.
The company said that the Twitch study data provided further evidence for use of Ferriscan for management of patients with sickle cell disease, adding impetus to its focus on sickle cell disease and its strategy to obtain expert advice regarding a renewed current procedural terminology (CPT) code application in the US.
Resonance said that an oral presentation by New York-based Cohen Children’s Medical Center’s Dr Banu Aygun showed how Ferriscan could be used to monitor iron unloading by therapeutic phlebotomy in previously transfused children with sickle cell anaemia.
The company said that new Ferriscan data from clinicians at China’s Guangxi Medical University was presented by Dr Rong Rong Liu showing the prevalence and severity of iron burden in non-transfusion-dependant thalassaemia in China as identified by Ferriscan in 158 patients and concluded that the first Ferriscan assessment should be performed as early as five years old.
Resonance was unchanged at 2.6 cents.

REDHILL BIOPHARMA

Israel's Redhill says an independent data and safety monitoring board has approved continuation of its phase III study with RHB-104 for Crohn's disease (BD: Jun 23, 2016).
In 2010, Israel's Redhill acquired Myoconda (RHB-104), Heliconda (RHB-105) and Picoconda (RHB-106) from Sydney's Giaconda (BD: Aug 17, 2010).
Today, Redhill said that following the pre-planned safety data review the board gave a unanimous recommendation to continue the study as planned, without modifications.
The company said that RHB-104 was a "potentially ground-breaking antibiotic combination therapy in oral capsule formulation, with potent intracellular, anti-mycobacterial and anti-inflammatory properties" based on evidence that Crohn's disease, and potentially other autoimmune diseases, were related to Mycobacterium avium subspecies paratuberculosis infection in susceptible patients.
Redhill said that the study was a randomized, double-blind, placebo-controlled first phase III study to evaluate the safety and efficacy of RHB-104 in patients with moderately to severely-active Crohn's disease.
The company said that it had enrolled 242 patients of the planned 410 patients in up to 150 clinical sites in the US, Canada, Europe, Israel, Australia and New Zealand.
Redhill said that two additional independent data and safety monitoring board meetings were expected to take place after 50 percent and 75 percent of the total patients completed 26 weeks of participation, with the second meeting expected by July 2017, which would evaluate the option of an early stop for success for overwhelming efficacy, according to a pre-specified statistical significance threshold for analysis of RHB-104 versus placebo in the primary endpoint.
The company said that if the pre-specified threshold was not met the study would continue to recruit all 410 patients by the end of 2017, with follow-up at week 26 and it was also preparing an open-label extension study for all patients who completed 26 weeks of treatment and failed to achieve remission at week 26, the study's primary endpoint.
The company said that patients with a Crohn's disease active index score of greater than 150 at week 26 would be offered treatment with RHB-104 for a 52-week period.
Redhill said that the extension study would be separate from the phase III trial and data collected would be supplemental to the trial data.
Separately, Redhill said that with Montreal, Quebec-based partner Intelgenx Corp, it had signed a licence with the Seoul-based Pharmatronic Co for the commercialization of Rizaport for acute migraine in the Republic of Korea (BD: Sep 22, 2016).
On the Nasdaq, Redhill fell three US cents or 0.26 percent to $US11.30 ($A15.22) with 26,351 shares traded.

IDT AUSTRALIA

IDT says it expects to receive $10,000,000 from the Tokyo, Japan-based I'rom Group for the acquisition of its Adelaide-based CMax clinical trial business.
IDT said the conditions for the sale had been completed and it would receive the first tranche of $10,000,000 in the staged $14 million transaction (BD: Oct 28, 2016).
The company said that I'rom would own 61 percent of the newly formed CMAX Clinical Research Pty Ltd with I'rom and IDT jointly managing the business and holding equal board representation.
IDT said that I'rom would integrate the business into its broader regulatory and clinical services businesses and it would assist I'rom in managing CMax, paving the way for I'rom to acquire the remaining shares over the next 12 months.
IDT fell half a cent or 2.9 percent to 17 cents.

SIRTEX MEDICAL

Sirtex has responded to an ASX 'aware' query saying it "has at all times been in complete compliance with [ASX] requirements".

The ASX said that "following a tip-off, ASX's discussion with Sirtex on December 2, 2016 [queried] whether the double digit growth guidance for dose sales was still current and Sirtex [confirmed] the guidance was current".

The ASX query noted Sirtex chief executive officer Gilman Wong's annual general meeting address and presentation on October 25 disclosing the expectation that "double digit dose sales growth will continue in FY17 whilst we await the results of the three major clinical studies due to report findings in the first half of the calendar year 2017".

The ASX said it had discussions with Sirtex on October 26, 2016 regarding the use of imprecise terms, such as "double digit" and Sirtex's confirmation that it believed the commentary it made around dose sales for 2016-'17 was appropriate, noting a number of factors beyond Sirtex's direct control.

The ASX noted the Sirtex announcement entitled 'Trading Update' released at 8:27am on December 9 disclosing the expectation that "on a full year basis worldwide dose sales growth is anticipated to be in the order of five to 11 percent compared to growth of 16.4 percent achieved in 2015-'16" and asked if Sirtex was familiar with the definition of "aware" in Chapter 19 of the Listing Rules.

The ASX asked Sirtex whether it considered the information on dose sales growth … to be information that a reasonable person would expect to have a material effect on the price or value of its securities and if yes, when did Sirtex first become aware of the decrease in anticipated dose sales growth for 2016-'17, as disclosed in the update?

A response signed by Sirtex chief financial officer and company secretary Darren Smith said the "board and senior management of [Sirtex] are very familiar with, and are committed to ensuring complete compliance with, the requirements of Listing Rules 3.1 and 3.1A, and Guidance Note 8".

Mr Smith said that Sirtex's business had a very short sales cycle, measured in days, with "no transparency on dose sales beyond a very short window", which was why Sirtex did not provide specific financial guidance to the market, using instead historical dose sale numbers and indications of estimated dose sales growth.

Mr Smith said the information on dose sales growth was information "that a reasonable person would expect to have a material effect on the price or value of its securities".

Mr Smith said that six-monthly planning was completed on December 5 with a board meeting scheduled December 6 at which chief executive officer Gilman Wong tabled, and spoke to, a paper which included a revised estimate of dose sales growth.

Mr Smith said that the paper was discussed by the board, but no revised estimate was adopted or approved, with further work on the revised estimate was required.

He said that updated information was circulated by senior management to the board in the afternoon of December 8 and a final revised estimate of dose sales growth was signed off by the board, with the related Update approved on the morning of December 9 and released to the market at about 8.30am.

"Given the fact that what is involved is a prediction of future results rather than a reflection of past results, it is not so much a question of when Sirtex first became aware of the decrease in anticipated dose sales growth for FY17, but rather a question of when, having regard to the information then available, the board of Sirtex revised its estimate of future dose sales growth for FY17," Mr Smith said.

"That was on the morning of 9th December 2016," Mr Smith said. "The Update announcement followed immediately afterwards."

Sirtex fell 42 cents or 2.5 percent to $16.40 with 793,282 shares traded.

PROTEOMICS INTERNATIONAL LABORATORIES

Proteomics says that its Promarkerd test predicts diabetic kidney disease across all major clinical definitions of rapid decline in kidney function.
Proteomics said that study results would be presented at the International Conference on Functional and Interaction Proteomics: Application in Food and Health, in New Delhi, India.
The company said that the study showed that Promarkerd's predictive ability had been improved and it correctly predicted 61 percent to 97 percent of individuals who went on to have a clinically significant decline in kidney function within four years.
Proteomics said that an inter-laboratory study showed robustness of the test.
The company said 415 million adults worldwide had diabetes and about one-third had chronic kidney disease which could lead to dialysis or kidney transplant.
Proteomics said that further analysis of the original four year clinical study data confirmed that 10 percentof patients experienced a rapid decline in their kidney function when measured according to a variety of definitions of kidney function decline and refinement of the Promarkerd algorithm enabled an average 84 percent of these people to be predicted up to four years in advance.
Proteomics was untraded at 25 cents.

CYNATA THERAPEUTICS

Cynata says it the Royal Adelaide Hospital has approved its phase I trial of Cymerus mesenchymal stem cell product CYP-001 for steroid-resistant graft-versus-host disease.
Earlier this week, Cynata said the UK National Health Service Health Research Authority approved the trial (BD: Dec 13, 2016).
Cynata fell 3.5 cents or five percent to 67 cents.

MMJ PHYTOTECH

MMJ says it welcomes the Canadian Government's final report into the legalization and regulation of recreational marijuana use.
The Canadian Government report, entitled, 'A Framework for the Legalization and Regulation of Cannabis in Canada - The Final Report of the Task Force on Cannabis Legalization and Regulation' recommends similar restrictions on marijuana sales to those of alcohol and tobacco.
MMJ said that one of the themes in the report was "the need for a safe and responsible production system, with the development of regulatory framework to support commercial production by the private sector a key priority".
The company said the current Canadian system for medical marijuana "could be used as an entry point for a new national system for legalized and regulated cannabis production".
MMJ said its United Greeneries subsidiary was "strategically positioned to build out large-scale horticultural operations" to meet forecast demand expected to be up to $C10 billion ($A10.1 billion) a year.
MMJ managing-director Andreas Gedeon said his company was "very encouraged by the task force's finding that the current Federal system governing cannabis use for medical purposes could also be used as the framework for commercial production".
"This would be a significant catalyst for United Greeneries as a current licenced producer, allowing it to establish a first moving advantage in the recreational market," Mr Gedeon said.
MMJ was up one cent or 5.3 percent to 20 cents.

OVENTUS MEDICAL

Oventus says it has a collaboration agreement with an unnamed dental corporate following last month's deal with 1300Smiles (BD: Oct 28, 2016).

Oventus said the company's name was "commercial in confidence" but the collaboration allowed the company's dentists to provide treatment for snoring and obstructive sleep apnoea with the use of its O2Vent T device.

Oventus chief executive officer Neil Anderson said the dental group's business model "focuses on allowing dentists to devote their whole working day to clinical dentistry and with access to the Oventus devices, dental sleep medicine can become an increasingly active service expansion and business opportunity".

Oventus fell one cent or 1.6 percent to 62 cents

PHOSPHAGENICS

Phosphagenics says a chicken feed study shows that both high dose vitamin E and its tocopheryl phosphate mixture statistically improve average live weight.

Phosphagenics said that compared to base feed, chicken feed containing tocopheryl phosphate mixture (TPM) at 10ppm and the high dose vitamin E feed improved average live weight at day-28 by 5.6 percent and 4.4 percent, respectively, and increased average daily gain by 5.7 percent and 4.7 percent respectively.

The company said that 10ppm TPM was the optimal TPM enhanced feed for broilers and was shown to produce the largest numerical improvement in live weight and average daily weight gain.

Phosphagenics said the study compared base feed without added vitamin E, standard feed with 20ppm additional vitamin E, high dose feed with 100ppm additional vitamin E and five different dose levels of added TPM.

The company said the study was conducted at an Australian research facility and tested a range of TPM doses across the life-cycle of more than 500 birds, assessing live weight, live weight gain, average daily gain and feed conversion rate.

Phosphagenics said that "the fiscally tight nature of the broiler market" meant that modest improvements translated into considerable financial benefits and savings to the industry, with a recent poultry industry report indicated that for every one percent improvement in feed conversion rate, the financial savings to the Australian industry was about $9.4 million.

Phosphagenics was unchanged at three cents.

RESPIRI

Respiri says it will accelerate development of its Sonosentry overnight asthma monitoring product.

Respiri said that asthma symptoms often worsened overnight and 70 percent of asthma deaths occurred at night.

The company said that parents were "distressed as their children suffer overnight symptoms and want an objective, home based monitoring tool and alarm system to give them peace of mind".

Respiri said that wireless technology and its software platforms would provide non-invasive, home-based monitoring, with a pilot program expected to be completed by April 2017.

Respiri was unchanged at 5.4 cents.

BIO-MELBOURNE NETWORK

The Bio-Melbourne Network says its February 2, 2017 Bio-Briefing is entitled 'Hot or Not - Trends for 2017'.

The Network said that five panellists would discuss global trends in the financial markets, intellectual property, emerging technologies for cancer immunotherapy, the challenges ahead for pharmaceutical manufacturing as well as the role of big data in the continuing convergence of health and information technology.

The Network said that the panellists would present a snap-shot of what was hot and what was not in their area of expertise before engaging in a panel session.

Bio-Melbourne Network chief executive officer Dr Krystal Evans said "the speakers selected have a terrific breadth of knowledge across emerging healthcare innovation and translation".

"This event has been fully subscribed each year so we're advising that those interested in attending register as soon as possible," Dr Evans said.

"With an increased rate of change in the innovation and financial landscape, both globally and locally, this is a great opportunity to hear from sector leaders on what you need to know heading into 2017," Dr Evans said.

The Network said that the speakers would be Phillips Ormonde Fitzpatrick partner Dr Debra Yin Foo, the Bank of Melbourne head of premium banking and business growth Jonathan Ayres, The Walter and Eliza Hall Institute immunology researcher Dr Ryan Cross, Healthkit managing-director Alison Hardacre and Centre for Biopharmaceutical Excellence director Steve Williams.

The Network said that the Bio-Briefing would be held at the offices of Phillips Ormonde Fitzpatrick, Level 16, 333 Collins Street, Melbourne on February 2, 2017, with registration from 4.15pm, presentations until 5.30pm and networking until 6.30pm.

To register go to: http://bit.do/hot-or-not.