Biotech Daily

Tuesday December 20, 2016

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: UNIVERSAL BIOSENSORS UP 15.5%**
- CYCLOPHARM DOWN 11%

*** REDHILL DOSES 1st YELIVA MULTIPLE MYELOMA PATIENT**

*** ZELDA, CURTIN UNI TRIAL MARIJUANA FOR PANCREATIC CANCER**

*** FACTOR RECRUITS 1st US VF-001 VENOUS LEG ULCER PATIENT**

*** UK OK FOR PRIMA AIPAC IMP321, PACLITAXEL BREAST CANCER TRIAL**

*** RECCE: 'EFFICACY CORRELATION' FOR RECCE 327 FOR FLU IN MICE**

*** VOLPARA RIGHTS ISSUE RAISES $3.7m, TOTAL RAISED $10.7m**

*** ANTISENSE OPTIONS RAISE $73k**

*** NOXOPHARM HITS $50m FOR 2 DAYS, CONVERTS 10m SHARES**

*** CEO DR GRAHAM KELLY, FAMILY TAKE 37% OF NOXOPHARM**

*** NEUROTECH APPOINTS SCIENTIFIC ADVISORY BOARD**

*** MTP CONNECT, ADVANCED MANUFACTURE GROWTH CENTRE PARTNER**

MARKET REPORT

The Australian stock market climbed 0.52 percent on Tuesday December 20, 2016 with the ASX200 up 29.0 points to 5,591.1 points. Eleven of the Biotech Daily Top 40 stocks were up, 13 fell, 14 traded unchanged and two were untraded. All three Big Caps were up.

Universal Biosensors was the best, up 4.5 cents or 15.5 percent to 33.5 cents with 135,000 shares traded. Dimerix, IDT and Psivida climbed more than 14 percent; Factor Therapeutics was up 3.1 percent; Ellex, Cochlear and Prima rose more than two percent; both Admedus and Atcor were up 1.5 percent; with Airxpanders, CSL, Resmed and Viralytics up by less than one percent.

Cyclopharm led the falls, down 10 cents or 11.1 percent to 80 cents with 20,000 shares traded. Benitec and Osprey lost five percent or more; Mesoblast fell four percent; Acrux and Neuren were down more than three percent; Genetic Signatures shed 2.4 percent; Clinuvel, Impedimed, Reva and Sirtex lost one percent or more; with Compumedics and Medical Developments down by less than one percent.

REDHILL BIOPHARMA

Redhill says it has dosed the first of 77 patients in its phase Ib/II study of Yeliva, or ABC294640, for refractory or relapsed multiple myeloma.

Redhill said the open-label, dose-escalation, phase Ib/II study at Duke University Medical Center would enrol patients who had previously been treated with proteasome inhibitors and immune-modulatory drugs (BD: Sep 9, 2016).

The company said that Yeliva, or ABC294640 was licenced from the Hummelstown, Pennsylvania-based Apogee Biotechnology Corp in 2015 and the study was supported by a $US2 million grant from the National Cancer Institute to Apogee in conjunction with Duke University, with additional support from Redhill.

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

Today, the company said that Yeliva was a first-in-class, orally-administered sphingosine kinase-2 (SK2) selective inhibitor, with anti-cancer and anti-inflammatory activities and it was pursuing several clinical studies with Yeliva in the US, targeting multiple oncology and inflammatory indications.

Redhill said that global sales of multiple myeloma therapies were estimated to be more than $US12 billion in 2016.

Last night on the Nasdaq, Redhill fell 49 US cents or 4.37 percent to $US10.71 ($A14.77) with 30,304 shares traded.

ZELDA THERAPEUTICS

Zelda says it has a research collaboration with Curtin University to test its medical marijuana formulations and protocols against in-vitro pancreatic cancer models.

Zelda said the aim was for the Perth, Western Australia-based University to test the impact of its cannabinoid formulations as stand-alone treatments and in combination with existing chemotherapy drugs such as Abraxane that was used to treat pancreatic cancer.

The company said there was evidence that cannabinoid extracts could impede cancer growth and potentially render the tumor more responsive to chemotherapeutic agents.

Zelda said the program would seek to identify whether Zelda formulations could generate anti-cancer activity both alone and in combination with chemotherapeutic agents.

The company said that pancreatic cancer was the twelfth most common cancer globally with more than 330,000 diagnoses in 2012 and a very low five year survival rate.

Zelda said that Curtin University's Prof Marco Falasca and his team were "experts in the investigation of cell signalling pathways, such as those found in cancerous tumor cells that [were] responsible for regulating the internal cellular processes where the uncontrolled growth begins".

The company said that Prof Falasca and his team discovered that lipid signalling was over-activated in the initial stages of pancreatic cancer and this in turn promoted the growth of cancerous cells.

Zelda said the team discovered a novel mechanism that used adenosine triphosphate - binding cassette (ABC) transporters and G-protein coupled receptors on the surface of cells that could halt cancer progression and cell signalling.

The company said the University would test its formulations against specific receptors and looking to replicate the positive effects observed in its breast cancer research program with trials expected to begin in early 2017 (BD: Nov 30, 2016).

Zelda executive chairman Harry Karelis said that pancreatic cancer had "astoundingly low" survival rates and the company hoped to demonstrate anti-cancer activity.

Zelda was up 0.1 cents or 2.7 percent to 3.8 cents.

FACTOR THERAPEUTICS

Factor Therapeutics says it has recruited the first of 168 patients in its US phase II trial of VF-001 for venous leg ulcers at Florida's Miami Dade Medical Research Institute.
Factor Therapeutics chief executive officer Nigel Johnson said the company was "delighted to have now formally launched this phase II trial".
The company said the trial was a multi-centre, double-blind, placebo-controlled study in conjunction with the standard care of compression bandaging and moisture-retentive dressings, comparing two dose levels of VF-001 with a placebo.
Factor Therapeutics said it intended to provide a recruitment update by April 2017 and was targeting a top-line efficacy read-out by the end of 2017 and the trial included a quality-of-life survey to use as a second confirmatory trial for the submission for a Conformité Européenne (CE) mark in Europe.
Factor Therapeutics was up 0.2 cents or 3.1 percent to 6.6 cents.

PRIMA BIOMED

Prima says it has UK regulatory and ethics approval for its phase IIb, active immunotherapy paclitaxel (AIPAC) trial of IMP321 for metastatic breast cancer.
Prima said that following the safety run-in phase, expected in late December, and subject to the dose-escalation committee meeting, screening for the larger, randomized phase of the multi-national, randomized, double-blind, placebo-controlled study of IMP321 plus paclitaxel in metastatic breast cancer was expected to begin in January 2017.
The company said that the safety run-in phase of 15 patients at 11 sites in Belgium, The Netherlands and Hungary with recruitment completed in October and the first safety and pharmacokinetic data expected this year, with the trial expected to take about three years.
Prima said that interim data from the first cohort of patients in its phase I trial of IMP321 with Keytruda for metastatic melanoma patients was also expected this year.
Prima was up 0.1 cents or 2.9 percent to 3.5 cents with 2.5 million shares traded.

RECCE

Recce says that a study of Recce 327 in a mouse model of virus-induced human influenza showed a correlation of efficacy from the doses administered.
Recce said the study, by an independent US contract research organization, observed two groups of 10 mice, both infected with influenza virus and beginning to display symptoms.
The company said there was a difference between the group treated with Recce 327 at 140mg/kg during each of the first five days and the group which received no treatment.
Recce executive chairman Dr Graham Melrose said the result warranted further investigation to determine a comparison of the optimal dosage amounts and timing, against efficacies of commercially established drugs.
"Our pre-clinical programs are on track and we are working towards bringing a potential treatment for sepsis and other infections to phase I clinical trials in 2017," Dr Melrose said.
Dr Melrose said that the company was focused on establishing manufacturing and compiling pre-clinical data for its investigational new drug application to the US Food and Drug Administration in 2017 and was developing, at lower priority, complementary capabilities of Recce 327 to augment its central capability as an antibiotic.
Dr Melrose said the additional data was aimed at broadening and potentially strengthening its application for Recce 327 as a new class of antibiotic.
Recce was untraded at 18 cents.

VOLPARA HEALTH TECHNOLOGIES

Volpara says its underwritten rights issue at 60 cents a share has raised $3.7 million taking the total raised with the November placement to $10.7 million (BD: Nov 22, 2016).
Volpara said that it received applications for about $2.3 million or 62 percent of the total entitlements available and all applications for additional shares were satisfied leaving a shortfall of about $1.4 million.
The company said that underwriter Morgans Corporate had placed the shortfall with investors.
Volpara said that the proceeds would be used for working capital and the expansion of the US sales force.
Volpara was up 0.5 cents or 0.8 percent to 60.5 cents.

ANTISENSE THERAPEUTICS

Antisense says it raised $73,169 through the issue of 36,584,664 options to eligible subscribers and issued 32,129,130 bonus options to eligible shareholders.
Antisense said that a total of 68,713,794 ANPOB options had been issued.
Antisense was untraded at 3.7 cents.

NOXOPHARM

Noxopharm says it has met a $50 million market capitalization criterion and converted 10,000,000 performance shares into unlisted shares, in escrow until August 2018.
Noxopharm said that following the conversion it had 33,560,000 listed shares and 51,611,429 unlisted shares, as well as 22,585,716 unlisted options exercisable at 30 cents each by February 28, 2021.
With 75,171,429 listed and unlisted shares prior to the conversion, Noxopharm was required to trade at or above 66.5 cents, which it did on November 23, remaining above that level until the close on November 24, and breaking through again on November 25, 2016, but closing at 59 cents.
According to the Noxopharm prospectus 6,320,352 performance shares were held by Milligene Pty Ltd an entity associated with founder and chief executive officer Dr Graham Kelly; with 1,424,808 shares held by David Hannon's DRH Superannuation Pty Ltd; 1,331,378 shares held by Adam Blumenthal's Anglo Menda; 366,246 shares held by Helium Management Pty Ltd, an entity associated with director Dr Ian Dixon; 278,608 shares held by John Thom; 187,047 shares held by Aquagolf Pty Ltd; and 91,561 shares held by Robert and Lesley Birch.
Noxopharm was up 0.5 cents or 1.05 percent to 48 cents.

NOXOPHARM

Noxopharm chief executive officer Dr Graham Kelly and associates have increased their substantial holding from 24,345,000 shares (32.38%) to 31,410,221 shares (36.88%).
The substantial shareholder notice said that the holders included Milligene Pty Ltd for the GE and PR Kelly Family Trust, Prue Kelly, Bende Holdings Pty Ltd, Phytose Corp and Boundaryone Superannuation Fund

NEUROTECH INTERNATIONAL

Neurotech says it has appointed a scientific advisory board to be led by founder and chief scientific officer Dr Adrian Attard Trevisan.

Last month, the Malta-based Neurotech listed on the ASX raising $7 million at 20 cents a share to market brain disorder products (BD: Nov 4, 2016).

Today, Neurotech said it had appointed University of Milan human physiology professor Prof Paolo Cavallari, London's Kings College neonatal medicine professor Prof Denis Azzopardi, former US EEG and Clinical Neuroscience Society president Dr David Cantor and England's Bedfordshire Centre for Mental Health senior research fellow Dr Anton Grech to the board with senior neuroscientist Dr Marco Rotonda as secretary.

The company said the board would act as strategic counsel, guiding management as it entered the market with its Mente Autism device, in addition to the development of other devices targeting various neurological disorders.

Neurotech said that the "key deliverable expected … [was] a company vision document, which would be delivered by the end of each year.

Neurotech was up 1.5 cents or 4.05 percent to 38.5 cents.

MEDICAL TECHNOLOGIES AND PHARMACEUTICALS INDUSTRY GROWTH CENTRE

Two Federal agencies MTP Connect and the Advanced Manufacturing Growth Centre say they will partner to accelerate the growth of advanced life sciences manufacturing.

The Medical Technologies and Pharmaceuticals Industry Growth Centre, or MTP Connect, and the Advanced Manufacturing Growth Centre said they had signed an agreement to promote advanced manufacturing in medical technologies, biotechnology and pharmaceuticals.

The two organizations said they were both established as part of the Federal Government's Industry Growth Centres Initiative and would work closely to foster collaboration to engage and strengthening the sector.

MTP Connect chief executive officer Sue MacLeman said the agreement would be "pivotal to increasing the value of advanced manufacturing in the [medical technologies and pharmaceuticals] sector, building on Australia's reputation for high-quality manufacturing and growing demand from Asia for Australian-manufactured products, including pharmaceuticals".

Advanced Manufacturing Growth Centre managing-director Dr Jens Goennemann said that the aim was "to align our strengths, not duplicate resources, in order to focus on specific areas where we know our offerings set us apart from other nations".

A media release from the two organizations said they would develop industry knowledge priorities, particularly technology priorities in areas of competitive advantage, increase management awareness of international best practices in advanced manufacturing processes to improve productivity and reduce costs, encourage greater introduction of complementary services by manufacturers and showcasing examples of firms that have successfully expanded up the value chain, identify opportunities for firms to collaborate on research and development pooling and shared resources and working with the Department of Trade to identify under-served markets and communicate these markets to manufacturers.