Biotech Daily

Monday October 10, 2016

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: LIVING CELL UP 9%; PRANA DOWN 10%**

*** FDA APPROVES LBT, HETTICH AUTO PLATE ASSESSMENT SYSTEM**

*** SIRTEX SIR-SPHERES SAFE FOR KIDNEY CANCER**

*** FDA 510k LEADS TO POLYNOVO BTM NEW ZEALAND LAUNCH**

*** USCOM BUDAPEST 12-MONTH REVENUE UP 48% TO $739k**

*** ITL SAMPLOK IN BIOMÉRIEUX UK TENDER**

*** FACTOR THERAPEUTICS IND FOR US PHASE II VF-001 WOUND TRIAL**

*** CELLMID $1m Q1 RECORD EVOLIS HAIR LOSS SALES**

*** MEDIBIO: '$11m FROM FEDERAL TAX INCENTIVE, GRANTS, OPTIONS'**

*** VOLPARA WEBSITE, SOCIAL MEDIA TO EXPLAIN BREAST DENSITY**

*** AUSTRALIAN ETHICAL TAKES MORE ELLEX PROFIT TO 6.4%**

*** REGAL FUNDS BELOW 5% OF IMPEDIMED, AGAIN**

*** FORMER POLYNOVO DIRECTOR DAVID KENLEY BELOW 5%**

*** WHITNEY GEORGE TAKES 7% OF RHINOMED**

*** TIM BATEMAN REPLACES ACRUX CFO, CO SEC SHARON PAPWORTH**

*** JOHN OSBORNE REPLACES AVEXA CO SEC LEE MITCHELL**

MARKET REPORT

The Australian stock market was up 0.15 percent on Monday October 10, 2016 with the ASX200 up 8.0 points to 5,475.4 points. Fourteen of the Biotech Daily Top 40 stocks were up, 19 fell, six traded unchanged and one was untraded.

Living Cell was the best, up 0.7 cents or nine percent to 8.5 cents with 225,292 shares traded. Genetic Signatures climbed 6.1 percent; Benitec, Bionomics, Oncosil and Uscom were up four percent or more; Cellmid was up 3.1 percent; Clinuvel and IDT rose more than two percent; Acrux, Admedus, Airxpanders and Pharmaxis were up more than one percent; with Compumedics and CSL up by less than one percent.

Prana led the falls, down 0.9 cents or 10.1 percent to eight cents, with 830,956 shares traded. Opthea lost 6.4 percent; Avita, Impedimed, Polynovo and Psivida fell more than four percent; Factor Therapeutics was down 3.1 percent; Nanosonics, Orthocell, Reva and Sirtex shed two percent or more; with Anteo, Atcor, Ellex, Mesoblast and Osprey down more than one percent.

LBT INNOVATIONS

LBT jumped 94.7 percent to 37 cents following US Food and Drug Administration clearance for its automated plate assessment system (APAS).

The company said that the FDA 510(k) de novo submission clearance was to LBT's Switzerland-based Clever Culture Systems AG joint-venture with Hettich AG for APAS as a class II medical device.

LBT said APAS was "a breakthrough artificial intelligence technology for the automated imaging, image analysis, interpretation and reporting of growth on microbiology culture plates after incubation" enabling faster diagnosis and reporting of infectious diseases.

LBT said that it had licenced APAS on a global, exclusive basis to Clever Culture Systems, which was integrating APAS with laboratory robotic instrumentation, with Clever Culture expected to bring APAS to market in 2017 as an automated stand-alone plate reader, APAS Independence, followed by the integrated incubator APAS Incubot.

LBT said the 510(k) de novo submission used a manual version of APAS to test 10,000 patients in a series of Australian and US clinical trials, in which APAS achieved its primary endpoints and the results matched or exceeded the findings of a panel of microbiologists.

LBT chief executive officer Brent Barnes said that FDA clearance followed "rigorous interrogation and validation of the capabilities of APAS".

"The successful clinical trial program completed in 2015 and clearance by FDA also validate the underlying technology that is the core platform of our company's vision to integrate imaging with interpretative intelligence to deliver faster and more secure diagnoses for patients," Mr Barnes said.

"FDA clearance is a fitting tribute to the many years of painstaking work by LBT's staff and partners, who together have made our shared vision a reality," Mr Barnes said.

LBT said that former chief executive officer Lusia Guthrie and chair of Clever Culture said that Clever Culture was in discussions with diagnostics companies for the licencing of the APAS product portfolio, including APAS Independence and APAS Incubot, plus flow-on product opportunities on the drawing board all aimed at the clinical microbiology laboratory.

LBT closed up 18 cents or 94.7 percent to 37 cents with 6.4 million shares traded.

POLYNOVO

Polynovo says it will launch its biodegradable temporising matrix (BTM) wound treatment in New Zealand this week, through Device Technologies Australia.

Polynovo chief executive officer Paul Brennan told Biotech Daily that the New Zealand regulator Medsafe recognized US Food and Drug Administration 510k and Conformité Européenne (CE) mark approvals.

Mr Brennan said that the company received FDA approval late last year and he expected first US sales before the end of this year.

Polynovo said that Australian sales would be through the Australian Therapeutic Goods Administration prescribers exemption scheme process until the TGA accepted the CE mark approval, expected in 2018.

The company said that the Sydney-based Device Technologies Australia Pty Ltd was "Australasia's largest independent distributor of high quality and innovative medical equipment, implants and consumables" and had been granted exclusive distribution rights for the sale of the BTM tissue scaffold in New Zealand and Australia.

Polynovo said that the BTM launch would be at the Australia New Zealand Burn Association conference in Auckland, New Zealand, October 11 to 15, 2016.

Polynovo fell 1.5 cents or 4.7 percent to 30.5 cents with 2.2 million shares traded.

SIRTEX

Sirtex says its 21-patient, phase I 'Resirt' trial of SIR-Spheres for primary renal cell carcinoma found no dose limiting toxicities or related serious adverse events.

Sirtex said that the study, co-authored by chief medical officer Dr David Cade, concluded that the study demonstrated "good tolerability of [SIR-Spheres radiation therapy] at all dose levels including imminent stasis in treating primary tumours in [renal cell carcinoma] patients otherwise unsuitable for conventional therapy".

The company said that data was presented in a poster session at the European Society for Medical Oncology Congress in Copenhagen, Denmark on October 9, 2016 and an abstract was available at http://bit.ly/2duVgzT (poster number 803P, page 287).

Sirtex said the Australian-based, single arm, dose escalation study of patients not suitable for curative therapy by surgical re-section, ablation or other conventional techniques increased radiation doses from 75 Gray to 300 Gray, and an "imminent stasis" group.

The company said that "imminent stasis" related to the blocking of the blood vessels to the tumor by the SIR-Spheres.

Sirtex said that the primary endpoints were safety and toxicity at 30 days post treatment and there were no dose-limiting toxicities and no serious adverse events related to SIR-Spheres microspheres.

The company said that 15 patients experienced 44 adverse events within 30 days of treatment, of which eight patients with grade 3 adverse events were unrelated to SIR-Spheres and eight patients had 12 grade 1-2 adverse events related to SIR-Spheres.

Sirtex said that the best overall tumor responses were one patient of 19 with a partial response, 17 with stable disease and one patient with progressive disease.

"We are pleased with the initial results of the Resirt study, given it represents our first clinical study investigating the use of SIR-Spheres microspheres outside of the liver," Dr Cade said.

Sirtex fell 62 cents or 2.0 percent to $30.49 with 231,760 shares traded.

USCOM

Uscom says its Budapest subsidiary has increased revenue 48 percent to $739,000 in the 12 months since its acquisition last year (BD: Sep 1, 2015).

Uscom said the Budapest, Hungary subsidiary, previously Thor Laboratories, reported a net loss before tax of $3,000.

Last year, Uscom says it had rebadged its Thor range of medical devices as the Spirosonic range of spirometers for improving diagnosis and treatment of asthma and chronic obstructive lung disease (BD: Nov 25, 2015).

Today, the company said it acquired Thor for $879,000 in cash and scrip for its "practice-leading pulmonary devices and consumables" which had Conformité Européenne (CE) mark and US Food and Drug Administration accreditation for manufacture and was acquired with assets of AU$248k and a total revenue of $500,000 in 2015.

Thor founder and Uscom's head of pulmonary markets George Ferenczi said that "the globalization of our operations supported by the association with the Uscom brand has improved our credibility and increased our visibility in the market and increases sales".

"This trend will continue as we begin to sell the new Spirosonic devices following regulatory approval in the European, US and Chinese markets," Mr Ferenczi said.

Uscom executive chairman Prof Rob Phillips said there was "a growing global focus on improving pulmonary disease monitoring, and this will rapidly convert into sales and revenue for Uscom via our new Spirosonic devices".

Uscom was up one cent or four percent to 26 cents.

ITL

ITL says the Lyon, France-based Biomérieux has won a UK National Health Service for bacterial screening of platelets, which includes its Samplok blood sampling system.
ITL said that Biomérieux distributed several of its products and its bio-medical division had partnered with Biomérieux for more than five years for the supply of the Samplok blood sampling system in the UK, generating $11.5 million in revenue.
The company said that Biomérieux won the tender with its Bact Alert microbial detection system, with its Samplok sampling device used to transfer platelets from the platelet bag to Biomérieux's reagent bottle.
ITL executive chairman Bill Mobbs said that the award for Biomérieux's standard-setting bacterial detection testing technology is very exciting and ITL is pleased to have [the] Samplok sampling kit included".
ITL fell half a cent or 2.2 percent to 22.5 cents.

FACTOR THERAPEUTICS

Factor Therapeutics says it has filed an amended investigational new drug application to the US Food and Drug Administration for a phase II VF-001 wound healing trial.
Factor Therapeutics said that the amended application included complete certificates of analysis for materials to be used in the planned phase II trial, comparability information and a revised clinical protocol, consistent with prior requests from the FDA and was in a 30-day review process by the FDA.
Factor Therapeutics chief executive officer Nigel Johnson said the company was awaiting a decision from the FDA about the company's clinical hold.
Factor Therapeutics executive director Dr Christian Behrenbruch said that the data submission was "high quality and we have every reason to believe we submitted a complete and approvable IND submission".
Factor Therapeutics fell 0.2 cents or 3.1 percent to 6.3 cents with 1.8 million shares traded.

CELLMID

Cellmid says it has sold a record $1,022,913 of Advangen Evolis products for hair loss in the three months to September 30, 2016.
Cellmid said it was the first time sales of the FGF5-inhibitor hair loss products had exceeded $1 million in a three month period.
Cellmid was up 0.1 cents or 3.1 percent to 3.3 cents with 9.4 million shares traded.

MEDIBIO

Medibio says it expects to receive about $11 million from a Federal Government R&D Tax Incentive, the exercise of options and Federal grants.
Medibio said it had lodged its tax return for the year to June 30, 2016 on September 23, including a claim for the Research and Development Tax Incentive for $3,074,224 and expected the Incentive within the next 14 days.
The company said that three shareholders had made commitments to exercise options which would result in a total of $900,000 of which $400,000 had been received.
Medibio said it had lodged an application for a $1 million Accelerating Commercialization grant and would apply for a $3 million co-operative research centre grant.
Medibio fell half a cent or one percent to 48.5 cents.

VOLPARA HEALTH TECHNOLOGIES

Volpara says it has launched a website and social media awareness program to explain the importance of breast density.

Volpara said the Breast Kept Secret website https://www.breastkeptsecret.com.au/, and its social media channels aimed "to encourage conversation and awareness around the importance of breast density in breast imaging, ensure women are informed of their breast density and outline steps they can take if they have dense breasts".

The company said that breast density awareness was very high in the US, with 27 states legislating that women must be advised of their breast density at the time of screening.

Volpara said that the US Food and Drug Administration was considering amendments to Federal regulations to address the issue of breast density notification.

Volpara fell two cents or 3.4 percent to 57 cents.

ELLEX MEDICAL LASERS

Australian Ethical Investment says it has again reduced its holding in Ellex from 8,757,718 (7.67%) to 7,268,018 shares (6.37%).

Australian Ethical said that between September 23 and October 5, 2016 it sold 1,489,700 shares for $1,733,245 or an average price of $1.16 a share.

Australian Ethical became substantial in Ellex in 2013 with 8,794,563 shares or 9.01 percent of which 5,000,000 shares were acquired in a capital raising at 26 cents a share (BD: Oct 3, 2013).

In 2013 and 2014 Australian Ethical bought shares at about 30 cents a share and first reduced its holding this year, selling shares from 75 cents to $1.09 a share.

Ellex fell two cents or 1.5 percent to $1.305.

IMPEDIMED

Regal Funds Management says the net disposal of 24,121 Impedimed shares has taken it below the five percent substantial shareholding level.

The Sydney-based Regal Funds said that between September 9 and 12, it bought 827,943 shares for prices ranging from $1.35 to $1.40 and share and between September 9 and October 5 sold 852,064 shares for prices ranging from $1.59 to $1.69 a share.

Last month, Regal Funds became a substantial shareholder in Impedimed, again, buying shares at prices ranging from 88 cents to $1.76 a share (BD: Sep 13, 2016).

Regal Funds previously became a substantial shareholder in Impedimed on July 1 with 18,682,335 shares or 5.00 percent of the company but on July 5, said it had been diluted below five percent through the issue of shares under the employee share option plan (BD: Jul 1, 2016).

Impedimed fell seven cents or 4.3 percent to $1.56.

POLYNOVO

Former director David Kenley says he has ceased his substantial holding in Polynovo.

Last December, Mr Kenley said he held 30,063,358 shares or 5.49 percent of Polynovo and today said that 2,572,733 shares were affected in the change which was attributed to "on market purchases and sales and dilution by Polynovo issuing capital".

In 2015, Polynovo sold its AOD9604 asset to Lateral Pharma of which Mr Kenley was chief executive officer for $1.5 million and potential sales royalties (BD: Apr 30, 2015).

RHINOMED

Whitney George says he has increased his substantial shareholding in Rhinomed from 43,566,205 shares (5.35%) to 55,566,205 shares (6.82%).
The Carlsbad, California-based W Whitney George said he acquired the shares between Jun 29 and October 6, 2016 at prices ranging between one and two cents.
In June, Mr George said he acquired shares at prices ranging from one cent a share to 2.2 cents a share and said that he was associated with the Toronto, Ontario-based Sprott Asset Management, whose website said he was the senior portfolio manager of the Sprott Focus Trust (BD: Jun 6, 2016).
Rhinomed was unchanged at 1.9 cents.

ACRUX

Acrux says that Tim Bateman will replace Sharon Papworth as chief financial officer and company secretary from October 28, 2016.
Acrux was up half a cent or 1.5 percent to 34 cents.

AVEXA

Avexa says that John Osborne will replace Lee Mitchell as company secretary, effective immediately.
Avexa fell 0.3 cents or 9.1 percent to three cents.