Biotech Daily

Friday May 27, 2016

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: ADMEDUS UP 8%, ANTISENSE DOWN 9%**

*** AVIRAGEN (BIOTA): CARDIAC ISSUE HALTS BTA585 RSV TRIAL**

*** EUROGOLD RAISES $3m FOR BARD1 LUNG CANCER TEST**

*** WEHI 'CELL DEATH TRIGGER COULD LEAD TO NEW DRUGS'**

*** OBJ, PROCTOR & GAMBLE SIGN NEW 5-YEAR DEAL**

*** SIMAVITA $1m FUNDING, EXIT TSX, 100% DIRECTORS POOL HIKE EGM**

*** FIL TAKES 8% OF IMPEDIMED**

*** HUNTER HALL TAKES 17% OF GI DYNAMICS**

*** CRYSTAL AMBER TAKES 10% OF GI DYNAMICS**

*** IMMURON REQUESTS 'RIGHTS ISSUE CAPITAL RAISING TRADING HALT'**

*** ADMEDUS APPOINTS 6% HOLDER MATHEW RATTY DIRECTOR**

*** RECCE APPOINTS BERNADETTE MURDOCH DIRECTOR**

MARKET REPORT

The Australian stock market climbed 0.33 percent on Friday May 27, 2016 with the ASX200 up 17.8 points to 5,405.9 points. Sixteen of the Biotech Daily Top 40 stocks were up, 13 fell, nine traded unchanged and two were untraded.

Admedus was the best, up three cents or 8.8 percent to 37 cents with 344,820 shares traded, followed by Cellmid up 8.3 percent to 2.6 cents with 9.9 million shares traded. Ellex and Viralytics climbed more than seven percent; Anteo, Impedimed and Genetic Technologies were up more than four percent; Actinogen, Biotron, Clinuvel, Mesoblast and Uscom rose more than two percent; Bionomics, Nanosonics and Polynovo were up more than one percent; with Resmed and Sirtex up by less than one percent.

Antisense led the falls, down 8.9 percent to 4.1 cents, with 445,460 shares traded. Factor Therapeutics (Tissue Therapies) and Pharmaxis lost more than five percent; Avita fell 4.55 percent; Acrux, IDT and Reva were down more than three percent; Medical Developments and Prima shed more than two percent; Opthea lost 1.05 percent; with Airxpanders, Cochlear, CSL, Pro Medicus and Starpharma down by less than one percent.

AVIRAGEN THERAPEUTICS (FORMERLY BIOTA PHARMACEUTICALS)

Aviragen says it has voluntarily decided to delay further enrolment in the UK phase IIa trial of oral BTA585 for respiratory syncytial virus (RSV) infections.

Aviragen said that the decision resulted from a laboratory report from one subject showing an increase of a cardiac enzyme level coupled with transient electro-cardiogram (ECG) changes, which led to a hospitalization of less than 24 hours.

The company said that the subject's ECGs were normal prior to hospitalization and the cardiac enzyme levels returned to baseline shortly thereafter.

Aviragen said that subsequent to the submission of the requisite safety report to the regulatory authorities, it received verbal communication from the US Food and Drug Administration that the investigational new drug application for BTA585 has been placed on clinical hold for studies being conducted in the US.

The company said that there were no BTA585 trials being conducted under the application and more specific written information from the FDA about the clinical hold was expected within 30 days.

Aviragen chief executive officer Dr Joseph Patti said that patient safety was “paramount to us, which led to our decision to voluntarily delay enrolment”.

“We have proactively reached out to the Medicines and Healthcare Products Regulatory Agency, the regulatory authority in the UK, to discuss this event and any implications it may have on the continued clinical development of BTA585,” Dr Patti said.

In April, the then Biota began its phase IIa challenge study of oral BTA585 for the treatment and prevention of respiratory syncytial virus infections (BD: Apr 12, 2016).

BTA585 was invented in Biota’s then Melbourne facility and has US Food and Drug Administration fast track designation.

In February, Biota said its 66-patient, phase I trial of BTA585 for RSV showed it was generally well tolerated at all dose levels and the safety and pharmacokinetic study found no serious adverse events and no drug-related clinically-significant adverse changes in electro-cardiogram or clinical laboratory values (BD: Feb 29, 2016).

In April, the company said that the double-blind, placebo-controlled, phase IIa trial was designed to evaluate the safety, pharmacokinetics and antiviral activity of orally-dosed BTA585 in healthy volunteers challenged intra-nasally with RSV.

Biota said at that time, that the primary endpoint was the “area under the curve” for the viral load in nasal wash among subjects who test positive for RSV prior to dosing.

Biota said that secondary efficacy endpoints included measures of RSV clinical symptoms and other viral load endpoints..

On the Nasdaq last night, Aviragen fell one US cent or 0.63 percent to $US1.59 ($A2.20 equivalent to 27.5 cents before departing the ASX) with 66,879 shares traded.

EUROGOLD

Eurogold says its placement to raise $3 million to acquire Bard1 AG has closed oversubscribed and it expects to relist as Bard1 Life Sciences with the ASX code BD1.

In December 2015 and February 2016 the Western Australian gold mining company said it hoped to acquire the Swiss public company, founded in 2011 by the University Hospital of Geneva’s the head of the molecular gynaecology and obstetrics laboratory Dr Irmgard Irminger-Finger (BD: Feb 24, Mar 24, 2016).

The company said at that time that Bard1 AG had developed “a simple blood test for screening and diagnosing lung cancer at early stages of disease progression”.

The company said that the lead manager was State One Equities.

Eurogold was untraded at 2.4 cents.

THE WALTER AND ELIZA HALL INSTITUTE OF MEDICAL RESEARCH

The Walter and Eliza Hall Institute says the discovery of a new way of triggering cell death could lead to drugs to treat cancer and autoimmune disease.

The Institute said that programmed cell death, or apoptosis, was a natural process that removed unwanted cells from the body.

WEHI said that the failure of apoptosis allowed cancer cells to grow unchecked or immune cells to inappropriately attack the body.

The Institute said that the Bak protein was central to apoptosis and in healthy cells, Bak was in an inert state but when a cell received a signal to die, Bak transformed into a killer protein that destroyed the cell.

The Institute said that researchers Dr Sweta Iyer, Dr Ruth Kluck and colleagues discovered a novel way of directly activating Bak to trigger cell death.

The research, entitled 'Identification of an activation site in Bak and mitochondrial Bax triggered by antibodies' was published in Nature Communications with an abstract at: http://www.nature.com/ncomms/2016/160524/ncomms11734/full/ncomms11734.html.

WEHI said that the researchers discovered that an antibody they had produced to study Bak, bound to the Bak protein and triggered its activation.

The article said that during apoptosis, Bak and Bax were activated by BH3-only proteins binding to the alpha2–alpha5 hydrophobic groove and Bax was also activated via a rear pocket.

The authors said that antibodies could directly activate Bak and mitochondrial Bax by binding to the alpha1–alpha2 loop.

The article said the monoclonal antibody, clone 7D10, bound close to alpha1 in non-activated Bak to induce conformational change, oligomerization, and cytochrome c release.

"Our identification of the alpha1–alpha2 loop as an activation site in Bak paves the way to develop intrabodies or small molecules that directly and selectively regulate these proteins," the abstract said.

Dr Kluck said the findings were completely unexpected.

"We were excited when we realised we had found an entirely new way of activating Bak," Dr Kluck said. "There is great interest in developing drugs that trigger Bak activation to treat diseases such as cancer where apoptosis has gone awry."

"This discovery gives us a new starting point for developing therapies that directly activate Bak and cause cell death," Dr Kluck said.

WEHI said that the researchers used information about Bak's three-dimensional structure to discover how the antibody activated Bak.

"It is well known that Bak can be activated by a class of proteins called 'BH3-only proteins' that bind to a groove on Bak," Dr Kluck said.

"We were surprised to find that despite our antibody binding to a completely different site on Bak, it could still trigger activation," Dr Kluck said.

Dr Kluck said that drugs that target the new activation site could be useful in combination with other therapies that promoted cell death by mimicking the BH3-only proteins.

"The advantage of our antibody is that it can't be mopped-up and neutralized by pro-survival proteins in the cell, potentially reducing the chance of drug resistance occurring," Dr Kluck said.

WEHI said that its researchers were working with collaborators to develop their antibody into a drug that could access Bak inside cells.

The Institute said the research was supported by the National Health and Medical Research Council, the Australian Research Council, the Victoria Government Operational Infrastructure Support Scheme and the Victorian Life Science Computation Initiative.

OBJ

OBJ says it has a new five-year transdermal product development agreement with Procter and Gamble, replacing the 2014 agreement (BD: Apr 28, 29, 2014).
OBJ said that the agreement included the over-arching, multi-product and multi-category terms of licence agreements from development programs undertaken by OBJ and funded by Procter and Gamble.
The company said that Procter and Gamble retained a worldwide exclusive right to commercialize OBJ's non-powered magnetic micro-array technology within specifically defined product categories.
OBJ said the Wave 1 Eye Wand was the first product developed and licenced under the initial agreement, proceeding from a launch in Asia to become an important product in Procter and Gamble SK-II's business.
The company said that 11 Work Plans had been announced by Procter and Gamble as part of the agreement to date, encompassing multiple brands and categories.
OBJ said that as well as extending the relationship to 2021, the new agreement allowed OBJ to provide additional technologies and product initiatives and Procter and Gamble would be able "to build innovative, high performance products based upon OBJ technology, with OBJ to realize additional fees accordingly".
The company said the agreement focused on strategic Procter and Gamble areas, allowing it to seek opportunities in categories not in development with Procter and Gamble
OBJ was unchanged at 7.9 cents with 3.2 million shares traded.

SIMAVITA

Simavita says a special meeting of shareholders will vote on a raft of resolutions, including directors pay and options, to re-capitalize and re-start the company.
In April, Simavita underwent a significant board and management change with Michael Spooner and Dr Gary Pace replacing chairman Michael Brown and chief executive officer Philippa Lewis (BD: Apr 27, 2016).
Today, the company said it had "implemented significant cost reduction programs" and was reviewing existing customer installations and business opportunities.
Simavita said that shareholders would vote to raise up to $10,000,000, of which $3,063,000 had been raised through debt notes at five cents a share for immediate and near term operating requirements.
The company said that the resolutions included the issue of 7,603,422 options each to Mr Spooner and to Dr Pace, exercisable at five cents each by June 28 2023 and vesting on the earlier of December 31, 2017 or on a change in control through an offer from a third party for more than 20 percent of the company's issued capital.
Simavita said that shareholders would vote to issue up to 138,740,000 shares at five cents each to raise $6,937,000 and vote to delist from the Toronto Stock Exchange as soon as is practicable, while maintaining its ASX listing.
Simavita said that if investors did not approve the refinancing resolutions, the company would be in default under the convertible note deeds and the debt notes and the principal amount plus interest will become repayable.
Simavita said that shareholders would vote to increase the directors remuneration pool by 100 percent from $350,000 to $700,000, saying the increase was necessary "to attract sufficient quality of directors to achieve the corporation's goals".
The meeting will be held at K&L Gates, Level 31, 1 O'Connell Street, Sydney, on June 23, 2016 at 10am (AEST).
Simavita was up 0.2 cents or 4.2 percent to five cents.

IMPEDIMED

The Singapore-based FIL Limited says it has increased its substantial shareholding in Impedimed from 21,137,709 shares (7.20%) to 30,920,035 shares (8.29%).
FIL said it bought and sold shares between December 8, 2015 and May 24, 2016, trading shares at prices between 78 cents and $1.23.
Impedimed was up four cents or 4.5 percent to 93.5 cents.

GI DYNAMICS

Hunter Hall Investment Management says it has increased its substantial shareholding in GI Dynamics from 75,779,090 shares (15.98%) to 81,523,123 shares (17.14%).
The Sydney-based Hunter Hall said it acquired the shares between March 8 and May 25, 2016 with the single largest purchase 2,912,603 shares for $58,558 or 2.01 cents a share.
GI Dynamics was up 0.4 cents or 20 percent to 2.4 cents with 3.3 million shares traded.

GI DYNAMICS

The Crystal Amber Fund says it has become a substantial shareholding in GI Dynamics with 47,359,151 shares or 9.96 percent.
The London and St Peter Port, Guernsey Island-based Crystal Amber Fund failed to provide the standard information required under the Corporations Act and did not disclose the price of the shares acquired nor its address details.
The company's website said it was listed on London's Alternative Investment Market.
Yesterday, the London-based M&G Investment Funds said it sold 46,030,187 GI Dynamics Chess depository instruments(CDIs) for $781,572 or an average price of 1.7 cents a share (BD: May 26, 2016).
The Crystal Amber Fund substantial shareholder notice was signed by Laurence McNairn and Danny Felbabel as "company secretary".

IMMURON

Immuron has requested a trading halt pending "an announcement to the market in relation to a proposed capital raising via rights issue".
Trading will resume on May 31, 2016 or on an earlier announcement.
Immuron last traded at 33 cents.

ADMEDUS

Admedus says it has appointed Mathew Ratty as a non-executive director.
Admedus said that Mr Ratty had "significant experience in both domestic and international capital markets as well as investment and funding feasibility analysis".
The company said that Mr Ratty was the co-founder of the Perth, Western Australia-based venture capital firm MC Management Group Pty Ltd, which was its second largest shareholder.
In 2014, MC Management said it held 6.2 percent of Admedus (BD: Nov 10, 2014).
Admedus said that Mr Ratty was currently a director of property investment and development firm Gladstone Bridge Pty Ltd.
The company said that Mr Ratty held Bachelor of Finance and Bachelor of Commerce from Curtin University.
Admedus was up three cents or 8.8 percent to 37 cents.

RECCE

Recce says it has appointed Bernadette Murdoch as an independent non-executive director.

Recce said that Ms Murdoch was currently Glaxosmithkline's Australasia head of corporate affairs and communications.

The company said that Ms Murdoch was previously an associate at public relations firm Burson-Marsteller and a consultant to CSL, Melbourne Water, Motorola and Australian Telecommunications Association.

Recce was up three cents or 12.5 percent to 27 cents.