Biotech Daily

Friday March 6, 2015

Daily news on ASX-listed biotechnology companies

*** ASX FLAT, BIOTECH UP: BIONOMICS UP 11%, GI DYNAMICS DOWN 50%**

*** DR MEGAN BALDWIN SHARPENS CIRCADIAN FOCUS**

*** LIVER INFECTIONS HALT GI DYNAMICS US TRIAL**

*** TGA APPROVES GENERA DIAGNOSTICS FOR REGISTER**

*** WEHI IDENTIFIES HUMAN ANTIGEN R ROLE FOR ANTIBODIES, IMMUNITY**

*** NANOSONICS DR RON WEINBERGER WINS 'INNOVATION HERO' GONG**

*** GENETIC TECHNOLOGIES REQUESTS CAPITAL RAISING TRADING HALT**

*** HUNTER HALL FORCED TO SELL MORE SIRTEX TO $7; BREAKS $2b**

*** STARFISH VENTURES INCREASES, DILUTED TO 8.6% OF IMPEDIMED**

*** MEDIBIO EGM BACKS INVATEC HEART-DEPRESSION TEST ACQUISITION**

MARKET REPORT

The Australian stock market slipped 0.09 percent on Friday March 6, 2015 with the S&P ASX 200 down 5.3 points to 5,898.9 points. Seventeen of the Biotech Daily Top 40 stocks were up, 12 fell, nine traded unchanged and two were untraded. All three Big Caps rose.

Bionomics was the best, up 5.5 cents or 11.1 percent to 55 cents with 550,373 shares traded.

Atcor, IDT, Medical Developments and Oncosil climbed more than 10 percent; Compumedics was up 8.3 percent; Universal Biosensors was up 7.8 percent; Impedimed was up five percent; Acrux, Antisense and Nanosonics were up more than four percent; Osprey and Resmed were up more than three percent; Sirtex rose 2.55 percent through the $2 billion mark; Anteo, Benitec, CSL and Living Cell were up by more than one percent; with Cochlear and Psivida up by less than one percent.

GI Dynamics led the falls, down 15 cents or 50 percent to 15 cents with 9.1 million shares traded. Optiscan and Prana lost more than six percent; Analytica, Mesoblast and Tissue Therapies fell more than four percent; Admedus and Starpharma were down more than three percent; Pharmaxis, Prima and Viralytics shed more than two percent; with Clinuvel down 1.9 percent.

CIRCADIAN TECHNOLOGIES

Dr Megan Baldwin has been the chief executive officer of Circadian for 54 weeks and in that time has reviewed the company's programs, changed priorities to her own field of ophthalmic indications and with a market capitalization of $9.5 million, raised $17.4 million.

Dr Baldwin says the company's vascular endothelial growth factor (VEGF) phase II-ready asset in oncology, VGX-100, is to be partnered or licenced and there are no plans to take the VGX-100 program for metastatic cancer and solid tumors cancer any further, without a partner or licencee.

Dr Baldwin said that a 43-patient phase I dose escalation trial of VGX-100 as a monotherapy and in combination with Avastin had been completed and apart from the published results, the company was completing biomarker analyses.

She said Circadian's focus was on OPT-302, formerly known as VGX-300, with a phase I dose escalation trial for wet age-related macular degeneration, planned to start by July 2015.

Dr Baldwin said the trial would be robust with more than 20-patients and would begin with a combination of OPT-302 and the existing drug Lucentis and at the top dose OPT-302 would be tested as a monotherapy and in combination with Lucentis, with each patient dosed monthly over three months.

Dr Baldwin said that "a large randomized controlled study of OPT-302 and Lucentis would be compared to Lucentis alone", pending the results of the phase I trial expected by April 2016.

She said the phase II trial was expected to begin within three months of the phase I results, by July 2016, and would recruit naïve patients and it was expected that some patients in the Lucentis-alone arm would not respond to Lucentis alone and they would be eligible for the combination treatment.

Dr Baldwin said that the rationale for the combination treatment was that Lucentis, like Avastin targeted VEGF-A, but OPT-302 was a soluble form of VEGF Receptor 3 (VEGFR-3) targetting VEGF-C and VEGF-D and therefore used in combination, provided "a more complete inhibition of blood vessel formation and a reduction of leakage into the eye".

Dr Baldwin said that wet age-related macular degeneration was the focus for Circadian but she expected the drug could have efficacy in other indications including diabetic macular oedema, diabetic retinopathy and retinal vascular occlusion.

Late last year Circadian appointed a scientific advisory board for the OPT-302 program that includes Arizona's Retinal Consultants Prof Pravin Dugel, the University of Sydney's Prof Mark Gillies, Johns Hopkins Wilmer Eye Institute's Prof Peter Campochiaro and Harvard Medical School's Prof Kameran Lashkari.

Dr Baldwin said at that time that the "internationally recognized key opinion leaders ... [would] be instrumental in assisting us move this important clinical program forward".

The change of focus reflects the dynamic Dr Baldwin's own background in both VEGF research and opthalmics.

Having won the award of Dux of her high school, Coomoora Secondary College in South Springvale, the then Megan Baldwin studied for a Bachelor of Science at the University of Melbourne, undertaking honors in type 2 diabetes at the Royal Melbourne Hospital and earning an award for "most outstanding Bachelor of Science honors research" in the Department of Medicine.

Having also made the University of Melbourne Dean's Honour Roll, Megan was accepted into the Ludwig Institute for Cancer Research and completed a Doctorate of Philosophy in Medicine working in the angiogenesis laboratory on VEGF-D, winning an Australian postgraduate award and a travel award to present at a diabetes conference in Finland, as well as the 2002 Anti-Cancer Council of Victoria Postdoctoral Research Fellowship.

From 2002 until 2007, Dr Baldwin was employed by Genentech in San Francisco as a post-doctoral researcher, supervised by Prof Napoleone Ferrara, who discovered VEGF-A and made the first VEGF antibody leading to the development of bevacizumab, or Avastin, and later ranibizumab, or Lucentis.

Genentech appointed Dr Baldwin market planning manager in its commercial division and she continued work on angiogenesis at the same time.

Returning to Australia, Dr Baldwin was appointed scientific affairs manager at Circadian in 2008, then head of preclinical research and development and in 2012 was appointed chief executive officer of the newly-created Opthea subsidiary, containing the company's ophthalmic assets.

A year ago, Dr Baldwin was appointed the chief executive officer of Circadian and began the reorganization of Australia's oldest ASX-listed biotechnology company.

Circadian has been through several guises, from its origins as a developer of the anti-jet lag drug melatonin, to an incubator for a raft of other biotechnology companies including Metabolic (later Calzada and now Polynovo), Antisense, Avexa and Optiscan, Dr Baldwin has clarified its narrative to a company specializing in ophthalmic indications.

She said that the $17.4 million capital raising was an exciting and complex operation meeting with US biotechnology, healthcare and life sciences specialist investors including the New York-based Baker Brothers and the San Francisco, California-based BVF Partners, who "saw we were undervalued with a molecule that is a selective protein hitting a VEGF pathway".

"It is a really exciting time to have the funding to execute what we told people we would do," Dr Baldwin said.

Circadian was unchanged at 16 cents.

David Langsam
Editor

GI DYNAMICS

GI Dynamics says that following four cases of bacterial liver infections, the US Food and Drug Administration has halted enrolment in its pivotal trial of Endobarrier in the U.S.
GI Dynamics said that monitoring and data collection involving the 325 currently enrolled patients of the planned 500-patient the trial of Endobarrier for obesity and type 2 diabetes would continue (BD: Apr 26, 2013).
The company said that the bacterial infections, known as hepatic abscess, were “a known event related to the use of Endobarrier but has recently presented at a higher than anticipated rate in the ‘Endo’ trial”.
GI Dynamics said that the FDA had requested additional information to further assess the risk to benefit profile of the Endobarrier gastric liner.
The company said that outside the US, the incidence rate of hepatic abscess with Endobarrier implantation was about one percent based on experience with more than 2,900 units shipped commercially since 2009.
GI Dynamics said that the Endobarrier’s overall risk to benefit profile, as established outside the US, was favorable and it continued to be available for use by physicians and patients in the countries where it was approved.
GI Dynamics said that patient safety was its first priority and the company had implemented several risk mitigation strategies in the Endo trial and was “expeditiously working to submit the requested information to the FDA for their review in an effort to resume enrolment”.
GI Dynamics fell 15 cents or 50 percent to 15 cents with 9.1 million shares traded.

GENERA BIOSYSTEMS

Genera says the Australian Therapeutic Goods Administration has provided a Conformity Assessment Certificate for its Paptype and RTI-plex assays and QPlots software.
Genera said that following certification and payment of the application fee the products could be included on the Australian Register of Therapeutic Goods, which took about 20 days and was expected by the end of March 2015.
The company said that following acceptance on Register and subject to the terms of the licence Genera would be permitted to supply the Paptype human papillomavirus test and RTI-plex respiratory tract pathogen test as in-vitro diagnostics approved products.
Genera said it would also “deliver” Conformité Européenne (CE) mark approval for the its Paptype and RTI-plex molecular diagnostic assays, which would allow marketing in Europe and parts of Asia.
Genera chairman Lou Panaccio said the approval was “clearly a significant milestone for our company and confirms our ability to develop [molecular diagnostic] assays that are able to be sold as approved [in-vitro diagnostic] products within regulated markets”.
Genera chief executive officer Richard Hannebery said that “after what can frankly be deemed a false start some five years ago, today we are very confident of the commercial prospects of both our Paptype and RTI-plex [molecular diagnostic] assays as well as additional Ampasand assays that will shortly follow”.
“The prospect of partnering our assays with a highly credible global [in-vitro diagnostic] partner remains strong and we aim to have an appropriately structured relationship that best positions the rapid uptake of Genera’s [molecular diagnostic] test menu in place by mid ... 2015,” Mr Hannebery said.
Genera was up one cent or 4.2 percent to 25 cents.

THE WALTER AND ELIZA HALL INSTITUTE FOR MEDICAL RESEARCH

The Walter and Eliza Hall Institute says that human antigen R (HuR) is critical for B cells, which make antibodies to fight infection and develop long-term post-vaccination immunity.
WEHI said that the role of the energy-producing HuR protein in immune cells was identified by Dr Kirsten Fairfax, working with Dr Manuel Diaz-Muñoz, Dr Martin Turner and colleagues at the Cambridge, UK-based Babraham Institute and showed that removing HuR prevented the proper growth and function of B cells.
The research, entitled 'The RNA-binding protein HuR is essential for the B cell antibody response' was published in Nature Immunology.
An abstract is at: http://www.nature.com/ni/journal/vaop/ncurrent/full/ni.3115.html.
"Immune cells called B cells mature in response to vaccines or exposure to new disease and are a key tenet of immunity," Dr Fairfax said.
"HuR manages a set of genes that determine how much energy B cells produce, known as the metabolic rate," Dr Fairfax said.
"We showed that without HuR to instruct them, these critical metabolic genes can no longer instruct the B cell to make the energy it needs to function and B cells are unable to mature into antibody-producing cells that provide immunity to disease," Dr Fairfax said.
"This final stage of maturation requires a substantial amount of energy and occurs in a B-cell factory, called the germinal centre," Dr Fairfax said.
"Germinal centres are the quality control check point for B cells," Dr Fairfax said.
"B cells that pass the test mature and transform into antibody-producing plasma cells, while those that fail quality control start the maturation process again," Dr Fairfax said.
"If the immune cell's metabolism isn't functioning properly, maturation in the germinal centre stalls and plasma B cells cannot develop," Dr Fairfax said.
"This is potentially disastrous for the immune system as plasma B cells protect the body from infections and generate immunity after vaccination to prepare for future infections," Dr Fairfax said.
The Institute said that understanding the processes that controlled B cell development, including metabolism, could help scientists find ways to boost the efficacy of vaccines or preserve the body's ability to develop immunity.
"As an example, some anti-cancer drugs that are used over extended treatment periods can impact cell metabolism," Dr Fairfax said.
"If these drugs impact on the metabolism of B cells, it may compromise a patient's ability to create the new plasma B cells required to prevent infections," Dr Fairfax said.
"Identifying which drugs have this impact and monitoring patients receiving these drugs will help clinicians guide cancer patients through treatment while ensuring efforts to restore their immune system are effective," Dr Fairfax said.

NANOSONICS

Nanosonics says the University of Sydney's Warren Centre for Advanced Engineering has awarded founder Dr Ron Weinberger its "innovation hero medal".
Nanosonics said that the award recognized outstanding innovations in engineering technology and was awarded to Australian-based people or teams that develop a new technology into a commercial product or service and create great benefit for Australia.
The company said that Dr Weinberger led the team development and commercialization of its ultrasonic nano-nebulisation Trophon EPR technology.
Warren Centre director Ashley Brinson said the Trophon was "exactly the type of technical advance that the ... Centre is proud to recognize for contributing to a higher quality of life".
Nanosonics rose seven cents or 4.1 percent to $1.78 with 691,744 shares traded.

GENETIC TECHNOLOGIES

Genetic Technologies has requested a trading halt pending a “significant announcement regarding capital raising activity”.
Trading will resume on March 10, 2015 or on an earlier announcement.
Genetic Technologies last traded at five cents.

SIRTEX MEDICAL

Hunter Hall Investment Management has again reduced its substantial holding in Sirtex from 4,675,173 shares (8.27%) to 4,055,173 shares (7.17%).
Hunter Hall sold shares between February 3 and March 4, 2015, with the single largest sale 212,640 shares for $7,296,073 or $34.31 a share.
Hunter Hall has been reducing its holding in Sirtex since May 2013 (BD: May 29, 2013).
Hunter Hall has been a long term shareholder in Sirtex and in 2009 increased to 16,684,884 shares (29.92%) when the company was at $2.35 a share (BD: Mar 5, 2009).
Biotech Daily understand that Hunter Hall has a limit to the percentage of one stock it may hold and as the Sirtex price keeps rising it needs to sell shares to remain below that cap.
Sirtex was up 89 cents or 2.55 percent to $35.79 with 288,437 shares traded.
Sirtex has closed above a market capitalization of $2 billion for the second time. According to data from Commsec, the company closed at $35.55 last week on February 27, 2015, with $35.38 the $2 billion mark.

IMPEDIMED

Starfish Ventures says it has increased its holding in Impedimed from 24,694,356 shares to 25,238,045 shares, but has been diluted from 22.7 percent to 8.61 percent.
The Melbourne-based Starfish, along with Christiana Panaccio, Michael Panaccio, John Dyson and Trudie Horsfall and Joyce Dyson said that since the last notice in 2009 they had acquired shares on-market, in share plans and entitlement offers.
Impedimed was up four cents or five percent to 84 cents with 1.1 million shares traded.

MEDIBIO (FORMERLY BIOPROSPECT)

Medibio says that shareholders at its extraordinary general meeting have overwhelmingly supported 16 resolutions relating to its Invatec cardiac test for depression acquisition.
The resolutions included the Invatec acquisition, the issue of shares and options and a consolidation, with the greatest dissent 12,413,094 votes (1.5%) against the consolidation and 813,372,190 votes (98.5%) in favor.
Medibio fell 0.1 cents or 25 percent to 0.3 cents with one million shares traded.