



Biotech Daily

Thursday October 23, 2014

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH EVEN: GI DYNAMICS UP 15%, USCOM DOWN 12%**
- * **BIO-MELBOURNE: 'NIMBLE NETWORK TO FIGHT INFECTIOUS DISEASE'**
- * **CALZADA FILES FOR NOVOSORB FDA APPROVAL, BARDA FUNDING**
- * **GI DYNAMICS 10-FOR-1 US CONSOLIDATION EGM**
- * **DR JOHN CHIPLIN REPLACES CYNATA DIRECTOR HOWARD DIGBY**
- * **IMUGENE DIRECTOR DR NICK EDE STEPS DOWN TO EXECUTIVE**
- * **ACUVAX 6-DAY DIRECTOR NIGEL LEE STEPS DOWN TO ADVISOR**
- * **ALCHEMIA'S PROF TRACEY BROWN WINS TELSTRA GONG**

MARKET REPORT

The Australian stock market slipped 0.05 percent on Thursday October 23, 2014 with the S&P ASX 200 down 2.8 points to 5,383.1 points.

Twelve of the Biotech Daily Top 40 stocks were up, 12 fell, nine traded unchanged and seven were untraded.

GI Dynamics was the best, up four cents or 15.4 percent to 30 cents with 249,210 shares traded, followed by Clinuvel up 13.9 percent to \$2.62 with 104,918 shares traded.

Universal Biosensors climbed 6.7 percent; Circadian was up 5.9 percent; Atcor rose 4.9 percent; Analytica, Neuren and Starpharma were up more than three percent; Impedimed and Phosphagenics rose more than two percent; Nanosonics and Tissue Therapies were up more than one percent; with CSL up 0.4 percent.

Uscom led the falls, down three cents or 12.0 percent to 22 cents with 22,000 shares traded, followed by Compumedics down 11.5 percent to 11.5 cents with 30,000 shares traded.

Biotron lost 8.7 percent; Acrux, Anteo and Cellmid fell more than seven percent; Benitec fell 5.8 percent; Ellex was down 3.2 percent; Prima shed 2.6 percent; Alchemia and Mesoblast were down more than one percent; with Cochlear, Resmed and Sirtex down less than one percent.

BIO-MELBOURNE NETWORK, WEHI, D3 MEDICINE

Nobel Laureate Prof Peter Doherty and D3 executives Dr Craig Rayner and Dr Leigh Farrell say Australia needs a quick, nimble network to respond to infectious diseases. Today's Bio-Melbourne Network Bio-Breakfast, hosted by the Walter and Eliza Hall Institute, was introduced to Medical Countermeasure Products Australia (MCPA), an industry-led, public and private sector partnership for medical countermeasures product development, in a discussion entitled 'Readiness is all – Melbourne's research and development capacities in emerging infectious disease'.

Bio-Melbourne Network chief executive officer Dr Krystal Evans told the more than 100 people at the Bio-Breakfast that emerging infectious diseases were imminent, real threats to Australia's healthcare, economy and security and quoted Hamlet: "If it be not now, it will come. The readiness is all." (Act 5, Scene 2)

Prof Doherty said that medical countermeasures for infectious diseases would translate science into real outcomes for patients.

Prof Doherty said that Ebola was so horrific that it was not that difficult to contain by isolating its victims and treating them, "but we totally dropped the ball, including the World Health Organisation".

Prof Doherty quoted the September 19, 2014 edition of 'Science' in which Glaxosmithkline's head of the Ebola vaccine program Dr Ripley Ballou said his company contacted WHO at the beginning of the outbreak in March and there was little interest, with the WHO response: "Thanks, we'll get back to you."

Prof Doherty said that the proposed Medical Research Future Fund "must be directed to practical ends" and that Australia was very good at early stage discoveries and had development and networking expertise, but was not good at bringing products to market, with Australian venture capital not like the West Coast of the US.

WEHI's infectious diseases clinician and laboratory head Dr Marc Pellegrini said that his department's focus was "promoting the death of infected cells to cure chronic human infection" and said there was value in repurposing existing drugs.

Dr Pellegrini said the Institute had partnered with Tetralogic to develop the cancer drug birinapant for hepatitis B and through its action in reducing the surface antigen, patients would be able to create their own virus antigens.

Dr Pellegrini said that working with Inc Research and Nucleus Network, a clinical trial was expect to start this month in Australia and New Zealand studying birinapant for hepatitis B with safety and seroconversion as the key endpoints.

Dr Farrell told the Bio-Breakfast that Australia was a member of a consortium with the US, UK and Canada for medical countermeasures and Australia's Defense Science and Technology Organisation workshops led to the establishment of the MCPA.

Dr Farrell said that the MCPA needed to be a public private partnership, working across the whole of Government and able to respond not just to current threats but also to "what is coming over the hill" and be recognized as world class development, delivering products.

Dr Farrell said the MCPA needed to raise \$30 million in the immediate future and become self-funding.

Dr Rayner, quoting WEHI's business development manager Dr Julian Clark, said: "We have A-class components and B-class wiring" and Australia needed to integrate its capabilities.

Dr Rayner said that the MCPA would have a small core staff, able to reach the required institutions, companies and regulators to expedite development.

Prof Doherty said that the Bill and Melinda Gates Foundation-funded Medicines for Malaria was a model for "how we harness and mobilize what we have".

CALZADA

Calzada says Polynovo has applied for US regulatory approval for Novosorb as a surgical wound dressing and applied for US funding for trials for third degree burns.

Calzada said that a 510(k) submission had been made to the US Food and Drug Administration for clearance to market wholly-owned subsidiary Polynovo's Novosorb biodegradable temporizing matrix as a surgical wound dressing and an application had been filed to the Biomedical Advanced Research and Development Authority for funding for the burns trial.

The company said that the biodegradable temporizing matrix (BTM) wound dressing was indicated for the management of wounds including partial and full thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic and vascular ulcers, surgical wounds, including donor sites and grafts, post- Moh's skin cancer surgery, post-laser surgery, podiatric, wound dehiscence, trauma wounds including abrasions, lacerations, second-degree burns and skin tears and draining wounds.

Calzada said that the BTM wound dressing had been used clinically in 24 free-flap donor site patients to date, including 14 under the Australian Therapeutic Goods Administration Authorised Prescriber Scheme.

The company said that the treatment of patients generated encouraging results beyond those gained in the free-flap trial indicating that BTM was safe, easy to use, and provided patients with medical benefits over existing treatments. (BD: Jul 26, Oct 10, 2014).

Calzada said that it expected the FDA to make a determination on the 510(k) submission by July 2015.

The company said it expected to be advised of the outcome of its Biomedical Advanced Research and Development Authority (BARDA) application by the end of 2014.

Calzada said that a BARDA contract would provide funding for FDA pre-market approval trials for third degree burns.

The company said that the pre-submission meeting with the FDA had been scheduled for October 30, 2014 at the FDA offices and director Dr David McQuillan and Royal Adelaide Hospital lead investigator Prof John Greenwood would attend the meeting.

Calzada chairman David Williams said the two applications were "significant regulatory steps towards the successful commercialization of BTM for wounds and burns".

"These events have been underpinned by years of research to develop a product of significant market utility using our Novosorb material," Mr Williams said.

Calzada was up 0.9 cents or 10.8 percent to 9.2 cents.

GI DYNAMICS

GI Dynamics shareholders will vote on a 10-for-one consolidation of its US shares, which will have no effect on the number or value of its Chess depositary interests (CDIs).

A spokesman for GI Dynamics told Biotech Daily that the company had 94,795,481 US shares on offer, equating to 473,977,405 CDIs.

The spokesman said that following the consolidation the ratio would change from five CDIs to each US share to 50 CDIs equal to each US share.

GI Dynamics said that the consolidation related to the listing requirements of the Nasdaq Capital Market.

The meeting will be held at the offices of Mintz, Levin, Cohn Ferris, Glovsky and Poeo, PC, 1 Financial Centre, Boston, Massachusetts on November 10, 2014 at 5pm (USEST), which will be November 11, 2014 at 9am (AEDT).

GI Dynamics was up four cents or 15.4 percent to 30 cents.

CYNATA THERAPEUTICS

Cynata says that Dr John Chiplin has been appointed as an independent non-executive director, replacing Howard Digby.

Cynata said that Dr Chiplin had experience in operational and investment roles and had been involved in recent transactions including the sale of US stem cell company Medistem to Intrexon, Sydney's Arana to Cephalon and Domantis to Glaxosmithkline. Dr Chiplin was formerly Arana's chief executive officer as well as a former director of Progen, Healthlinx and Calzada (BD: Nov 6, 2008; Jun 14, 2012).

Cynata said that Dr Chiplin was a director of Benitec, Adalta and Sciencemedia, and held a Bachelor of Science and Doctorate of Philosophy from the University of Nottingham. Cynata was up one cent or 2.7 percent to 38 cents.

IMUGENE

Imugene says that Dr Nick Ede has resigned as a director and would continue as the head of manufacturing and operations.

Imugene said that Dr Ede's resignation was foreshadowed in previous announcements relating to the appointment of chief executive officer Charles Walker.

Imugene was up 0.1 cents or 10 percent to 1.1 cents with 1.1 million shares traded.

ACUVAX

Acuvax says that Nigel Lee has resigned as a director six days after his appointment, "due to restrictions in place from his previous overseas employer".

Last week, Acuvax said that Mr Lee's appointment was related to the proposed change of activities through the acquisition of Activistic (BD: Oct 8, 17, 2014).

Today, the company said that Mr Lee would be chairman of the advisory board assisting to develop strategy and establish new partnerships in global markets, tasked with expanding the advisory board.

The company said the resolution to elect Mr Lee as a director would be removed from the November 26, 2014 annual general meeting agenda.

Acuvax was untraded at 0.1 cents.

ALCHEMIA

Alchemia says that chief scientific officer Prof Tracey Brown has won Telstra's Victorian Business Woman of the Year and the Telstra Private and Corporate Sector Award.

Alchemia said that Prof Brown was the inventor of its Hyact platform, used to transport cancer drugs to tumors and increase the drug's effectiveness without increasing toxicity.

"I have been working tirelessly for more than 15 years to develop better, less toxic and more effective cancer treatments," Prof Brown said.

"My mother was diagnosed with ovarian cancer at just 53 years of age and while supporting her through this devastating disease and chemotherapy treatments, I realized that there was a significant unmet need for better therapies," Prof Brown said.

Alchemia said that Prof Brown was eligible for the National Telstra Australian Business Woman of the Year Award to be announced on November 26, 2014.

Alchemia fell one cent or 1.6 percent to 60 cents with 1.6 million shares traded.