Biotech Daily

Wednesday July 3, 2013

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH EVEN: ANTISENSE UP 10%, USCOM DOWN 9%**

*** GI DYNAMICS PLACES $57.5m, PLAN FOR $2.5m MORE**

*** SIRTEX CLAIMS DOSE SALES UP 19%, IMPLIES $98m REVENUE**

*** AUSTIN APPROVES PRANA ALZHEIMER'S IMAGING TRIAL EXTENSION**

*** DISSIDENTS WIN BIONICHE AUGUST EGM**

*** USCOM: PAPERS BACK MONITOR FOR PAEDIATRIC SEPSIS, EMERGENCY**

*** NOVOGEN REQUESTS CAPITAL RAISING TRADING HALT**

*** HARTNELL FAMILY, ROBINWOOD TAKE 20% OF ADVANCED SURGICAL**

*** ONCOSIL APPOINTS DR NEIL FRAZER CEO, BOARD CHANGES**

*** IMMURON LOSES DIRECTOR DR STEWART WASHER**

MARKET REPORT

The Australian stock market tumbled 1.86 percent on Wednesday July 3, 2013 with the S&P ASX 200 down 89.9 points to 4,744.1 points.

Twelve of the Biotech Daily Top 40 stocks were up, 11 fell, 13 traded unchanged and four were untraded. All three Big Caps fell.

Antisense was the best, up 0.1 cents or 10 percent to 1.1 cents, with 50,000 shares traded.

Viralytics climbed 8.7 percent; Universal Biosensors was up 7.1 percent; Nanosonics was up 6.1 percent; GI Dynamics was up 5.9 percent; Avita and Prana were up more than three percent; Psivida rose 2.7 percent; Anteo was up 1.7 percent; with Heartware, Sirtex and Starpharma up by less than one percent.

Yesterday's best, Uscom, led the falls, down two cents or 8.7 percent to 21 cents, followed by Benitec down 0.1 cents or 7.1 percent to 1.3 cents with 4.1 million shares traded.

Genetic Technologies, Medical Developments and Patrys fell four percent or more; Pharmaxis lost 3.3 percent; CSL, Osprey and QRX shed two percent or more; with Alchemia, Cochlear, Neuren and Resmed down by more than one percent.

GI DYNAMICS

GI Dynamics says it has received commitments for an oversubscribed private placement raising $57.5 million for its US pivotal trial of Endobarrier for obesity and type 2 diabetes.
GI Dynamics said it had received applications for 108.5 million CHESS depositary interests (CDIs) at 53 cents each from sophisticated, professional and accredited investors in Australia, the US and other jurisdictions.
The company said it would offer a share purchase plan at the same price and in parcels of up to $15,000 to shareholders at the record date of July 2, 2013 to raise up to $2.5 million.
GI Dynamics said the funds from the placement and share plan were for its US pivotal clinical trial and general working capital.
The company said the share plan would open on July 12 and close on July 26, 2013.
GI Dynamics chief executive officer Stuart Randle said the company was “very pleased with the successful completion of this financing”.
“With the FDA’s approval last year to allow us to move forward with a pivotal trial in the United States rather than a pilot trial, our clinical investment needs increased,” Mr Randle said.
“This financing allows us to fully and rapidly resource our pivotal trial, the Endo trial, in the United States while continuing to expand our commercial footprint and sales ramp in Europe, Australia, South America and the Middle East and build the case for reimbursement in key markets,” Mr Randle said.
GI Dynamics said the placement comprised 71,833,628 CDIs under its 25 percent placement capacity and an additional 36,656,938 CDIs, subject to shareholder approval at an extraordinary general meeting scheduled to be held about July 29, 2013.
GI Dynamics was up 3.5 cents or 5.9 percent to 63 cents.

SIRTEX MEDICAL

Sirtex says that SIR-Spheres dose sales grew 19 percent for the 12 months to June 30, 2013 compared to the previous year.
Sirtex said that dose sales of the SIR-Spheres for liver cancer for the three months to June 30, 2013 was up 13.1 percent compared to the previous corresponding period.
Last year, Sirtex said that dose sales of SIR-Spheres increased 26 percent for the three months to June 30, 2012 and 23 percent for the full year (BD: Jul 4, 2102).
Sirtex did not disclose the value or quantity of the sales, today, but last year posted revenue for the 12 months to June 30, 2012 of $86.6 million, of which $82.6 million was for sales of 6,144 doses of SIR-Spheres (BD: Aug 29, 2012).
An increase of 19 percent would imply revenue of about $98.3 million from sales of 7,311 doses for the year to June 30, 2013, not including any variation relating to exchange rates.
Sirtex said that despite the higher base, the result showed continued strong dose sales growth following the 23 percent growth in 2011-‘12, 19 percent growth in 2010-‘2011 and 14 percent growth in 2009-‘10.
Sirtex said that SIR-Spheres sales in the Americas was up 17 percent for the three months and 21 percent for the year, Asia Pacific sales were up 21 percent for the quarter and 30 percent for the year, with EMEA (Europe, Middle East and Africa) sales up one percent for the quarter and nine percent for the year.
Sirtex chief executive officer Gilman Wong said the unstated number of doses was “the highest number of doses we have sold in a quarter adding to our successful history”.
“We have now achieved 36 consecutive quarters of dose sales growth, which we expect to continue,” Mr Wong said.
Sirtex was up five cents or 0.4 percent to $12.10 with 317,194 shares traded.

PRANA BIOTECHNOLOGY

Prana says it has approval from Melbourne's Austin Health for a 12-month open label extension study with Alzheimer's disease patients in its Imagine trial.

In 2012, Prana began the 40-patient, 12-month, randomized, double-blind, placebo-controlled phase II imaging trial of PBT2 for Alzheimer's disease (BD: May 6, 2012) .

Prana said last year that the Melbourne-based study would assess the safety and tolerability of PBT2 and its effect on amyloid levels in the brains of patients with prodromal or mild Alzheimer's disease and the primary outcome was the evaluation of the effect of PBT2 compared to placebo on brain amyloid levels after 52 weeks of treatment as measured by carbon 11-Pittsburgh imaging compound-B (PiB) positron emission tomography (PET) imaging at 26 and 52 weeks after beginning treatment with PBT2 or the placebo.

Today, Prana said that 15 percent of participants in Imagine had finished the 12 months of treatment and all had completed at least six months of treatment.

Prana said that patients who had completed the 12-month trial were eligible for the open-label extension study.

The company said that all participants in the extension study would receive a 250mg once-daily oral dose of PBT2 for an additional 12 months, with the first patient expected to start in August, 2103.

Prana executive chairman Geoffrey Kempler said the company was looking forward to the completion of the Imagine trial to see the effects of PBT2 over 12 months and expected to report the results in March 2014.

"This will allow us to take the steps necessary to progress the commercialization of PBT2 for Alzheimer's," Mr Kempler said.

"What is so helpful about the open-label study is that it will provide ongoing information to support the safety, tolerability and efficacy of PBT2 over a 24 month period," Mr Kempler said.

Prana was up one cent or 3.6 percent to 28.5 cents.

BIONICHE LIFE SCIENCES

Dissident Bioniche investors appear to have forced an extraordinary general meeting of the company to spill the board.

Following last year's return to Bioniche of its phase III bladder cancer drug Urocidin by Endo Pharmaceuticals, a shareholder group led by William Wells and Greg Gubitz said they represented more than five percent of the company's shareholding and attempted to requisition a general meeting (BD: Nov 6, 2012; Jan 20, Apr 24, 26; May 6, 15, 2013).

The Bioniche board rejected the request and a second requisition was made, which Bioniche also resisted.

In April, Mr Wells and Mr Gubitz strongly criticized Bioniche's board, management and share price and said Bioniche had a history of losses, with not one year of positive earnings and had lost more than 96 percent of its share price value since 1996.

The group said it had contacted Bioniche in 2012 to offer advice and provide tangible solutions to fix the company.

Today, Computershare Toronto, acting as agent for Mr Wells, published a letter on Bioniche's ASX site saying a meeting would be held on August 27, 2013, "to replace the board of directors with seven independent nominees", despite Bioniche saying there was no need for a meeting until the company's scheduled annual general meeting.

Bioniche was untraded at 30 cents.

USCOM

Uscom says two new peer-reviewed papers support its ultra-sonic cardiac output monitor for paediatric sepsis and paediatric emergency medicine.

Uscom said that a London collaboration of the paediatric intensive care units at Kings College Hospital and the Great Ormond St Hospital for Children, conducted over 36 months demonstrated that the serial use of Uscom to identify different haemodynamic patterns in paediatric sepsis improved clinical management of children.

The company said the study, entitled 'Evolution of haemodynamics and outcome of fluid refractory septic shock in children', published in Intensive Care Medicine, was the basis for a major trial to establish global practice management protocols based on its monitor.

Uscom said the Canadian study, entitled 'Urgent Ultrasound Guided Hemodynamic Assessments by a Pediatric Medical Emergency Team: A Pilot Study' published in Public Library of Science One, was a collaboration between the University of Ottowa and McMasters University in Ontario and evaluated Uscom in pediatric medical emergency with the device operated by physicians and non physicians in acutely ill children.

An abstract is at: http://www.plosone.org/article/info:doi/10.1371/journal.pone.0066951.

The company said the study concluded that Uscom was applicable in that setting and could be used to identify therapeutic goals for more effective management.

Uscom executive chairman Robert Phillips said the centres had been "using the monitor in clinical practice for a number of years and progressively working to define its role as best practice in the management of children; this is the time consuming and thorough process of medical adoption".

"These studies provide further evidence that Uscom is being adopted as the gold standard cardiac monitor in paediatrics, particularly for best management of sepsis and septic shock in children," Mr Phillips said.

Uscom fell two cents or 8.7 percent to 21 cents.

NOVOGEN

Novogen has requested a trading halt pending an announcement "in relation to a proposed material capital raising".

Trading will resume on July 5, 2013 or on an earlier announcement.

Novogen last traded at 19 cents.

ADVANCED SURGICAL DESIGN & MANUFACTURE

The Hartnell family, through Robinwood Investments has increased its substantial holding in Advanced Surgical from 6,164,112 shares (14.9%) to 8.747,424 shares (19.9935%)

The substantial shareholder notice said that the Sydney and Bowral New South Wales based Hartnell family and Robinwood acquired 2,055,072 shares for $226,058 or 11 cents a share on April 3, sold 45,000 shares for $4,275 or 9.5 cents a share on July 1 and acquired a further 572,140 shares at an undisclosed price and date.

Advanced Surgical was untraded at 9.5 cents.

IMMURON

Immuron says that non-executive director Dr Stewart Washer has retired effective today.

Immuron said that Dr Washer was appointed a director in February 2012 and cited other business interests as the reason for his retirement. Dr Washer is chairman of Isonea.

Immuron was up 0.1 cents or 25 percent to 0.5 cents with two million shares traded.

ONCOSIL MEDICAL (FORMERLY NEURODISCOVERY)

Oncosil says it has appointed Dr Neil Frazer as its chief executive officer effective from July 2, 2013, appointed Martin Rogers chairman and made other changes to its board.

Oncosil is developing its Oncosil device, a targeted brachy-therapy treatment developed under a licence from Psivida's Psimedica for its Brachysil product (BD: Feb 7, 2103).

In February, Neurodiscovery said that Oncosil had completed two phase II studies as Brachysil in pancreatic cancer and a phase III study was planned to begin in 2013.

Today, Oncosil said that Dr Frazer had more than 25 years of drug development experience in multiple therapeutic areas, including more than six years of oncology drug development.

The company said that Dr Frazer had been responsible for successful US Food and Drug Administration applications for 10 new chemical entities in multiple therapeutic areas and more than 20 applications for the line extensions of pharmaceutical drug applications.

Oncosil said that Dr Frazer has "a high level of expertise in the FDA's investigational new drug planning, submission and reviewing process", which was the designation the company was seeking for its Oncosil class III medical device in addition to seeking approval by the European Medicines Agency.

The company said that Dr Frazer began his medical career as a UK-based anaesthetist and had worked in Europe and in the US conducting phase I to phase IV clinical trials, leading to product registrations in Europe and the US.

Oncosil said that Dr Frazer held senior management roles with Glaxo, Glaxo-Wellcome and Clintrials Research and had held executive medical roles with Pharmalink FHI, Shire Pharmaceuticals, Erimos Pharmaceuticals and Chimerix Inc and was most recently Prima's chief medical officer and executive director developing its CVac ovarian cancer vaccine.

The company said that Dr Frazer's remuneration package was "majority performance-based, with any performance consideration dependent on share price appreciation and regulatory approvals … [and was] undertaken with the assistance of Forrest Capital.

Oncosil said that deputy chairman Martin Rogers would replace chairman Dr Roger Aston, who in turn would become a non-executive director.

The company said that Simon O'Loughlin had resigned as a non-executive director and Neurodiscovery founder and former executive director David McAuliffe would assist with the transition over the coming months and resign as executive director.

Oncosil said that Jillian McGregor has been appointed as general counsel and joint company secretary.

Mr Rogers told Biotech Daily that company secretary Rob Hodby would remain for the transition period.

Oncosil has formally relocated from Perth to Castlereagh Street, Sydney.

Oncosil was up 0.1 cents or 2.4 percent to 4.2 cents.