Biotech Daily

Friday April 26, 2013

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH FLAT: ACRUX UP 19%, NANOSONICS DOWN 7%**

*** ACRUX, ELI LILLY AXIRON Q1 SALES UP 55% ON Q4, 128% ON Q1, 2012**

*** CSIRO LICENCES RAFT POLYMERIZATION TECHNOLOGY TO MIRUS BIO**

*** RESMED RECORD Q3 REVENUE, PROFIT**

*** OBJ: 'NOVUS CITES BOSTON BOMBING FOR UNDERWRITING BALK'**

*** GI DYNAMICS ENROLLING US ENDOBARRIER TRIAL PATIENTS**

*** CALZADA, METABOLIC 'CLARIFY' AOD9604 SPORTS CLAIMS**

*** JOHNSON & JOHNSON REDUCES 1.8% IN GI DYNAMICS**

MARKET REPORT

The Australian stock market slipped 0.1 percent on Friday April 26, 2013 with the S&P ASX 200 down 4.9 points to 5,097.5 points.

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

Acrux was the best, up 67 cents or 19.4 percent to $4.12 with 4.7 million shares traded, followed by Alchemia up 11.8 percent to 42.5 cents with 785,543 shares traded and Avita up 10 percent to 11 cents with 37,918 shares traded.

GI Dynamics and Neuren climbed more than six percent; Allied Health and Tissue Therapies were up more than three percent; Bionomics and Starpharma rose more than two percent; Viralytics was up 1.75 percent; with Heartware and Universal Biosensors up by less than one percent.

Nanosonics led the falls, down three cents or 6.9 percent to 40.5 cents with 420,501 shares traded, followed by Pharmaxis down 6.7 percent to 14 cents, with 10.9 million shares traded and Cellmid down 6.45 percent to 2.9 cents with 1.5 million shares traded.

Clinuvel lost 4.5 percent; Anteo, Impedimed and Patrys were down more than three percent; Genetic Technologies shed 2.5 percent; CSL, Prima, Psivida, QRX and Sirtex were down more than one percent; with Cochlear, Mesoblast and Resmed down by less than one percent.

ACRUX

Acrux says Eli Lilly's Axiron net sales for the three months to March 31, 2013 increased 55.2 percent to $US37.1 million compared to the three months to December 31, 2012.
Earlier this year, the US-based Eli Lilly said that sales totaled to $US73.9 million ($A70.7 million) for the year to December 31, 2012, with Axiron sales of $US16.3 million in the three months to March 31, 2012; $US17.7 in the three months to June 30; $US16.0 in the three months to September 30 and $US23.9 million in the three months to December 31, 2012 (BD: Jan 30, 2013).
Acrux chief financial officer Jon Pilcher told Biotech Daily at that time that the company was confident that the $25 million royalty figure for reaching $100 million in sales in a calendar year would be achieved in 2013.
Mr Pilcher said in January that that the royalty rate was on an increasing scale but Acrux was entitled to 11 percent of the then current sales.
Acrux was up 67 cents or 19.4 percent to $4.12 with 4.7 million shares traded.

THE COMMONWEALTH SCIENTIFIC AND INDUSTRIAL RESEARCH ORGANISATION

The CSIRO says it has licenced its reversible addition-fragmentation chain transfer polymerisation technology (Raft) to the Madison, Wisconsin-based Mirus Bio.
Mirus Bio describes itself as "the transfection specialists" working in non-viral gene delivery.
The CSIRO said that the licence would enable Mirus Bio to use the technology to expand its high-end polymer development capabilities for the biotechnology industry.
Mirus scientific operations vice-president Dr Scott Hayes said the agreement would allow the company to broaden its expertise.
"This agreement with CSIRO broadens the scope of specialized polymer design tools available to Mirus and facilitates our continued efforts to improve nucleic acid transfer capabilities," Dr Hayes said.
"We expect that utilization of Raft will lead to new discoveries and expedite our product development efforts," Dr Hayes said.
CSIRO Materials Science and Engineering chief Dr Cathy Foley said that Mirus scientists were "leaders in introducing innovative products in this area and have developed a range of delivery technologies for researchers in the biotech industry that can make use of our polymer technology".
"Raft has very broad applicability in the biotech and biomedical industry because of the need for new and improved multifunctional polymers for many different applications," Dr Foley said.
"Raft enables the rapid, rational design and prove-out of bespoke macromolecules," Dr Foley said.
The Organisation said that reversible addition-fragmentation chain transfer polymerization, was a platform for making better polymers, using simple, free-radical chemistry to enable the synthesis of tailor-made polymers with predetermined molecular weights, narrow poly-dispersities and complex architectures.
The CSIRO said that Raft was very broadly applicable to polymers particularly in the areas of industrial, personal care, agricultural and biomedical polymers where higher order functionality was required and the Raft process had given rise to a new branch of polymer chemistry.
The CSIRO said that to date, more than 4,000 papers had been published on Raft, coupled with more than 400 patents granted globally.

RESMED

Resmed says it has posted record revenue up 10 percent to $US383.6 million and net profit after tax up 31 percent to $US84.9 million for the three months to March 31, 2013.
Resmed said diluted earnings per share was 58 US cents for the three months, a 32.0 percent increase over the three months to March 31, 2012.
The company said research and development expenditure for the quarter was $US31.2 million, or 8.1 percent of revenue.
Resmed fell four cents or 0.9 percent to $4.46 with 2.6 million shares traded.

OBJ

OBJ claims that Novus Capital has terminated the underwriting of about $2.7 million in a rights issue citing the Boston Marathon bombing as a reason for reneging.
Earlier this week OBJ said it had raised $859,832 of a hoped for $3.53 million, but Novus Capital has terminated the underwriting agreement (BD: Apr 23, 2013.
OBJ said it received acceptances for 51,892,727 new shares at 1.5 cents a share and 20,757,091 free attaching options, 22.07 percent of the securities offered, raising $778,391.
The company said that the total shortfall was 183,206,723 new shares and 73,282,689 free attaching new options worth about $2,748,100.
OBJ said that Novus had been advised of the shortfall but it had received a notice from Novus "purporting to terminate the underwriting agreement".
Today, OBJ alleged that "it had received a notice from Novus purporting to terminate the underwriting agreement (termination notice), on the basis that: the terror attack in Boston, US, on April 15, 2013 has had a materially adverse effect on the company, constituting a termination event described in section 8.2(r) of the prospectus; and there has been a material adverse change in the condition, financial position or prospects of the company as a result of a decline in the company's share price since the company announced its intention to undertake the offer, constituting a termination event described in section 8.2(e) of the prospectus".
Biotech Daily contacted Novus Capital but no one was available to comment.
OBJ said on April 23, that with its professional advisers, it was considering the validity of, and its response to, the termination notice.
On February 28 when the rights issue was announced OBJ fell 0.6 cents or 28.6 percent to 1.5 cents with 20.8 million shares traded falling a further 0.2 cents or 16.7 percent to one cent with 6.0 million shares traded on April 23.
Today, OBJ was up 0.2 cents or 20 percent to 1.2 cents with three million shares traded.

GI DYNAMICS

GI Dynamics says seven of up to 25 US sites have begun enrolling the 500 patients for its pivotal clinical trial of Endobarrier for obesity and uncontrolled type 2 diabetes.
GI Dynamics chief executive officer Stuart Randle said the company was "very pleased" with the quality of the clinical sites and enthusiasm of the physicians and clinical teams.
GI Dynamics said that the centres actively enrolling subjects were: New York's Beth Israel Medical Center; Montana's Billings Clinic; the Hyattsville, Maryland Medstar Health Research Institute, the New Orleans, Louisiana-based Tulane University Health Science Center; The University of Alabama at Birmingham; the University of Colorado in Denver; and the University of Texas Southwestern Medical Center in Dallas.
GI Dynamics was up four cents or 6.6 percent to 65 cents.

CALZADA

Calzada subsidiary Metabolic Pharmaceuticals says that reporting of sports medicine allegations have contained factual errors and misrepresentations about AOD9604.

In 2007 the then Metabolic (now Calzada) obesity drug program was closed following a 536-subject phase IIb trial which showed that weight loss compared to placebo at the primary and secondary endpoints of 12 or 24 weeks of treatment did not reach statistical significance (BD: Feb 21, 2007).

The then Metabolic chief executive officer Dr Roland Scollay told Biotech Daily that some participants in the trial had lost 2kg at 12 weeks and 2.6kg at 24 weeks as well as demonstrating waistline reductions, but these subjects did poorly on the diet and exercise program required by the US Food and Drug Administration.

“The trial was well-performed, on time and on budget and gave a definitive answer to the questions. Unfortunately the outcome is that it is not a commercial proposition,” Dr Scollay said.

Subsequently, Calzada licenced AOD9604 to Phosphagenics for use as AOP9604 in its Bodyshaper rub-away-the-fat-crème, which has not attracted significant sales and following a trial period was rejected by UK retail chain Boots (BD: Sep 26, 2012).

Today, Calzada said that AOD9604 was “a small peptide compound modeled on the fat metabolizing region of human growth hormone” but was a small fragment of human growth hormone (hgH), was not hGH, was not a variant of hGH and consisted of less than eight percent of the homology of hGH, with substantial scientific and medical evidence showing that AOD9604 had none of the safety concerns associated with hGH.

Calzada said that Metabolic conducted six human clinical studies involving 925 patients and while the trials proved that AOD9604 was profoundly safe, they did not show a clinically meaningful weight loss outcome across the total trial population.

Calzada said that in the past two years preclinical studies have found that AOD9604 might have potential use as a treatment for the repair of cartilage, muscle and joint disorders.

Calzada said that past in-vitro, pre-clinical and human trials showed clear scientific and medical evidence that AOD9604 did not increase insulin-like growth factor 1 (IGF-1) and there was no evidence that AOD9604 increased the number of muscle or cartilage cells.

Calzada said that in 2010 it released two statements to the ASX regarding black market sales of AOD9604, saying it was being manufactured in China and elsewhere and sold in direct contravention of the company’s patent position, primarily to distributors, gymnasiums, weight control centres, private clinics and individuals.

Calzada said it did not manufacture or supply AOD9604 and the World Anti-Doping Authority had advised that AOD9604 fell into the S0 non-approved substances category.

The company said that AOD9604 had not been approved by any regulatory authority as a pharmaceutical product, but Australian doctors could legally prescribe AOD9604 with prescriptions made up by a compounding pharmacy.

Following ‘generally recognized as safe’ status, a product containing AOD9604 in its intended use in foods, drinks and dietary supplements could be marketed as safe for human oral consumption in the US at daily amounts of up to 1mg per day and that since April 2011, AOD9604 had been used as an ingredient in the topical Bodyshaper cream available through pharmacies and cosmetic counters at shops in Australia and Asia.

Metabolic said that scientific and medical testing showed AOD9604 had the potential to safely improve the body’s fat, bone, muscle and cartilage and the black market use indicated it was being used to reduce body fat and/or aid in cartilage and muscle repair.

Calzada said it was investigating commercial opportunities for AOD9604 especially for osteoarthritis and other joint diseases.

Calzada was up 0.9 cents or 12.7 percent to eight cents with 1.2 million shares traded.

GI DYNAMICS

Johnson & Johnson Development Corporation says it has reduced its substantial holding in GI Dynamics from 5,740,011 US common shares equivalent to 28,700,055 Chess depositary interests (CDIs) and 5,300,909 CDIs (a total of 34,000,954 CDIs or 12.28%) to 30,130,115 CDIs (10.49%).

Johnson & Johnson did not disclose the value of the share sale.