Biotech Daily

Monday June 25, 2012

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: NANOSONICS UP 6%, ALLIED HEALTH DOWN 15%**

*** PHARMAXIS GAINS FIRST BRONCHITOL REIMBURSEMENT**

*** CLINUVEL PLACEMENT RAISES $6.2m**

*** BIOXYNE EXTENDS TRIAL RESULTS SUSPENSION**

*** GE TAKES $7.5m NANOSONICS CONVERTIBLE NOTES**

*** TWO OF THREE STARPHARMA VIVAGEL BV TRIALS RECRUITED**

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*** QRX REQUESTS FDA APPLICATION REVIEW TRADING HALT**

MARKET REPORT

The Australian stock market closed down 0.5 percent on Monday June 25, 2012 with the S&P ASX 200 down 20.4 points to 4,027.8 points. Seven of the Biotech Daily Top 40 stocks were up, 22 fell, seven traded unchanged and four were untraded.

Nanosonics was the best, up three cents or six percent to 53 cents with 460,671 shares traded. Uscom climbed 4.4 percent; QRX was up 3.3 percent; Psivida, Starpharma and Viralytics were up more than one percent; with Cochlear and Sirtex up by less than one percent.

Allied Health led the falls, down 0.3 cents or 15 percent to 1.7 cents with 1.45 million shares traded. Sunshine Heart lost 9.1 percent; Avita and Tissue Therapies were down more than seven percent; Cellmid fell 6.25 percent; Antisense, Bionomics, Impedimed and Living Cell were down more than five percent; Circadian, Optiscan, Patrys and Prima fell more than four percent; Anteo, Phosphagenics and Prana were down more than three percent; Acrux shed 2.3 percent; Alchemia, Heartware and Mesoblast were down more than one percent; with Biota, CSL and Pharmaxis down by less than one percent.

PHARMAXIS

Pharmaxis says that the Australian Pharmaceutical Benefits Scheme listing of Bronchitol for cystic fibrosis is its first reimbursement for Bronchitol or the active drug mannitol.
Pharmaxis said that Australia's Minister for Health Tanya Plibersek announced Bronchitol would be reimbursed for the treatment of cystic fibrosis patients, including children older than six years, who cannot use or are non-responsive to medicines already listed on the Pharmaceutical Benefits Scheme (PBS).
Pharmaxis chief executive officer Dr Alan Robertson told Biotech Daily that the listing was the first time Bronchitol had received reimbursement in any jurisdiction.
Dr Robertson said the active ingredient in Bronchitol was mannitol which was also used in the company's Aridol asthma test and although doctors were reimbursed for conducting the test, the drug itself was not reimbursed.
In a media release Dr Robertson said that cystic fibrosis was "a challenging disease to treat and Bronchitol represents the first new drug ever listed on the PBS to tackle the fundamental problem responsible for loss of lung function".
"We are pleased that this innovation will shortly be available to patients through the Pharmaceutical Benefits Scheme and look forward to monitoring the impact of Bronchitol on people's lives over the coming years," Dr Robertson said.
"This reimbursement decision is a testament to the dedication of the many people involved in developing Bronchitol for cystic fibrosis and we welcome the news," Dr Robertson said.
Cystic Fibrosis Australia chief executive officer David Jack said that "new therapeutic advances are desperately needed and the PBS listing is excellent news".
"Improving lung function and preventing lung infections are key to maintaining good health, so new treatment options have the potential to make a real difference in the lives of CF patients," Mr Jack said.
Pharmaxis said that when Bronchitol was listed on the Pharmaceutical Benefits Scheme, the approved price would be $31.00 per day.
The company said that Bronchitol was approved for marketing in Australia and Europe and a new drug application had been lodged with the US Food and Drug Administration seeking marketing approval in the US.
Pharmaxis fell half a cent or half a percent to $1.00.

CLINUVEL PHARAMCEUTICALS

Clinuvel says it has raised $6.2 million through the placement of shares at $1.75 a share.
Clinuvel said the placement to institutional and professional investors was at a 4.3 percent premium to the 20-day volume weighted average price and 9.4 percent above the closing price on June 20, 2012.
The company said the funds were for the ongoing development of Scenesse for a phase III trial in erythropoietic protoporphyria and working capital,
Clinuvel was unchanged at $1.60.

BIOXYNE

Bioxyne says its shares will remain suspended until its phase IIb trial results of HI-164OV for chronic obstructive pulmonary disease exacerbations are "fully assessed".
Bioxyne said it had received "both the initial results and further very detailed analyses of the data" and the analysis was ongoing and required professional validation.
Bioxyne said it expected to release a detailed announcement after June 27, 2012.
Bioxyne last traded at 24 cents.

NANOSONICS

Nanosonics says General Electric's Healthymagination Fund has made a strategic investment with $7.5 million in convertible notes.
Nanosonics said the notes would convert at 75 cents a share and were for four year, with an interest rate of six percent and would be issued in two tranches
The company said that the GE Halthymagination Fund invested in "highly promising healthcare technology companies" and the investment was "a strong endorsement of its proprietary infection control technology and growth potential".
Nanosonics said its Australian researched, developed and manufactured Trophon EPR was one of the first non-GE developed products to be certified by GE's Healthymagination program, which certified technologies that improved health outcomes and lowered costs.
Nanosonics said that GE had a first right of refusal, for exclusive distribution of the Trophon EPR in Japan, one of the largest health care markets.
The company said it was actively pursuing regulatory approval in Japan and the proposed extension of Nanosonics' partnership with GE in Japan was "a significant opportunity".
Nanosonics was up three cents or six percent to 53 cents.

STARPHARMA

Starpharma says recruitment has been completed for its phase II Vivagel bacterial vaginosis recurrence prevention trial as well as the first of two phase III treatment trials.
Starpharma said the 205-patient, US phase II prevention study was being conducted under a US Food and Drug Administration investigational new drug application and had enrolled patients with a prior history of recurrent bacterial vaginosis.
The company said the trial's primary objective was to determine the efficacy of two strengths of Vivagel (containing 1% or 3% SPL7013) used every second day over 16 weeks, compared with a placebo gel in preventing recurrence of bacterial vaginosis.
Starpharma chief executive officer Dr Jackie Fairley said that high rates of recurrence were driving significant demand for an effective approach to prevent the recurrence.
Dr Fairley said that bacterial vaginosis had "a significant impact on the quality of life of women who suffer chronic bouts, but worse, can lead to more serious reproductive and sexual health complications".
Starpharma said the first of two phase III bacterial vaginosis treatment studies had completed recruitment of 250 patients and two studies were the subject of an agreement with the FDA under the special protocol assessment, which confirmed that the trial design, clinical endpoints and statistical analyses were acceptable for approval once completed.
Starpharma said that all three trials were expected to be completed by the end of 2012.
The company said that other activities to support its proposed new drug application submission for Vivagel for the treatment of bacterial vaginosis, which would follow soon after the announcement of phase III trial results, were well advanced.
Starpharma said it had completed full scale up of the Vivagel active ingredient, SPL7013, to the tens of kilograms scale under good manufacturing practices at an FDA and EU-certified manufacturer, as well as scale-up to the hundreds of kilograms scale.
The company said that bacterial vaginosis was the most common vaginal infection and the most common cause of vaginal irritation, discharge and malodor and was most prevalent in the US, where it affected one-third of the adult female population and up to 50 percent of the female population in some regions.
The company said existing treatments were considered suboptimal with relatively low cure rates and high rates of recurrence, unpleasant side-effects and bacterial resistance.
Starpharma was up 2.5 cents or 1.9 percent to $1.315.

GI DYNAMICS

GI Dynamics says data has been presented showing that its Endobarrier reduces weight and blood glucose levels in non-severely obese patients.

GI Dynamics said that the study entitled 'Metabolic Improvement in Type 2 Diabetes in Subjects without Severe Obesity with the Endoscopic Duodenal-Jejunal Bypass Liner' was presented at the American Society for Metabolic and Bariatric Surgery meeting in San Diego.

The company said the data was presented by the Sao Paulo, Brazil-based Hospital Alemao Oswaldo Cruz's Dr Ricardo Cohen

GI Dynamics said the non-randomized, single-arm, single-center study evaluated Endobarrier therapy in 20 patients with uncontrolled type 2 diabetes and a mean body mass index (BMI) of 30.0 kg/m2 (range: 23-36) over a one-year period.

The company said that 16 patients completed one year of Endobarrier therapy with a statically significant mean decrease in HbA1c of 1.1 percent, from 8.6 percent at baseline to 7.5 percent ($p < 0.05$) and HbA1c levels of less than or equal to 7.0 percent in 62.5 percent of the patients.

According to the US National Institutes of Health, an HbA1c of less than 5.7 percent is normal, with 5.7 percent to 6.4 percent described as "pre-diabetes" and 6.5 percent or above as a diagnosis of diabetes.

See: http://www.nlm.nih.gov/medlineplus/ency/article/003640.htm.

GI Dynamics said that a statically significant decrease in total body weight loss of 9.4 percent ($p < 0.05$) was also observed, along with statically significant reductions in total cholesterol from 218 mg/dL at baseline to 189 mg/dL ($p < 0.05$) and low density lipoprotein from 135 mg/dL at baseline to 111 mg/dL ($p < 0.05$).

The National Institutes of Health says that total cholesterol below 200 mg/dL is "desirable" and low density lipoprotein levels below 100 mg/dL were "optimal" with 100 mg/dL to 129 mg/dL described as "near or above optimal".

"Our data point to a substantial improvement in glycaemic control and other metabolic parameters even among overweight but not severely obese diabetic patients during Endobarrier therapy," Dr Cohen said.

"These are promising data and suggest that Endobarrier may play a valuable role for overweight patients struggling to control their diabetes and lose weight," Dr Cohen said.

GI Dynamics chief commercial officer Mark Twyman said the study population had a BMI lower than any previous Endobarrier study.

"…even so, Endobarrier therapy produced meaningful and clinically significant benefits with regard to glycaemic control, weight loss and other metabolic parameters," Mr Twyman said.

GI Dynamics was untraded at 87.5 cents.

CORRECTION: MEDICAL DEVELOPMENTS INTERNATIONAL

Last Friday's edition reported that Medical Developments upgraded its profit guidance for the year to June 30, 2012 from the previous estimate of $2.2 million to $2.45 million.

The accompanying headline mistakenly said the upgrade was to $2.2 million and not $2.45 million.

The Friday sub-editor responsible for the error has sought asylum at the Embassy of Ecuador and cannot be suitably punished at this stage.

Medical Developments fell four cents or 5.1 percent to 75 cents.

COGSTATE

Cogstate says that Merck Canada Inc has the exclusive right to market and promote its cognition test in Canada, with the first commercial sale expected by the end of 2012.
Cogstate did not disclose the financial terms of the agreement.
Cogstate said the test assessed cognition in patients and the reports could allow physicians to identify subtle changes indicative of the early stage of a neurodegenerative disease, such as Alzheimer's disease.
The company said the test could be used to monitor changes in cognitive function following concussion or after treatment with drugs or other types of interventions.
Cogstate said that the partnership would provide Canadian physicians with a tool to help them with early detection of cognitive decline in their patients.
Merck Canada executive Christian Sauvageau said the partnership was "part of Merck's ongoing commitment to finding treatments for diseases involving the central nervous system".
Cogstate chief executive officer Brad O'Connor said the agreement was "the first stage of commercializing the Cogstate test in general practice medicine".
"It is an important milestone in the company's strategy to establish the Cogstate test as the gold standard for measuring cognitive change and making it a routine part of wellness care around the world," Mr O'Connor said.
"Cogstate's test allows for regular and standardized testing of cognitive function to detect even subtle change that could signify the earliest stage of dementia," Mr. O'Connor said.
Cogstate was up five cents or 20 percent to 30 cents.

BENITEC BIOPHARMA

Benitec says the validity of its UK Graham patent is over, following the withdrawal of the application for revocation of the patent by the applicant.
Benitec said the by the UK Intellectual Property Office had accepted its amended claims.
The company said the application for revocation was received in late 2010 by the UK Intellectual Property Office from UK-based patent attorneys Sterling IP, acting on behalf of an unknown client.
Benitec and the Commonwealth Scientific and Industrial Research Organisation responded to all of the issues raised and in 2011 decided to slightly amend the claims to provide greater clarity, in particular that the claims were to double stranded constructs.
The company said the applicant initially objected to the amended claims, but subsequently withdrew the objection to the amendments and withdrew their application for revocation of the patent.
Benitec said the amended claims were published on the UK Intellectual Property Office website on May 16, 2012 allowing for a four week period for objections, no objections were received, the amended claims stand and the revocation action was concluded.
Benitec chief executive officer Dr Peter French said the conclusion was "a great outcome".
"Whilst I was always confident that we would prevail in the application for revocation of the UK patent, the process was more prolonged than we would have liked," Dr French said.
"The result is further testimony to the robustness of the Graham patents and of their breadth of their coverage," Dr French said.
"Our claim amendments bring greater clarity to the patent in what is a complex area and should assist potential licensees to understand the full implications of Benitec Biopharma's dominant patent position in ddRNAi," Dr French said.
Benitec was unchanged at 1.7 cents with 1.2 million shares traded.

CALZADA, METABOLIC

Calzada says wholly-owned subsidiary, Metabolic Pharmaceuticals' AOD9604 has conditional approval as 'generally recognized as safe' (GRAS).

Metabolic chief executive officer David Kenley told Biotech Daily that the generally recognized as safe program was approved by independent committees under the auspices of the US Food and Drug Administration.

Calzada said that generally recognized as safe products could be consumed at up to 1mg per day and the conditional approval was dependent on arranging publication of the previously completed primary safety studies in a peer-reviewed scientific journal and a journal article was under preparation.

The company said that approval would enable AOD9604 "to be legally and ethically sold as a component in conventional foods and eventually as a dietary supplement" in the US and would be exempt from any further pre-market approval requirements of food ingredients.

Calzada said that the company intended to use the peptide in foods and the GRAS status added "significant value to AOD9604 with commercial benefits anticipated through its licencing to companies who wish to use it in food, drink, and later in dietary supplements".

Metabolic developed AOD9604 for obesity but a phase II trial showed no significant efficacy in subjects compliant with FDA exercise and diet regime (BD: Feb 21, 2007).

The company licenced AOD9604 to Phosphagenics for use as a transdermal fat remover (BD: Oct 19, 2010) and has explored its efficacy for bone disease (BD: Feb 10, 2011).

In a media release Mr Kenley said that the "achievement of a self-affirmed conditional GRAS status is a major value creating milestone for AOD9604".

"This status is only possible due to the profound safety and tolerability track record of AOD9604 resulting from the Company's past more than $50 million investment in the peptide," Mr Kenley said.

"We now plan to licence our intellectual property to US-based companies interested in adding a potential weight management capability to their consumer product range," Mr Kenley said. "We aim to receive a significant level of royalties on sales of such products, firstly in the US market and then explore the potential in Europe and the rest of the world."

Metabolic said that GRAS products were faster and cheaper to get to market and the dietary supplement market for fat reduction, was large and growing.

Calzada was up half a cent or 9.4 percent to 5.8 cents.

BIODIEM

Biodiem says it has completed the licence of vaccine technology from the John Curtin School of Medical Research at the Australian National University (BD: Jun 6, 2012).

Biodiem said earlier this month that the technology's first disease indication of the technology was dengue fever and it could also facilitate the design of vaccines against other infectious diseases including Murray Valley encephalitis and Japanese encephalitis.

Biodiem said at that time that the acquisition would complement its product portfolio of vaccine and antimicrobial technologies and the strategy to provide treatments for infectious diseases with attractive market potential.

The company said that the agreement would provide an exclusive licence to the technology in exchange for royalties to the Australian National University on any sales, or received as a result of outlicencing the technology for specific disease targets.

Biodiem said the agreement allowed it to outlicence the technology for other disease targets to accelerate development with minimal financial outlay by Biodiem.

Biodiem was unchanged at six cents.

CBIO

CBio says it is continuing its review and restructure to manage its finances and has identified necessary activities, with total employee numbers adjusted downwards.
CBio said that scientific activities directed to drug formulation and elucidating the mechanism of action of Chaperonin 10 (XToll) have been ongoing.
The company said that legal proceedings by the company against former officers was progressing swiftly.
CBio said it had begun legal proceedings against the former executive chairman Stephen Jones, former chief executive officer, former chief financial officer and former company secretary in relation to payments of $736,600 related to the departure of the executives from the company, “an additional $183,333 as performance bonuses relating to the capital raisings undertaken” and $459,000 to SGB Jones Pty Ltd after Mr Jones resigned as an executive chairman and consultant to the company as well as $100,000 to Mr Jones in relation to a performance bonus relating to the capital raisings undertaken.
CBio fell 0.3 cents or 4.4 percent to 6.5 cents.

QRX PHARMA

QRX has requested a trading halt pending an announcement “in relation to the results of the new drug application review pf Moxduo by the US Food and Drug Administration”.
Trading will resume on June 27, 2012 or on an earlier announcement.
QRX last traded at $1.70.