



Biotech Daily

Tuesday September 6, 2011

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH DOWN: CIRCADIAN UP 7%; CLINUVEL DOWN 8%**
- * **GI DYNAMICS LISTS ON ASX TOMORROW, READY FOR LOCAL SALES**
- * **NZ PATENT FOR BPH, CORTICAL DYNAMICS BRAIN MONITOR**
- * **PRANA EGM TO EXTEND PLACEMENT, ELECT LAWRENCE GOZLAN**

MARKET REPORT

The Australian stock market fell 1.6 percent on Tuesday September 6, 2011 with the S&P ASX200 down 66.4 points to 4,075.5 points.

Six of the Biotech Daily Top 40 stocks were up, 19 fell, six traded unchanged and nine were untraded. All three Big Caps fell.

Circadian was the best, up four cents or 7.3 percent to 59 cents with 36,881 shares traded, followed by Anteo up 0.4 cents or 6.15 percent to 6.9 cents with 3.4 million shares traded.

Living Cell, Phylogica and Tissue Therapies were up more than one percent, with Mesoblast up 0.8 percent.

Clinuvel led the falls, down 13 cents or 8.1 percent to \$1.47, with 10,500 shares traded, followed by Patrys down 7.1 percent to 6.5 cents with 825,000 shares traded.

Allied Health, Impedimed and Sirtex lost six percent or more; Reva fell 4.1 percent; Phosphagenics and Prana were down more than three percent; Acrux, Alchemia, Bionomics, Biota, Nanosonics and Prima shed two percent or more; Pharmaxis, Psivida, QRX and Starpharma were down more than one percent; with Cochlear, CSL, Resmed and Viralytics down by less than one percent.

GI DYNAMICS

GI Dynamics expects to begin trading on the ASX tomorrow at 11am under the code GID, having raised \$80 million at \$1.10 a share for its Endobarrier gastric sleeve device.

GI chief financial officer Robert Crane told Biotech Daily the company was “pleased to complete the offering in the current climate” having raised \$80 million but not the extra \$15 million in potential oversubscriptions.

Mr Crane said the funds would be used to commercialize the gastric sleeve as a treatment for both diabetes and obesity.

He said GI had Conformité Européenne (CE) mark and Australian Therapeutic Goods Administration approval and was selling the device in Europe and South America.

Mr Crane said that he expected the first Australian implants “within months rather than years” and would begin by training specialist researchers at major public teaching hospitals in Melbourne and Sydney.

Mr Crane said the 60cm implantable and removable Endobarrier was best compared to Roux-en-Y gastric bypass surgery in which a surgeon created a small stomach pouch and a connection to the small intestine, effectively bypassing a portion of the stomach and the small intestine, altering food digestion and hormone signaling.

He said the Endobarrier cost \$4,000 and a further \$4,000 for the implantation compared to \$15,000 for gastric banding and up to \$30,000 for Roux-en-Y gastric bypass.

Mr Crane said the Endobarrier had “hormonal effects on diabetes, the urge to eat and metabolism and evidence that it works”.

He referred to a 2004 meta-analysis of 22,094 bariatric surgery patients by Dr Henry Buchwald published in the Journal of the American Medical Association which concluded that “diabetes was completely resolved in 76.8 percent of patients and resolved or improved in 86.0 percent; hyperlipidaemia improved in 70 percent or more of patients”.

An abstract is available at: <http://jama.ama-assn.org/content/292/14/1724.abstract>.

In its prospectus, GI said the Endobarrier was implanted in less than 30 minutes, remained in the body for up to 12 months and could be removed in about 15 minutes.

Mr Crane said that rat trials showed a 20 to 25 percent reduction in calorie intake with a 20 percent increase in energy burn rate.

He said that the company had conducted 13 human trials with more than 500 devices implanted and saw an average decrease in body mass index over 12 months from 45.3kg/m² to 37.8kg/m² along with statistically significant falls in blood glucose levels from 174.9mg/dL (9.7mmol/L) to 137.8mg/dL (7.65mmol/L) and a reduction in HbA1c levels from 8.9 percent to 6.6 percent.

Mr Crane agreed that although the falls were significant, the patients remained morbidly obese, with blood glucose levels above the US National Institutes for Health normal level of 100mg/dL and in the risk category for type 2 diabetes.

“The challenge is to take it off and keep it off,” Mr Crane said noting that although the average patient weight fell from 110kg to about 87kg at 52 weeks, once the Endobarrier was removed the weight returned to about 93kg in 24 weeks, but HbA1c remained below seven percent at 24 weeks after the device had been removed.

Mr Crane said GI had spent \$50 million in research and development for the anchoring device for the Endobarrier.

The GI prospectus said it was engaged in US litigation brought by WL Gore & Associates which supplied the material used to manufacture the Endobarrier liner, claiming it was the co-owner of the company’s 21 issued US patents and 14 US patent applications and the supply agreement was void, removing Gore’s obligation to supply the material.

GI said it was “vigorously defending all of the claims made by Gore and is pursuing counterclaims against Gore”.

BPH ENERGY, CORTICAL DYNAMICS

BPH says its 3.6 percent subsidiary Cortical Dynamics has been granted a New Zealand patent for relating to its Brain Anaesthesia Response (BAR) monitor.

BPH said the patent was entitled 'Brain Function Monitoring and Display Systems' and provided protection until June 6, 2027.

BPH said Cortical had patents awarded in Australia, New Zealand, the People's Republic of China and the US.

Cortical chairman David Breeze said the granted patent was "strategically important and will add value to Cortical's commercialization efforts".

"The grant of the New Zealand patent is a significant addition to Cortical's suite of intellectual property," Mr Breeze said.

BPH said Cortical had applied to list on the ASX and an initial public offer would close on September 26, 2011 (BD: Aug 16, 2011).

BPH said the BAR monitoring system measured brain electrical activity through an electroencephalogram to indicate how deeply anaesthetised a patient was during an operation.

The company said the monitor was designed to assist anaesthetists and intensive care staff in ensuring patients do not wake up unexpectedly, as well as reducing the incidence of side effects associated with the anaesthetic.

BPH fell 0.1 cents or 3.45 percent to 2.8 cents.

PRANA BIOTECHNOLOGY

Prana says shareholders will vote to extend their authority for a share placement of up to 100,000,000 shares and elect Lawrence Gozlan as a director.

Prana said shareholders supported the placement in June 2011, requiring the shares be issued no later than September 10, 2011 and the company said it required an extension of time, which required shareholder approval (BD: May 12, 2011).

Mr Gozlan was appointed to the board last month (BD: Aug 8, 2011)

The meeting will be held at Suite 1, 1233 high Street, Armadale, Victoria on October 7, 2011 at 10.30am (AEST).

Prana fell half a cent or 3.2 percent to 15 cents.