



Biotech Daily

Thursday March 8, 2012

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH UP: BIONICHE UP 27%, PRIMA DOWN 7%**
- * **OSPNEY \$20m IPO OPENS**
- * **MELBOURNE CENTRE 1st TO USE GI DYNAMICS ENDOBARRIER**
- * **GI DYNAMICS 10-PATIENT DATA SHOWS HbA1c REDUCTION**
- * **CATHRX CUTS COSTS, OUTSOURCES, MOVES FOCUS TO UK TRIAL**
- * **WEHI, COELIAC AUSTRALIA \$570k COLLABORATION**
- * **NEUREN APPOINTS BRUCE HANCOX DIRECTOR**

MARKET REPORT

The Australian stock market climbed 0.66 percent on Thursday March 8, 2012 with the S&P ASX 200 up 27.3 points to 4171.0 points.

Thirteen of the Biotech Daily Top 40 stocks were up, nine fell, 11 traded unchanged and seven were untraded.

Bioniche was the best, up 14 cents or 27.45 percent to 65 cents with 97,276 shares traded; followed by Avita up 17.65 percent to 20 cents with 2.2 million shares traded; Phylogica up 15.2 percent to 5.3 cents with 1.8 million shares traded; Living Cell up 14.1 percent to 10.5 cents with 1.6 million shares traded; and Viralytics up 13.6 percent to 37.5 cents with 325,144 shares traded.

Antisense climbed 4.8 percent; Alchemia, Impedimed, Pharmaxis, Reva and Starpharma rose more than two percent; Anteo was up 1.4 percent; with Acrux up 0.8 percent.

Prima led the falls, down 1.5 cents or 7.1 percent to 19.5 cents, with 10.6 million shares traded.

Universal Biosensors lost 5.6 percent; Genetic Technologies and Prima fell three percent or more; Allied Health and Tissue Therapies shed more than two percent; QRX was down 1.1 percent; with Cochlear, CSL, Heartware and Mesoblast down by less than one percent.

OSPREY MEDICAL

Osprey says its fully underwritten, initial public offer to raise \$20 million and list on the ASX has opened with 50,000,000 Chess depository interests available at 40 cents each. Osprey said the funds were to conduct a pivotal clinical trial and seek US Food and Drug Administration clearance of its Cincor contrast induced nephropathy contrast removal system (BD: Mar 1, 2012).

The Cincor system is a vacuum-assisted catheter to remove potentially toxic dyes used to image cardiac vessels in angioplasty and stent insertion procedures.

The company said the funds would also be used for a market launch in Europe, further develop the Cincor platform technologies for additional applications, conduct a medico-economic study to assist in both market adoption and reimbursement coding for the system and provide ongoing working capital.

Osprey said the offer was fully underwritten by Shaw Corporate Finance.

The company said the offer closing date was April 2, with trading expected to begin on April 16, 2012 under the ASX code of OSP.

The company said the Cincor system has Conformité Européenne (CE) mark approval with a commercial rollout planned for European market in 2012 and a US registration directed pivotal clinical trial in 2012 aiming for approval and US launch in 2014.

Osprey said that based on the offer price its market capitalization following the offer would be about \$40.4 million and most of the company's funds, so far, came from Australian institutional funds including CM Capital Investments and Brandon Capital Partners.

Osprey chief executive officer Mike McCormick said the funds would also be used to begin commercialization in Germany and the Netherlands.

The prospectus is available at <http://www.ospreymed.com/investors.php> or from Shaw Corporate Finance.

GI DYNAMICS

GI Dynamics says the Melbourne-based Epworth Centre for Bariatric Surgery will be the first Australian centre to commercially insert its Endobarrier for obesity and diabetes.

GI Dynamics said that the Epworth Centre for Bariatric Surgery was unrelated to the nearby Epworth Private Hospital and would be its first 'center of excellence' with the first Endobarrier gastrointestinal liner expected to be inserted into a patient by July 2012.

The company said the Therapeutic Goods Administration approved device was "a thin, flexible, tube-shaped liner that forms a physical barrier between food and part of the wall of the intestine".

GI Dynamics said the device had been "clinically proven to lower HbA1c levels, achieve weight loss of more than 20 percent and improve other important metabolic functions including cholesterol, blood pressure and triglycerides, all of which contribute to the severity of type 2 diabetes".

Epworth Centre for Bariatric Surgery director Dr Harry Frydenberg said the Centre was "privileged to be the first centre to offer this innovative treatment option to patients in Australia as part of a comprehensive approach to diabetes and weight management".

"Despite the pharmaceutical, surgical and lifestyle treatment options currently available, there are patients for whom these treatments are not fully effective," Dr Frydenberg said.

"The Endobarrier offers us a completely new way to treat patients with the potential for substantial weight loss, improvement in diabetes and better overall health," Dr Frydenberg said.

GI Dynamics said the Endobarrier was available in Chile and some European countries.

GI Dynamics was up six cents or 6.45 percent to 99 cents.

GI DYNAMICS

GI Dynamics says interim data on its Endobarrier in 10 type 2 diabetes patients with low body mass index shows a reduction in blood glucose levels.

GI Dynamics said that Endobarrier treatment reduced HbA1c (blood glucose) levels from 8.8 percent (+/- 0.3%) to 7.7 percent (+/- 0.5%) after one year of implantation.

The US National Institutes of Health says that a normal level is less than 5.7 percent, pre-diabetic was 5.7 to 6.4 percent with results above 6.5 percent classified as diabetic.

GI Dynamics said the study data demonstrating glycaemic control, weight loss and other metabolic benefits were discussed at the Society of American Gastrointestinal and Endoscopic Surgeons meeting in San Diego, California.

The company said the study was a non-randomized, single-arm, single-center study evaluating Endobarrier treatment in 20 patients with type 2 diabetes over a one-year period and with one year of follow-up analysis.

GI Dynamics said the full data set and results, including impact on weight, lipids and glycaemic control, had been accepted for oral presentation at the American Society for Metabolic and Bariatric Surgery meeting, June 17-22, 2012 in San Diego.

CATHRX

Cathrx hopes to continue commercialization of its reprocessable cardiac catheters using UK contractors rather than the previous German potential partner.

Cathrx executive chairman Denis Hanley told Biotech Daily that the deal with the unnamed German company was intended to demonstrate that there was a market demand for the catheters.

Mr Hanley said that despite a signed term sheet in 2011 the German company asked a series of questions that delayed negotiations, which would have included "significant money to be paid on signing" and there was a sense that the company was effectively delaying payment.

"We formed the view that they were not going to pay the money," Mr Hanley said and noted that the end of 2011 was a difficult time in Europe with German banks not being as forthcoming as they had been previously.

Mr Hanley said in a presentation filed with the ASX that a cash burn of \$600,000 a month was not sustainable and to demonstrate the potential for the catheters the company had changed its method of operation from its own manufacturing capacities to a less expensive outsourced Malaysian contractor.

Mr Hanley said the company had a memorandum of understanding with a UK contractor to remanufacture product in the UK, as well as undertake distribution and sales.

He said the clinical marketing was effectively to one customer, the British National Health Service, and a key UK doctor was prepared to support a trial of the catheters, expected to begin by July 2012 and take about one month.

Mr Hanley said that pending regulatory issues for changes to the manufacturing location, the catheters could be on sale in the UK "this year".

"There is no reprocessing currently in the UK and it is 50 percent cheaper for the hospital," Mr Hanley said.

He said the company needed to raise funds, but the need was not desperate.

Mr Hanley said the company had raised the possibility of delisting from the ASX due to the share price volatility reflecting a lack of liquidity, but said "the board hasn't decided to delist" and made the statement in the presentation as a matter of market transparency.

Cathrx had \$2,929,191 in cash and cash equivalents at December 31, 2011,

Cathrx fell 0.1 cents or 2.7 cents to 3.6 cents.

WALTER AND ELIZA HALL INSTITUTE FOR MEDICAL RESEARCH

The Walter and Eliza Hall Institute and Coeliac Australia have formed a three-year, \$570,000 partnership to research new treatments and tests for coeliac disease.

A WEHI media release said the program would be funded by an ongoing Coeliac Australia appeal to develop better treatments for children with coeliac disease, effective treatments following accidental gluten consumption and a diagnostic test for people on gluten-free diets.

Coeliac Australia president Hugh Sheardown praised the research efforts of Dr Bob Anderson and Dr Jason Tye-Din, who lead the Institute's coeliac disease research team.

"The research being undertaken is critical to unlocking a greater understanding of coeliac disease, particularly in the under-researched area of children," Mr Sheardown said.

"This is the largest research funding project Coeliac Australia has ever undertaken, and we are very happy to partner with the Walter and Eliza Hall Institute to improve the understanding, diagnosis and treatment of this disease," Mr Sheardown said.

WEHI said that coeliac disease affected more than one percent of the population and was caused by an abnormal immune response to gluten.

The Institute said that a gluten-free diet was the only treatment, but it was expensive and often difficult to follow and without treatment, patients had an increased risk of other immune diseases, osteoporosis and some types of cancer.

The Institute said that Dr Anderson and Dr Tye-Din's research had led to the development of a potential vaccine for coeliac disease, Nexvax2, which was in clinical trials (BD: May 9, 2011) and in December 2011, the Institute said that more than \$US20 million had been raised by the US-based Immusant Inc to develop the Nexvax2 therapeutic vaccine for coeliac disease (BD: Jan 22, 2012).

A WEHI spokeswoman said the funds were research into projects other than Nexvax2.

Dr Tye-Din said that the Coeliac Australia appeal would support a number of vital research projects to improve the diagnosis and treatment of coeliac disease.

NEUREN PHARMACEUTICALS

Neuren says it has appointed Bruce Hancox as a director.

Neuren said that Mr Hancox had "a long and distinguished career in business in New Zealand and Australia" and was formerly Brierley Investments' general manager, group chief executive and chairman.

The company said that since becoming an Australian resident in 2006, Mr Hancox had pursued private investment interests and had been a director of and consultant to companies and acted as advisor on takeovers.

Neuren said Mr Hancox was appointed a director of the Retail Food Group in 2007 and became its chairman in 2011.

The company said Mr Hancox held a Bachelor of Commerce from Canterbury University, New Zealand.

Neuren was unchanged at 2.3 cents.