

# Biotech Daily

Monday February 20, 2012

# Daily news on ASX-listed biotechnology companies

- \* ASX, BIOTECH UP: SUNSHINE HEART UP 20%, LIVING CELL DOWN 17%
- \* GI DYNAMICS TO IMPLANT AUSTRALIAN ENDOBARRIER 'BY JULY'
- \* UNIVERSAL BIOSENSORS REVENUE DOWN 19% TO \$15m, LOSS UP 122%
- \* DR GREG COLLIER, DR JAMES CAMPBELL LAUNCH VITALITY DEVICES
- \* AVITA APPOINTS BANK OF NEW YORK MELLON TO LIST ON US OTCQX
- \* ITL H1 REVENUE DOWN 21% TO \$17m, PROFIT UP 930% TO \$1.1m
- \* ORBIS REDUCES TO 16.5% OF PHOSPHAGENICS
- \* CELL SIGNALS REDUCES, DILUTED TO 7% OF CELLMID
- \* NUSEP LOSES DIRECTOR JOHN O'CONNOR

#### MARKET REPORT

The Australian stock market climbed 1.43 percent on Monday February 20, 2012 with the S&P ASX 200 up 60.2 points to 4256.1 points.

Seventeen of the Biotech Daily Top 40 stocks were up, 11 fell, seven traded unchanged and five were untraded. All three Big Caps were up.

Sunshine Heart was the best following its listing on the Nasdaq, up 0.7 cents or 20 percent to 4.2 cents with 6.3 million shares traded, followed by Avita up 2.5 cents or 18.5 percent to 16 cents with 1.6 million shares traded.

Anteo, Prima and Viralytics climbed more than seven percent; Alchemia and Cathrx were up more than four percent; Acrux, Circadian, Cochlear, Neuren, Psivida and Starpharma were up more than three percent; Bionomics rose 2.1 percent; Biota, CSL, Nanosonics and QRX were up more than one percent; with Impedimed and Resmed up by less than one percent.

Living Cell led the falls, down 1.2 cents or 17.4 percent to 5.7 cents, with 71,936 shares traded, followed by Bioniche down 16.7 percent to 50 cents with 10,000 shares traded.

Cellmid lost 7.1 percent; Benitec and Phylogica were down five percent or more; Antisense fell 4.55 percent; Phosphagenics and Tissue Therapies shed more than two percent; with Mesoblast, Pharmaxis and Sirtex down more than one percent.

#### **GI DYNAMICS**

GI Dynamics executives are in Australia preparing for the country's first commercial implant of the Endobarrier for obesity and type 2 diabetes, expected by July 2012. GI Dynamics president and chief executive officer Stuart Randle, accompanied by chief financial officer Robert Crane and chief commercial officer Mark Twyman were in Melbourne today as part of the preparations for the launch.

Mr Randle told Biotech Daily that the executives were meeting with physicians and prospective employees as well as investors prior to beginning clinical activity in the next few months.

Last year, GI Dynamics raised \$80 million and listed on the ASX to commercialize the Endobarrier, which has Australian Therapeutic Goods Administration approval and Conformité Européenne (CE) mark authorization for marketing (BD: Sep 6, 2011). Mr Randle said that a pivotal US Food and Drug Administration trial was being planned, but the company had delayed the study so that it could negotiate a 12 month trial rather than proceed with the previously approved six month trial.

Mr Crane said that the date generated from earlier trials showed increasing benefit to patients from a longer duration.

Mr Crane said that a trial in Brazil had shown reductions in both HbA1c blood glucose control and obesity, with sustained improvement for up to six months after removal of the Endobarrier.

Mr Randle said he hoped to begin the US trial "by the end of the year".

Mr Randle said that the company expected to publish longer term follow-up data later this year and had three fully-enroled trials underway: one investigating the use of the Endobarrier for diabetics with lower body-mass-indices; one for a new anchor design, holding the Endobarrier in place at the top of the duodenum; and a trial studying removal at different time points.

Mr Randle said that the Endobarrier was originally planned to reduce obesity but the trials had shown a significant reduction in diabetes and the company wanted its US FDA-approved trial to be designed to allow treatment for diabetes as part of the label. GI Dynamics was up 12 cents or 12.9 percent to \$1.05 with 33,980 shares traded.

#### **UNIVERSAL BIOSENSORS**

Universal Biosensors says its net loss after tax for the 12 months to December 31, 2011 was up 122 percent to \$14,692,117 on revenue down 19 percent to \$14,696,452. Universal Biosensors said that revenue from services, primarily contract research and development, fell from \$6,420,027 at the end of 2010 to \$2,632,870 at December 31, 2011, but in October 2011 the company began a new contract with Johnson & Johnson's Lifescan "to determine the feasibility of an innovative blood glucose product".

The company said that research and development expenses were up 46.7 percent to \$9,812,396 for the 12 months, while general and administrative expenses were constant at \$7.2 million.

Universal Biosensors said that net tangible asset per share fell 26.7 percent from 30 cents at December 31, 2010 to 22 cents at December 31, 2011.

The company said diluted loss per share was nine cents compared with four cents in the previous corresponding period.

Universal Biosensors said it had cash and equivalents fell from \$23,271,766 at December 31, 2010 to \$15,089,209 at December 31, 2011.

Universal Biosensors was unchanged at 72 cents.

# **VITALITY DEVICES**

Former Chemgenex executives Dr Greg Collier and Dr James Campbell have created Vitality Devices to distribute Israeli-designed technology in the Asia-Pacific region.

Dr Collier told Biotech Daily that he and Dr Campbell would be joint managing directors of the company, initially specializing in two electronic impulse devices, one to improve cardiac contractility and the other to treat obesity and type 2 diabetes.

Dr Collier said that both devices were invented by Harvard University and Israel Technion's Prof Shlomo ben Haim.

Dr Collier said the devices had Conformité Européenne (CE) mark approval and the Australian Therapeutic Goods Administration process was underway.

Dr Collier said a chief executive officer would be appointed and the company was likely to have offices in Australia and Singapore, with sales expected to begin "this year".

In a media release, Vitality said it had agreements with the two Israel-based and related companies Impulse Dynamics NV and Metacure to distribute the devices in the Asia-Pacific region and the United Arab Emirates.

Vitality said it would distribute Impulse Dynamics' Optimizer System for chronic heart failure and Metacure's Diamond System for type 2 diabetes and metabolic diseases. Vitality said it would "specialize in commercializing medical technology in the Asia Pacific region [and] focus on the Impulse Dynamics and Metacure implants as the cornerstone of its commercial platform, adding additional medical devices over time".

Impulse Dynamics and Metacure chief executive officer Dr Irit Yaniv said the partnership agreement with Vitality was "a strategic asset".

"With the growing incidence of chronic heart failure and metabolic disease throughout the Asia Pacific region, we view these markets as a primary commercial target and source of growth for our companies," Dr Yaniv said.

Vitality said the Optimizer implant used cardiac contractility modulation to improve exercise tolerance and quality of life in congestive heart failure patients.

According to Metacure's website the Tantalus II or Diamond System sends electrical stimulation to the stomach and by enhancing the activity of gastric muscles when the patient eats, modifying hormone secretion, favorably affecting glucose and fat metabolism, while causing the patient to feel satiated sooner and consume less.

#### **AVITA MEDICAL**

Avita says it has begun the process of listing on the Over The Counter Quality Exchange (OTCQX) and has appointed Bank of New York Mellon as the depositary bank. Avita said it expected that the application and registration process would take eight to 10 weeks, subject to completion of due diligence and approval by the Over The Counter Markets Group.

Avita was up 2.5 cents or 18.5 percent to 16 cents with 1.6 million shares traded.

#### ITL

ITL says its revenue for the six months to December 31, 2011 fell 21 percent to \$17,221,000 but profit was up 930 percent to \$1,082,000.

The company said the net asset backing per share was up 7.9 percent to 12.3 cents. ITL said diluted earnings per share was 0.8 cents for the six months to December 31, 2011 compared to 0.1 cents for the previous corresponding period.

ITL fell half a cent or 3.3 percent to 14.5 cents.

#### **PHOSPHAGENICS**

Orbis Investment Management has reduced its substantial holding in Phosphagenics from 178,351,933 shares (17.53%) to 167,786,403 shares (16.49%).

Orbis said it sold 10,565,530 shares between January 3 and February 12, 2012 for \$2,154,414 or an average price of 20.4 cents each.

Phosphagenics fell half a cent or 2.4 percent to 20 cents with 1.4 million shares traded.

# CELLMID

Cell Signals Inc has reduced its substantial holding in Cellmid and been diluted through a placement, share rights issue and a convertible note facility.

Cell Signals said in its substantial shareholding that it had reduced and been diluted from 35,000,000 shares (16.46%) to 29,000,000 shares (6.80%).

Cellmid fell 0.1 cents or 7.1 percent to 1.3 cents with 5.2 million shares traded.

### **NUSEP**

Nusep says that John Paul O'Connor has resigned as a director, effective from February 19, 2012.

Nusep was untraded at 5.7 cents.