Biotech Daily

Tuesday February 23, 2010

Daily news on ASX-listed biotechnology companies

*** ASX EVEN, BIOTECH DOWN: GENETIC TECH UP 11%; USCOM DOWN 13.5%**

*** CHINA'S AOXING PHARMA DEAL FOR QRX'S MOXDUO IV OPIOID**

*** HEARTWARE FINISHES TRIAL ENROLMENT; REVENUE UP, LOSS DOWN**

*** PRIMA PLACES $2.5m SHORTFALL SHARES**

*** COGSTATE H1 PROFIT DOWN 59% TO $527k, ON REVENUE UP 31%**

MARKET REPORT

The Australian stock market was flat, climbing 0.02 percent on Tuesday February 23, 2010 with the S&P ASX 200 up 0.8 points to 4718.3 points.

Thirteen of the Biotech Daily Top 40 stocks were up, 16 fell, 10 traded unchanged and one was untraded. All three Big Caps were up.

Genetic Technologies was best, up 0.4 cents or 11.4 percent to 3.9 cents with 44,450 shares traded, followed by Optiscan up 7.1 percent to 7.5 cents with 10,000 shares traded.

Circadian climbed 6.2 percent; Chemgenex was up 5.1 percent; QRX was up 4.8 percent; Prana was up 3.3 percent; Cellestis, Impedimed, Living Cell, Sirtex and Sunshine Heart rose more than two percent; with Novogen up one percent.

Uscom led the falls, down 10 cents or 13.5 percent to 64 cents with 16,000 shares traded, followed by Prima down 11.4 percent to 15.5 cents with 7.7 million shares traded.

Antisense and Psivida lost more than seven percent; Bone fell 6.7 percent; Biota and Compumedics were down five percent or more; Phosphagenics fell 4.8 percent; Acrux and Clinuvel were down more than three percent; Benitec, Nanosonics and Tissue Therapies shed more than two percent; with Alchemia, Bionomics and Phylogica down more than one percent.

QRX PHARMA

QRX and the Aoxing Pharmaceutical Co will collaborate to develop an intravenous formulation of QRX's Moxduo morphine and oxycodone combination for pain.

QRX said that China Aoxing was a US-incorporated specialty pharmaceutical company with its main operations in China, specializing in research, development, manufacturing and distribution of narcotics and pain-management products.

The company said China Aoxing was based in Shijiazhuang City, about 270km south west of Beijing, with "the largest and most advanced manufacturing facility for highly regulated narcotic medicines" (http://www.chinapainmed.com).

It has one of the few 'good manufacturing practice' facilities licenced for the manufacture of narcotic medicines by the China State Food and Drug Administration, QRX said.

QRX said Aoxing would fund the development of Moxduo IV for China in exchange for exclusive marketing rights in China but QRX would retain ownership of Moxduo IV and might use Aoxing's clinical work for product registration purposes outside China.

QRX chief executive officer Dr John Holaday told Biotech Daily that milestones would be paid "in kind" but there would "undisclosed attractive royalties on completion".

Dr Holaday said he hoped Moxduo IV would on the market in China in 2014.

In a media release Dr Holaday said the strategic alliance "furthers our Moxduo IV development objectives and provides access to an important and rapidly growing market".

"By leveraging China Aoxing's technical resources, we are able to cost effectively advance development of Moxduo IV," Dr Holaday said.

"Our team will work closely with China Aoxing to ensure the development program meets both US Food and Drug Administration and China State Food and Drug Administration regulatory requirements," Dr Holaday said.

QRX said that China Aoxing had also licenced the rights to the China market for the immediate release capsule Moxduo IR, which was in pivotal phase III studies in the US.

The company said a binding term sheet had been signed by the parties and the transaction was expected to be closed by the end of March 2010.

China Aoxing chairman and chief executive officer Zhenjiang Yue said his company was "excited to enter into this strategic alliance with QRX Pharma to co-develop two promising drugs for China and ex-China markets".

"This partnership further solidifies China Aoxing's leading position in the rapidly growing narcotics and pain management market in China," Mr Yue said.

"It also bolsters our capability to develop and bring to market innovative, high-value medicines that have the potential to address significant unmet medical needs," he said.

"We believe that the partnership will generate significant opportunities and benefits for both companies," Mr Yue said.

QRX said that in July 2009, it began a comparative proof-of-concept study to evaluate the efficacy and safety of Moxduo IV versus intravenous morphine alone for the treatment of moderate to severe post-operative pain in patients following hip replacement surgery.

The company said data from the study was expected to be available by July 2010 and might serve as a predictor of Moxduo IV's clinical benefits and provide guidance for the design of clinical trials with China Aoxing which may be used to support any later submission of a new drug application to the FDA.

QRX said that Moxduo IV was one of three complementary dual opioid products in development and the immediate release Moxduo IR was in pivotal phase III trials and clinical studies for a controlled-release oral formulation would begin "in the near future".

QRX said studies demonstrated that its dual opioids provided as good or better pain relief with significantly fewer side effects.

QRX climbed four cents or 4.8 percent to 87 cents.

HEARTWARE INTERNATIONAL

Heartware has completed patient enrolment for its 'Advance' ventricular assist system bridge-to-heart transplantation clinical trial.

Heartware said the clinical trial was a US Food and Drug Administration-approved investigational device exemption (IDE) study designed to evaluate its left ventricular assist system for patients with end-stage heart failure.

The company said the primary endpoint for the trial was survival at 180-days, defined as alive on the originally implanted device or transplanted or explanted for recovery.

Heartware said that secondary endpoints included adverse events such as bleeding and infection, as well as functional status, hospitalization, assessment of neuro-cognitive function and patient quality of life.

Heartware chief executive officer Doug Godshall said there was "a growing enthusiasm from investigators during this study and we are grateful for their continued support".

"We also had an unexpected acceleration to the completion of the enrollment phase of the trial," Mr Godshall said.

"During routine discussion with the FDA, we were asked to change the definition of 'enrolled' in our IDE protocol to include patients who were consented to enter the trial, as opposed to those who were consented and met all inclusion and none of the exclusion criteria," Mr Godshall said.

"With two additional implants scheduled, this modification will result in 30 US clinical sites implanting a total of 140 patients, making Advance the largest bridge-to-transplant pivotal trial to date," Mr Godshall said.

Heartware said the final implant was scheduled for February 25, 2010 which would result in the final patient reaching the 180-day follow up by the end of August 2010.

The company said that the submission to the FDA of the pre-market approval would occur in early December rather than late December or early January as previously expected.

Heartware said it was seeking FDA approval to implant additional bridge-to-transplant patients under a continued access protocol in any US center that implanted a patient under the trial.

The company said that there was no guarantee that a continued access protocol would be granted, but the FDA has allowed them following full enrollment in prior ventricular assist device trials, as it makes the technology available to patients and clinicians while also providing additional safety data for the FDA to evaluate.

Heartware said it had submitted a protocol to FDA for a destination therapy (DT) trial in the US and the company was "actively engaged in discussions with the FDA regarding finalization of the DT protocol".

The company said the destination therapy trial was expected to begin by July 2010.

Separately, Heartware said it had received $US24.2 million ($A26.9 million) in revenue for the year to December 31, 2009, compared with $US332,000 for the year to December 31, 2008.

Heartware said it had received revenue of $US12.2 million for the fourth quarter ended December 31, 2009 compared to $US7.5 million for the third quarter ended September 30, 2009.

The company said its net loss was $US20.9 million, or a loss of $US2.15 per basic and diluted share, compared to a $US23.8 million net loss, or $US3.00 per basic and diluted share, for 2008.

Heartware was unchanged at $1.20.

PRIMA BIOMED

Prima has raised $2.5 million through the placement of 17,602,741 share purchase plan shortfall shares at 14 cents a share.

Prima said the placement was to investors including New York-based investment fund Springtree Special Opportunities Fund and sophisticated investor Laurence Freedman.

Prima said the funds would be used to commercialize CVac ovarian cancer vaccine.

Springtree Global Investors' managing director Jeff Easton said his company was "delighted to continue to provide funding for Prima Biomed as it pursues its commercialization plans for CVac".

"Prima was our first investment in the Australian market and we look forward to working with the company as it develops a world's first vaccine treatment for ovarian cancer patients," Mr Easton said.

Prima fell two cents or 11.4 percent to 15.5 cents with 7.7 million shares traded.

COGSTATE

Cogstate says its net profit after tax for the six months to December 31, 2009 fell 59.2 percent to $526,623 on revenue up 30.9 percent to $5,136,711.

Cogstate said the decline in profit could be attributed to "non-operating contract termination fees paid during the period ($238,472) and a decrease in foreign exchange gains compared to the prior period ($788,411)".

No dividend will be paid.

Net tangible assets per share was up 23.1 percent to 8.0 cents.

Cogstate was untraded at 28 cents.