



# Biotech Daily

Tuesday August 25, 2009

*Daily news on ASX-listed biotechnology companies*

- \* **ASX DOWN, BIOTECH UP: BENITEC UP 25%, SUNSHINE HEART DOWN 14%**
- \* **QRX MORPHINE-OXYCODONE BEATS PARACETAMOL-OXYCODONE**
- \* **MESOBLAST'S ANGIOBLAST RAISES \$10m**
- \* **JAPAN GRANTS CIRCADIAN'S VEGENICS VEGF-C PATENT**
- \* **CELLESTIS RECORD PROFIT UP 391% TO \$8m; REVENUE UP 80% TO \$35m**
- \* **COGSTATE POSTS \$1.4m MAIDEN PROFIT**
- \* **THREE PRIVATE BIOTECHS WIN \$70,400 COMET GRANTS**
- \* **ASX NAMES COMPANIES FAILING TO PAY LISTING FEES**

## MARKET REPORT

The Australian stock market fell 0.46 percent on Tuesday August 25, 2009 with the S&P ASX 200 down 20.3 points to 4405.8 points.

Eighteen of the Biotech Daily Top 40 stocks were up, 11 fell, eight traded unchanged and three were untraded.

Benitec was best, up 0.8 cents or 25 percent to four cents with 120,000 shares traded, followed by Cathrx up 8.33 percent to 32.5 cents.

Compumedics climbed 7.5 percent; Avexa was up five percent to 10.5 cents with 1.6 million shares traded; Universal Biosensors rose four percent; Clinuvel and Pharmaxis were up more than three percent; Starpharma rose 2.4 percent; Acrux, Alchemia, Cochlear, Heartware, Impedimed, Sirtex and Psivida were up more than one percent; with Biota, Mesoblast, Peplin and Progen up by less than one percent.

Sunshine Heart led the falls, down 0.8 cents or 13.8 percent to five cents with 805,270 shares traded, followed by Antisense down 7.7 percent to 3.6 cents.

Cellestis, Nanosonics and Prana lost more than six percent; Genera fell 5.2 percent; Circadian fell 4.7 percent; Viralytics was down 3.45 percent; Tissue Therapies shed 2.04 percent; Chemgenex and Novogen were down more than one percent; with CSL and Resmed down by less than one percent.

## [QRX PHARMA](#)

QRX says its Moxduo morphine oxycodone is more tolerable and has fewer side effects than oxycodone paracetamol tablets at the same analgesic dose following total knee replacement surgery.

QRX said it had completed a pilot study to evaluate the analgesic efficacy and safety profile of Moxduo IR (immediate release) capsules in patients with moderate to severe pain following total knee replacement surgery and when compared at equi-analgesic doses with Percocet (5mg oxycodone and 325mg paracetamol), Moxduo IR “demonstrated greater overall tolerability with substantially fewer incidences of moderate to severe nausea, vomiting, constipation, and hypotension”

QRX said Moxduo IR was scheduled for launch in 2011 and targeted the acute pain market; a \$2.5 billion segment of the \$7 billion spent annually on US prescription opioids. QRX chief executive officer Dr John Holaday said the study reinforced earlier clinical findings that showed improved tolerability “and again demonstrates the value of our dual-opioid platform as Moxduo IR opens the therapeutic window for treating patients suffering from acute post-surgical pain”.

“We believe the Moxduo product portfolio, including immediate release, controlled release and intravenous formulations, will significantly improve patient care, providing equal or better analgesia with fewer and/or less intense side effects than current standards of care,” Dr Holaday said.

QRX said Moxduo IR was the first patented analgesic product that consisted of two opioid drugs.

The company said other products combined an opioid with acetaminophen or paracetamol and had been “the subject of recent FDA scrutiny due to their potential for causing significant adverse effects on liver and gastrointestinal function”.

QRX said that more than 400 patients in six clinical trials had received Moxduo IR for different forms of post-surgical pain including bunionectomy and total knee replacement. The company said the study results with Moxduo IR “consistently demonstrate fewer side effects than observed with morphine alone, oxycodone alone and now with Percocet”.

QRX said that in the 44-patient open label trial, each group of patients who experienced moderate to severe post-operative pain following total knee replacement surgery were treated every four to six hours over a 48-hour period.

The study compared the analgesic efficacy and safety profile of Moxduo IR against control groups of patients receiving Percocet and a flexible dosing regimen of Moxduo IR (12mg morphine, 8mg oxycodone) against a fixed low dose (3mg morphine, 2mg oxycodone). Patients receiving the flexible dosing regimen of Moxduo IR achieved significantly greater pain relief than those receiving the low dose formulation ( $p < 0.05$ ).

QRX said the data collected from the study would provide additional guidance for optimizing the design and implementation of pending pivotal phase III studies as the company prepares for new drug application filings with the US Food and Drug Administration in 2010.

QRX said that based on its July 2008 FDA meeting, final phase III studies for Moxduo IR would include a double-blind combination rule trial in patients experiencing post-surgical pain following a bunionectomy that compared Moxduo IR against morphine alone and oxycodone alone; as well as a double-blind controlled study to evaluate the effectiveness of Moxduo IR in patients following total knee replacement.

No additional pharmacology, toxicology or long-term clinical safety studies will be required for regulatory submission and market approval, the company said.

QRX was up eight cents or 15.7 percent to 59 cents.

## MESOBLAST

Mesoblast says its US sister company Angioblast Systems has closed a \$10 million equity-based financing from institutional and sophisticated investors.

Mesoblast owns about 38 percent of Angioblast and the founder and executive director of both companies Prof Silviu Itescu owns "about 40 percent" of Angioblast and less than 30 percent of Mesoblast (BD: Aug 19, 2009).

The company said new investors oversubscribed the financing, with \$3 million coming from existing Angioblast shareholders.

Mesoblast said the capital was raised through non-redeemable convertible securities converting into common shares at the time of Angioblast's next financing event, defined as an initial public offer, merger and acquisition, or private equity round of at least \$10 million. In view of Angioblast's successful capital raising, Mesoblast said it did not need to participate in the current financing round.

The company said it would allocate an increased portion of its \$16.5 million funds to "a major new orthopedic clinical application during the course of the current financial year". Mesoblast was up one cent or 0.95 percent to \$1.06.

## CIRCADIAN

Japan has granted a patent for the VEGF-C protein, gene and antibodies to VEGF-C as well as the use of these molecules in a broad range of indications, including cancer.

Circadian said the patent was held by its wholly-owned subsidiary Vegedics.

The company said vascular endothelial growth factor (VEGF) C was "a major novel target for cancer and other diseases" and was closely related to VEGF-A, the target of Genentech's Avastin, a cancer therapy with global sales of more than \$US7.5 billion a year.

Circadian said the Japanese patent together with the VEGF-C patents granted in the US and Europe provided "a major commercial advantage and access to the world's major pharmaceutical markets".

The company said Japan was the world's second largest market for pharmaceuticals after the US.

Circadian chief executive officer Robert Klupacs said that the development of antibody drugs targeting angiogenic molecules such as VEGF-C was "widely considered one of the most promising strategies in the pharmaceutical industry".

Vegedics owns global rights to an extensive intellectual property portfolio covering angiogenesis targets VEGF-C, VEGF-D and the receptor protein VEGFR-3.

Circadian fell 3.5 cents or 4.7 percent to 71.5 cents.

## CELLESTIS

Cellestis says its net profit after tax for the 12 months to June 30, 2009 was up 391 percent to \$8,232,000 on revenue up 80 percent to \$35,241,000.

Cellestis said nearly all of the revenue, \$34,461,000, was from sales of its Quantiferon tests for tuberculosis.

Cellestis said that a final fully franked dividend of 2.0 cents a share with a record date of September 25, 2009 would be paid on October 9, 2009.

Cellestis paid a maiden dividend of one cent in February 2009.

Diluted earnings per share was 8.45 cents up 388.4 percent from 1.73cents the previous year.

Cellestis fell 25 cents or 6.25 percent to \$3.75.

### COMET GRANTS

Three life sciences companies are among 52 projects to win a share of the Federal Government's \$3.6 million Commercialising Emerging Technologies (COMET) grants. The Minister for Innovation, Industry, Science and Research, Senator Kim Carr, announced the grants today, citing the Victorian company Biofirst which received a \$70,400 grant to develop an organically-derived control for powdery mildew, a common plant disease.

### WARRAPHARM

University of Wollongong spin-out Warrapharm Pty Ltd was awarded \$70,400 for two novel anti-cancer reformulations of commonly prescribed colorectal cancer drugs. The media release from Senator Carr's office said Warrapharm had developed a production method for a composite reformulation based on the cytotoxic drug combination of 5-fluorouracil and folinic acid, respectively.

The inventors are Prof John Bremner, Prof Phil Clingan and Dr Julie Locke.

The method provides for an essentially pH neutral reformulation that allows the ingredients to be administered concurrently as an all-in-one regimen.

The media release said a core element of the innovation was the use of excipient-based technologies to encapsulate the active ingredients which protect against the degradation of active compounds and increase formulation stability.

This encapsulation technology may also increase the in vivo half-life of active 5FU, which is about 20-30 minutes in its unencapsulated state, potentially leading to an improved efficacy profile.

The funds will be used for strategic business planning, market research and proven technology activities.

### LUMIGENIX

Sydney-based Lumigenix Pty Ltd received \$70,400 for a consumer genomics service, providing customers with both general interest information about ancestry and personalized information about their genetic risks for a range of major diseases such as colorectal cancer, coronary artery disease, breast cancer and prostate cancer. Individual subscriber ancestry and disease risk information would be derived from analysis of DNA samples obtained using buccal swabs.

The inventors are Dr Mervyn Thomas and Dr Allan Rae.

### CONTINENCE CONTROL SYSTEMS

Contenance Control Systems International won \$70,400 to control fecal and urinary incontinence using electrically stimulated transplanted smooth muscle tissue.

The media release said Contenance Control had developed a technology using a small amount of smooth muscle obtained from the patient, wrapped around the urethra.

Following implant, the transplanted tissue would be invaded by blood vessels and in time, nerves and the resulting transplanted tissue could be activated by electrical pulses, similar to the way in which a pacemaker can deliver electrical pulses to the heart.

A small stimulator is implanted in the abdominal wall and when the patient needs to urinate, a controller is used to send radio signals to the implanted stimulator to temporarily stop stimulation and the transplanted muscle relaxes allowing urine to exit the body.

The funds will be used for strategic business planning and intellectual property strategies.

Contenance Control chief executive officer Linda Laidlaw said the technology originated with Cochlear and was developed with expertise from the University of Melbourne.

Ms Laidlaw said Cochlear was an investor in her company.

### COGSTATE

Cogstate has reported its first full-year net profit after tax for the 12 months to June 30, 2009 of \$1.4 million on revenue climbed 120 percent to \$8.6 million.

The company said it had combined cash and traded debtors of \$5.1 million at June 30, 2009 and had signed 32 sales contracts for its cognitive tests with a combined value of \$9.3 million.

Cogstate was unchanged at 26 cents.

### ASX LISTING FEES

The ASX compendium of entities that have not paid listing fees includes seven life sciences companies.

The ASX said that any entity if not already suspended that had not paid its annual listing fees by the close of business on August 24, 2009 would be suspended from official quotation before the beginning of trading on August 25, 2009.

The companies cited include Apollo Life Sciences, Avastra, Dia-B Tech, Medic Vision, Narhex Life Sciences, Polartechnics and Ventracor.

All companies were already suspended from trading.