



Biotech Daily

Thursday August 14, 2014

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH UP: USCOM UP 24%, OPTISCAN DOWN 10%**
- * **QRX ENDS DUAL OPIOID MOXDUO PROGRAM, \$3m FOR ALTERNATIVES**
- * **ADMEDUS WA FACILITY SHIPS 1st CARDIOCEL TO THE US**
- * **GENETIC TECHNOLOGIES, HISTOGENETICS SETTLE PATENT CASE**
- * **COGSTATE \$800k COGNITION CONTRACT WITH UNNAMED COMPANY**
- * **ITL REVENUE UP 4% TO \$26m, PROFIT DOWN 18% TO \$2m**
- * **EXECUTIVE CHAIRMAN BILL MOBBS TAKES 39% OF ITL**
- * **AUSTRALIAN SUPER TAKES 6% OF ORTHOCELL**

MARKET REPORT

The Australian stock market climbed 0.61 percent on Thursday August 14, 2014 with the S&P ASX 200 up 33.8 points to 5,548.5 points.

Fifteen of the Biotech Daily Top 40 stocks were up, 12 fell, 10 traded unchanged and three were untraded. All three Big Caps were up.

Uscom was the best, up five cents or 24.4 percent to 25.5 cents with 6,400 shares traded followed by Genetic Technologies up 10.7 percent to 3.1 cents with 1.1 million shares traded.

Admedus and IDT climbed more than six percent; Bionomics, CSL, Medical Developments and Mesoblast rose more than four percent; Nanosonics and Tissue Therapies were up more than three percent; Circadian and Sirtex rose more than two percent; Acrux, Benitec, GI Dynamics and Neuren were up more than one percent; with Cochlear and Resmed up more than one percent.

Optiscan led the falls, down 0.4 cents or 10.3 percent to 3.5 cents with 100,626 shares traded.

Prana lost 6.5 percent; Clinuvel and Osprey fell more than five percent; Avita, Biotron, Ellex and Pharmaxis fell four percent or more; Phosphagenics and Starpharma were down more than three percent; Viralytics fell 1.85 percent; with Alchemia down 0.9 percent.

QRX PHARMA

QRX has halted development of the dual-opioid Moxduo and will cut costs to “a small core team tasked with exploring all strategic alternatives” with about \$3 million in cash.

In May 2007, QRX listed on the ASX to develop the two-to-three ratio morphine and oxycodone combination drug claiming that it provided greater pain relief and fewer side effects than its component parts (BD: Nov 26, 2007).

An equi-analgesic trial showed no significant differences between Moxduo consisting of 12mg morphine and 8mg oxycodone compared to either 24mg morphine or 16mg oxycodone and the company was rebuffed by the US Food and Drug Administration three times (BD: Jun 27, 2012; Aug 28, 2013; Apr 23, May 26, 2014).

The founding chief executive officer Dr John Holiday resigned and 10 percent shareholder the Walker Group called and won a board spill (BD: Jun 3, Jul 9, 2014).

Today, QRX said it was “halting all further development work on the Moxduo portfolio of products”.

QRX said that following the third FDA complete response letter and an end of review meeting with the FDA the management team “conducted a detailed review of the Moxduo technology with particular emphasis on the [end of review] meeting with the FDA and made a recommendation to the board to halt all further development of the Moxduo ... programs”.

The company said that the Moxduo program would require a repeat phase II clinical study, followed by one or more pivotal phase III clinical studies.

QRX said that the FDA had advised that agreement on a special protocol assessment would be unlikely for these studies and given specific issues related to the design of these clinical studies, such as a primary endpoint of 90 percent oxygen saturation and flexible dosing, both which have been strongly encouraged by FDA, “the likelihood of success is now in considerable doubt”.

The company said that the time and cost for such a development program would be significant and was not commercially justified given the limited residual patent life.

QRX said that with immediate effect, it would implement “a reduction in its overhead structure, minimizing non-essential expenditure and retaining only a small core team tasked with exploring all strategic alternatives for the company and its assets”.

The company said it reported \$10.5 million in cash reserves at June 30, 2014, but as noted in the recently filed Appendix 4C the company had set aside in escrow \$3.62 million to cover potential liabilities of its current employees, consultants and the former chief executive officer arising from notice entitlements, termination payments and where applicable, retention payments.

The Appendix 4C said that QRX had a net cash burn of \$3,563,000 for the three months to June 30, 2014.

QRX said that in addition, the company had been carrying as a liability excess annual leave entitlements.

The company said that in July the company paid down \$430,000 of this liability and the estimated free cash at September 30, 2014 would be about \$3.0 million.

QRX's 2013 annual report said that the company had \$107,304,000 in unused tax losses for which no deferred tax asset had been recognized at June 30, 2013.

The annual report said that the potential tax benefit at the 30 percent taxation rate would amount to \$32,191,000.

QRX fell 3.3 cents or 45.2 percent to four cents with 13.4 million shares traded.

ADMEDUS

Admedus says it has dispatched its first shipment of Cardiocel bovine cardiac patch to the US from its Western Australian manufacturing plant.

Admedus said it acquired the facility in January this year to scale up manufacturing of Cardiocel for supply to global markets (BD: Jan 19, Feb 10, 2014).

Admedus chief executive officer Lee Rodne said that the manufacturing team had “done a remarkable job in getting production up and running in such a short time”.

“This is a significant milestone for the company and will culminate in the official opening of the facility on August 15,” Mr Rodne said.

Admedus said that since its initial order in June, there were nine centres using the product including “some of the leading cardiovascular surgical units in the country”.

“Our sales teams have been able to generate considerable interest for Cardiocel from surgeons globally, particularly with our strong pre-clinical data and successful patient outcomes to date,” Mr Rodne said.

Mr Rodne said that the facility also enabled Admedus to undertake additional product development to expand the range of regenerative tissue products for both cardiovascular applications and for other surgical indications that require repair and reconstruction.

Admedus said that Cardiocel had been used in a range of cardiovascular repair and reconstruction procedures in both adults and children, including hole-in-the-heart repairs and heart valve reconstructions.

The company said that in the US, Cardiocel had been used in less-invasive robotic surgery to repair defective heart valves which was “a major step forward for the use of Cardiocel in cardiovascular surgery”.

Admedus was up one cent or 6.9 percent to 15.5 cents with 8.5 million shares traded.

GENETIC TECHNOLOGIES

Genetic Technologies says it has a settlement and release agreement with the Ossining, New York-based Histogenetics LLC.

Genetic Technologies said that the terms of this agreement were covered by formal confidentiality provisions and could be disclosed.

The company said that the agreement was a result of its continuing patent assertion efforts in the US.

Genetic Technologies chief executive officer Alison Mew told Biotech Daily that the legal action was initiated in the District Court of Delaware in December 2012.

Genetic Technologies was up 0.3 cents or 10.7 percent to 3.1 cents with 1.1 million shares traded.

COGSTATE

Cogstate says it has a \$800,000 contract with an unnamed company to provide cognition testing technology and services for a phase II glioblastoma, or brain tumor, trial.

Cogstate said that 230 patients would be tested at 65 sites in 12 countries.

The company said that the study would run for 34 months, with a high proportion of the services delivered in the first 12 months.

Cogstate said that a large percentage of the total contract value would be recognized in the 2014-'15 financial year and the contract brought the total value of clinical trial sales contracts since July 1, 2014 to more than \$9.0 million.

Cogstate was up three cents or 11.5 percent to 29 cents.

ITL

ITL says revenue for the 12 months to June 30, 2014 was up four percent to \$25,864,000 with net profit after tax down 18 percent to \$2,021,000.

ITL said that cash at June 30, 2014 was down 70.4 percent to \$122,000 compared to the previous year's \$412,000.

The company said that basic earnings per share fell 5.1 percent to 2.41 cents compared to the previous year's 2.54 cents and net tangible asset backing per share was down 4.0 percent from 10.1 cents to 9.7 cents.

ITL said that a fully franked 0.5 cent dividend per share for shareholders on the record date of August 26, 2014 was expected to be paid on September 2, 2014.

ITL was untraded at 20.5 cents.

ITL

ITL executive chairman William Mobbs has increased his holding in the company from 30,183,307 shares (26.16%) to 32,997,746 shares (38.63%).

Mr Mobbs said that he was issued 2,442,000 shares for \$488,400 or 20 cents a share and his percentage increased through the consolidation of the share base with an ongoing buy-back.

ORTHOCELL

Australian Super Investments as trustee for Australian Super Private Equity Trust Matthew has become a substantial shareholders in Orthocell with 4,619,190 shares (5.60%).

Orthocell was up 1.5 cents or 4.05 percent to 38.5 cents.