

Biotech Daily

Wednesday April 29, 2009

Daily news on ASX-listed biotechnology companies

- * ASX DOWN, BIOTECH UP: PROGEN UP 9%, GENETIC TECHNO DOWN 20%
- * QRX EXPLAINS DUAL OPIOID'S LOWER SIDE EFFECTS
- * AVEXA HAS \$12.8m CASH, MORE EXPECTED
- * TISSUE THERAPIES: 'OUTSTANDING' 2nd TORONTO PATIENT RESULT
- * STIRLING'S IMMUNOXEL 'EFFECTIVE' FOR 'FLU; RAISES \$1.8m
- * JOHN HUNTER HOSPITAL JOINS CATHRX TGA TRIAL
- * ANTHONY BARTON INCREASES TO 15% OF PHYLOGICA
- * VIRALYTICS HAS LESS THAN 2 QUARTERS CASH, FUND RAISING
- * ACUVAX HAS ONE QUARTER CASH, \$10m DRAW DOWN FACILITY
- * NANOSONICS RELEASES 92m ESCROW SHARES

MARKET REPORT

The Australian stock market fell 0.35 percent on Wednesday April 29, 2009 with the S&P ASX 200 down 13.1 points to 3,695.3 points.

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

Progen was best, up eight cents or 9.1 percent to 96 cents with 12,590 shares traded.

Viralytics, Tissue Therapies and Optiscan climbed more than seven percent; Phosphagenics recovered 6.9 percent; Antisense, Circadian and Living Cell were up five percent or more; Bionomics and Cochlear rose more than two percent; Pharmaxis and Resmed were up more than one percent; with CSL, Heartware, Mesoblast and Peplin up by less than one percent.

Genetic Technologies led the falls, down one cent or 20 percent to four cents with 163,751 shares traded, followed by Biota retreating a further 11.71 percent to \$1.32.

Psivida lost 6.1 percent; Alchemia fell 4.2 percent; Benitec, Clinuvel and Sirtex were down more than three percent; Genera and Novogen shed more than two percent; with Cellestis, Chemgenex and Phylogica down by less than one percent.

QRX PHARMA

QRX Pharma chief executive officer Dr John Holaday has explained how his company's Moxduo dual opioid can have reduced side effects compared to its component parts. In Melbourne with chief financial officer Chris Campbell to meet investors and media, Dr Holaday told Biotech Daily that pilot study results published last week (BD: Apr 20, 2008) showed that Moxduo composed of 6mg morphine and 4mg oxycodone was as effective in pain control as 12mg morphine alone and nearly as effective as 8mg oxycodone alone. But the trial showed that Moxduo had dramatically fewer and lower moderate to severe adverse events compared to the doses of morphine and oxycodone alone.

QRX compared oral 12mg/8mg Moxduo immediate release (IR) and 6mg/4mg Moxduo IR to 12mg morphine; 8mg oxycodone; 6mg morphine; and 4mg oxycodone.

Asked whether it would be better to trial Moxduo against an equivalent dose so that 12mg/8mg Moxduo would be compared to say 24mg morphine or 16mg oxycodone.

Dr Holaday said the US Food and Drug Administration rules for combination drug trials included the requirement that the combination drug had to show better responses than the component doses.

He said that 8mg oxycodone was considered to have the same pain relief strength as 12mg morphine.

But Dr Holaday said the side effects of nausea, vomiting and respiratory depression would be greatly increased with a dose of 24mg morphine or 16mg oxycodone.

He said that Moxduo reduced those side effects because oxycodone effectively blocked the pathways that trigger those responses, reducing the impact of the morphine side effects, while allowing the pain relief.

"Kappa agonists like oxycodone block the effect of μ -agonists like morphine," Dr Holaday said.

"The analgesia shines through but the side effects are dramatically reduced," he said "Using equivalent doses of Moxduo with its components of morphine or oxycodone alone, one finds a significant reduction in side effects such as nausea and vomiting and respiratory depression," Dr Holaday said.

He said the lower dosed 6mg/4mg Moxduo was superior to morphine 12 mg or oxycodone 8mg alone in terms of side effects.

"The physician can prescribe a drug with equivalent pain relief and fewer side effects, thereby increasing the therapeutic window," Dr Holaday said.

QRX was untraded at 47 cents.

AVEXA

Avexa says its total operating and investing cash burn was \$7,715,000 for the three months to March 31, 2009 with cash at the end of the quarter of \$12,761,000. In its Appendix 4C quarterly report Avexa provided explanatory notes saying the cash burn had been reduced for the quarter and funds were expected from a rights issue to raise up to \$14.8 million if fully subscribed.

Avexa said the cash burn was \$4.7 million lower than the previous quarter "due to lower payments for research and development and lower staff costs".

"In addition to the cash balance of \$12.76 million at March 31, 2009, the company announced a one-for-two rights issue on March 25, 2009. Under the Rights Issue the company may raise up to \$14.8 million if fully subscribed," Avexa said.

The company said the rights issue closed on April 27, 2009 and the results would be announced tomorrow April 30, 2009.

Avexa was unchanged at 9.9 cents with 1.3 million shares traded.

TISSUE THERAPIES

Tissue Therapies says Vitrogro has reduced a chronic diabetic ulcer in the second patient in its Toronto trial by 32 percent.

Tissue Therapies said the ulcer on the patient's left heel was reduced over six weeks, "despite significant complicating clinical factors including severe diabetes, kidney failure requiring dialysis and continued heavy growth of bacteria in the ulcer despite antimicrobial therapy".

The company said the reduction of the diabetic ulcer by one third in six weeks was "exceptional since this patient has had his right lower leg amputated and uses a right lower leg prosthesis [artificial leg] that prevents him from effectively unloading his left heel ulcer". Unloading and weight redistribution is usually essential for the healing of chronic wounds.

Tissue Therapies chief executive officer Dr Steven Mercer said that "in many ways the results from this patient are even more outstanding than the first patient where a 29 percent reduction was achieved in six weeks".

"Healing 32 percent of a chronic diabetic ulcer in six weeks would be an excellent result in any patient, but given the clinical complications this man suffers including an artificial right lower leg preventing unloading of his left heel ulcer, this really is an exceptional outcome," Dr Mercer said.

"I am also delighted to say that the first patient has continued to heal his chronic diabetic ulcer up to week 12 of the study despite being a diabetic with high blood pressure and continuing to smoke," Dr Mercer said.

A Perth, Western Australia, trial of the Vitrogro wound healing treatment has been completed in venous ulcer patients.

Tissue Therapies climbed 1.5 cents or 7.5 percent to 21.5 cents.

STIRLING PRODUCTS

Stirling Products says its natural product Immunoxel has "clinically demonstrated it can be effective when used to avoid infection from or treat most influenza strains" Stirling said this was "also expected to be the case with swine flu".

The company said a clinical trial conducted in the 2007-'08 influenz season in the Ukraine featured as a poster presentation 'Effect of immunomodulator Dzherelo (Immunoxel) in treatment of seasonal flu' at the World Congress on Vaccines Immunization and Immunotherapy in Milan in September, 2008.

Earlier this month Stirling said a 12-patient trial in Kiev "confirmed a complete cure" of the seven extensively drug-resistant tuberculosis (XDR-TB) patients supplemented with the botanical immunotherapy product, Immunoxel which demonstrated 100 percent effectiveness and reduced treatment duration to under four months in all patients as opposed to the general 18-24 months of treatment with standard drugs (BD: Apr 16, 2009).

Stirling managing director Peter Boonen told Biotech Daily at that time, his company was involved in the commercialization of Immunoxel and the intellectual property was owned by the Kiev-based Ekomed.

Immunoxel is one of 26 phyto-pharmaceutical or botanical products being commercialized under a Zodiac Capital licence and subject to shareholder approval, Stirling has agreed to a joint venture with Zodiac Capital.

Separately, Stirling said that pending shareholder approval it had raised \$1.8 million through the issue of 75 million shares and two sets of convertible notes. Stirling was unchanged at 3.2 cents with 25.1 million shares traded.

CATHRX

Cathrx says the John Hunter Hospital in Newcastle has joined its clinical trial of quadrapolar and decapolar diagnostic catheters.

Cathrx said the clinical trial would gather data for Australian Therapeutic Goods Administration approval of the catheters.

The company said the John Hunter Hospital was a leading teaching hospital and major cardiology and cardiac surgery centre.

Cathrx said the Australian approved trial began at Sydney's Westmead Hospital in November 2008.

Cathrx chief executive officer Neil Anderson said that the catheters had Conformitée Européenne (CE) mark approval and were on sale in Europe and the Australian trial was being conducted to enable Cathrx to file for Australian approvals.

The company said the protocol at the John Hunter Hospital called for use of Cathrx's diagnostic catheters undergoing electrophysiology procedures that require the use of diagnostic catheters.

There will be an equal number of Cathrx and control patients and the primary end-point is a confirmation of diagnostic capability.

Cathrx said last year that the trial protocol called for the use of its catheters in 30 patients with 30 control patients (BD: Nov 190, 2008).

The company said cardiac catheters were "minimally invasive tools widely used by specialist clinicians to diagnose and treat different types of cardiac arrhythmias". Cathrx was untraded at 68 cents.

PHYLOGICA

Anthony Barton & Associates has increased its substantial shareholding in Phylogica from 15,130,415 shares (9.2%) to 28,160,323 shares (15%) on April 29, 2009.

Phylogica fell 0.1 cents or 1.45 percent to 6.8 cents.

VIRALYTICS

Viralytics says its total operating and investing cash burn for the three months to March 31, 2009 was \$653,000 with cash at the end of the quarter of \$976,000.

Last week Viralytics announced a plan to raise \$3 million through the an option rights issue (BD Apr 22, 2009).

Viralytics was up 0.3 cents or 7.69 percent to 4.2 cents.

ACUVAX

Acuvax says its net operating cash flow for the three months to March 31, 2009 was \$255,000 with cash at the end of the guarter of \$231,000.

Acuvax said in its Appendix 4C quarterly report it had "an equity draw down facility of up to \$10 million with investment bank Fortrend Securities of Melbourne".

"Subsequent to quarter end Acuvax received payments of \$296,036 and \$56,062 from the Australian Taxation Office in relation to research and development activities," the company said.

Acuvax was untraded at 4.8 cents.

NANOSONICS

Nanosonics says 92,235,861 fully paid ordinary shares will be released from escrow on May 17, 2009.

Following the release from escrow Nanosonics will have a total of 195,470,047 shares on issue with no further shares remaining in escrow.

Nanosonics was unchanged at 32 cents.