Biotech Daily

Tuesday September 29, 2009

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: LIVING CELL UP 11%; SUNSHINE HEART DOWN 16%**

*** ACRUX PHASE III TESTOSTERONE SUCCESS; DEAL IN 2010**

*** SAFETY MEDICAL – THE DIRECTORS' CUT**

*** OPTISCAN PLEADS SCHULTZ TO ASX 89% JUMP QUERY; LOSS DOWN**

*** JP MORGAN BELOW 5% OF QRX PHARMA**

*** ALL CHANGE AT NORWOOD ABBEY FOR CHINA COAL CO**

MARKET REPORT

The Australian stock market climbed 1.62 percent on Tuesday September 29, 2009 with the S&P ASX 200 up 75.7 points to 4753.1 points.

Nineteen of the Biotech Daily Top 40 stocks were up, seven fell, eight traded unchanged and six were untraded. All three Big Caps were up.

Living Cell was best, up 2.5 cents or 11.1 percent to 25 cents with 644,229 shares traded.

Cathrx and Psivida climbed more than eight percent; Bionomics, Biota, Prana and Tyrian were up more than four percent; Cellestis and Labtech were up more than three percent; Alchemia, Benitec, Circadian, Genera, Pharmaxis, Resmed and Universal Biosensors rose more than two percent; Clinuvel and CSL were up more than one percent; with Acrux, Cochlear, Mesoblast and Starpharma up by less than one percent.

Sunshine Heart led the falls, down 0.9 cents or 16.4 percent to 4.6 cents with 3.1 million shares traded, followed by Optiscan down one cent or 7.7 percent to 12 cents.

Chemgenex, Impedimed and Sirtex lost more than three percent; with Nanosonics and Progen down two percent or more.

ACRUX

Acrux expects a licencing deal and US Food and Drug Administration approval for its Axiron testosterone therapy by the end of 2010.

At a media and analyst presentation in Melbourne to announce the results of the company's phase III trial of Axiron, Acrux chief executive officer Dr Richard Treagus said partnering talks had been held since the phase II trial results in 2007 (BD: Jul 16, 2007).

"The phase III clinical trial has exceeded all our expectations," Dr Treagus said.

He said that Axiron more than met FDA endpoints of more than 75 percent of the 155 male patients achieving normal testosterone levels at 120 days.

Dr Treagus said that after just 15 days of treatment 76 percent of patients had normal testosterone levels and at the 120 day mark 84 percent had average testosterone levels.

As well as efficacy, Dr Treagus said there were no serious adverse events with the measured dose under-arm application, but there were transient application site reactions.

Dr Treagus said 16 percent of patients did not respond to treatment.

He said compared to the competitor gels which were messy and took up to 10 minutes to dry on the torso, Acrux's Axiron applied to the armpit dried quickly and was more convenient to use.

Dr Treagus said that there was a distinctly lower likelihood of accidental testosterone transfer with his company's product than the existing treatments for hypogonadal men and said that it was unlikely that Axiron would have to carry a "black label" warning on the packet.

Dr Treagus said that most subjects in the trial responded to a standard 60mg per day dose of Axiron's 2.0 percent testosterone solution.

In an audio-visual demonstration the container was shown to squirt a 30mg dose into an applicator cup, which would then be used on each armpit to provide a 60mg daily dose.

Patients requiring a lower dose could apply the lotion to one armpit, while those requiring higher doses could increase the number of applications.

Dr Treagus said the Axiron container would hold a one month supply for $US260 ($297).

He said that 60mg per day was the optimum dose for three-quarters of the trial patients.

Dr Treagus said there was no likely environmental impact from either the increased testosterone in men using Axiron or any wastage being flushed through the sewerage system.

Dr Treagus said the market for supplemental testosterone was about $1 billion a year, dominated by North America and growing strongly.

Dr Treagus told Biotech Daily that he expected to complete a licencing deal within the next 12 months at the same time that Acrux was preparing its new drug application for the FDA.

He said that FDA approval would remove some risk from any potential deal, but a deal could be made prior to FDA approval.

He told the meeting that Acrux expected to file the new drug application this year and the FDA would take about 12 months to make its decision.

Dr Treagus said he expected a licencing deal to be completed in 2010 with revenue returning to the company in 2011.

He said Finland's Orion would manufacture the Axiron kit.

Dr Treagus said granted patents covered the technology until 2017 with pending patents covering the application of testosterone to the armpits until 2026.

Dr Treagus said two-thirds of surveyed patients preferred the Acrux application to the existing gels but "nine out of 10 physicians" preferred the treatment.

Acrux traded between $1.555 and $1.69 closing up one cent or 0.62 percent at $1.61 with 1.4 million shares traded.

OPTISCAN

Optiscan has told the ASX that it was not aware of any information it had not announced which, if known, could explain recent trading in its securities.

The ASX said the company's share price rose from 7.4 cents on September 22, 2009 to 14 cents, an 89.2 percent increase, on September 28 and noted an increase in volumes.

Optiscan said it reported on August 3, 2009 that trials of a new model confocal microscope would be conducted between August and November 2009, "but as the trial outcomes are unknown, the company does not believe this matter could be a factor in recent price movements, particularly in view of the fact that there was no perceptible price movement upon or after release of this information".

Optiscan said it expected its loss to be significantly lower than last year's $1.68 million.

Optiscan fell as low as 10 cents closing down one cent or 7.7 percent at 12 cents.

SAFETY MEDICAL

Safety Medical has reduced managing director John Riemelmoser's total salary package and director fees for chairman John Darley.

Safety Medical said its remuneration committee "reviewed directors' and executives' remuneration due to the changes in the group structure and the resultant commitment expectations".

Mr Riemelmoser's remuneration package will be reduced 13.3 percent from $299,750 to $260,000 per year and Mr Darley's directors fees will be reduced by 25 percent from $60,000 to $45,000 a year.

Safety Medical said the cuts should be seen "in light of the recent structural changes, including the sale of the Bagot Press business and the new global opportunity" relating to the $42.5 million Hungarian joint venture announced last week (BD: Sep 21, 2009).

Safety Medical fell 0.7 cents or 12.3 percent to five cents.

QRX PHARMA

JP Morgan Securities Australia has ceased its substantial holding in QRX Pharma further reducing its holding to less than five percent of the company.

Yesterday JP Morgan said it had reduced its holding to 4,279,359 shares (5.71%) from 6,222.599 shares (8.3%) it held on January 27, 2009.

QRX was unchanged at 80 cents.

NORWOOD ABBEY

Norwood Abbey has appointed two coal-oriented directors replacing two pharmaceutical industry directors.

Earlier this month Norwood Abbey said it would become a China-based coal trading company (BD: Sep 14, 2009).

Leo Peng Wei Le and Spencer Chan Kum Ee will replace Elizabeth Wyatt and Richard Zahn as directors.

Norwood Abbey is suspended and last traded at 0.6 cents.