



# Biotech Daily

Monday May 27, 2013

*Daily news on ASX-listed biotechnology companies*

**\* ASX, BIOTECH DOWN: BENITEC UP 14%, ANTISENSE DOWN 10%**

**\* ACRUX, ELI LILLY CHALLENGE ISRAEL'S PERRIGO ON AXIRON PATENTS**

**\* DATAPHARM: COMPLETE NSW TRIAL INSURANCE SURVEY**

## MARKET REPORT

The Australian stock market fell 0.47 percent on Monday May 27, 2013, with the S&P ASX 200 down 23.6 points to 4,959.9 points.

Twelve of the Biotech Daily Top 40 stocks were up, 14 fell, nine traded unchanged and five were untraded. All three Big Caps fell.

Benitec was the best, up 0.2 cents or 14.3 percent to 1.6 cents, with 1.7 million shares traded.

Tissue Therapies climbed 8.3 percent; Neuren was up seven percent; Ellex rose five percent; Living Cell was up 4.35 percent; Clinuvel and Psivida was up more three percent; Alchemia, Medical Developments and Reva rose more than two percent; Bionomics was up 1.4 percent; with Sirtex up 0.1 percent.

Antisense led the falls, down 0.1 cents or 10 percent to 0.9 cents with 1.2 million shares traded.

Cellmid and Phosphagenics lost more than seven percent; Nanosonics was down 6.1 percent; Phylogica and QRX fell more than four percent; Prima was down 3.9 percent; Acrux, Atcor, Cochlear, Mesoblast, Starpharma and Universal Biosensors shed two percent or more; Impedimed and Optiscan were down more than one percent; with CSL and Resmed down by less than one percent.

## ACRUX

Acrux says that with Eli Lilly Export SA it has taken legal action against Perrigo Israel Pharmaceuticals for infringement of three of the seven US patents that cover Axiron. Acrux said the issued patents relating to the testosterone replacement therapy were owned by Acrux DDS Pty Ltd, a wholly owned subsidiary of Acrux and were exclusively licensed to Lilly.

Acrux said the lawsuit was filed in the US District Court for the Southern District of Indiana in response to notice letters sent by Perrigo regarding its filing with the US Food and Drug Administration for an abbreviated new drug application for a testosterone metered dose transdermal product.

The company said that the Perrigo letters said that the abbreviated new drug application contained Paragraph IV certifications with respect to US Patent Numbers 8177449, 8419307 and 8435944, which were expected to expire in 2030, 2026 and 2027 respectively, relating to the application of testosterone formulations to the underarm and to the applicator used to apply Axiron.

Acrux said that a Paragraph IV certification alleges invalidity, unenforceability and/or non-infringement of a patent.

The company said that the application "does not contain Paragraph IV certifications with respect to the four other issued patents that cover Axiron, which expire in 2017".

Acrux said that it and Eli Lilly were committed to asserting their intellectual property rights for Axiron.

Acrux said it expected that the conduct of the lawsuit would not have a material impact on its operating expenditure.

Acrux chief financial officer Jon Pilcher told Biotech Daily that Eli Lilly would fund all legal fees for the defence.

Acrux fell nine cents or 2.4 percent to \$3.72 with 577,542 shares traded.

## DATAPHARM AUSTRALIA, NEW SOUTH WALES GOVERNMENT

Datapharm project manager Luke Edington has called on the biotechnology sector to complete a survey of clinical trial costs, before it closes on Friday.

Earlier this month, Mr Edington said that the New South Wales committee of Ausbiotech was concerned about the doubling of the minimum requirement for clinical trials indemnity insurance from \$10 million to \$20 million and a consequent increase in premiums and clinical trial costs in that state (BD: May 13, 2013).

Mr Edington told Biotech Daily that he had been involved in the industry attempt to convince the New South Wales Government to reverse its decision and the survey would assist that aim.

Ausbiotech has said that it was working with the Pharmaceuticals Industry Strategy Group and the Clinical Trials Action Group to support a national policy on clinical trials.

Mr Edington said that the New South Wales Government required evidence that the increase in the insurance coverage was having an impact on companies and trial and urged biotechnology and related companies to complete the survey at:

<http://www.researchreceptor.com/quick-survey-help-reduce-the-nsw-clinical-trial-indemnity-insurance-minimum-requirement>.

The survey closes on May 31, 2013.

Datapharm is a private company.

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