



# Biotech Daily

Thursday July 31, 2014

*Daily news on ASX-listed biotechnology companies*

- \* **ASX UP, BIOTECH DOWN: CIRCADIAN UP 11%, ANTEO DOWN 15%**
- \* **US SAFE STATUS FOR CALZADA'S TROUBLESOME AOD9604**
- \* **BIOTECH DAILY APPENDIX 4C QUARTERLY REPORTS POLICY**
- \* **UNILIFE HAS ONE QUARTER CASH**
- \* **GENERA HAS ALMOST TWO QUARTERS CASH - SALES, MERGER**
- \* **GENETIC TECHNOLOGIES HAS ONE QUARTER CASH, 'TRANSACTIONS'**

## MARKET REPORT

The Australian stock market was up 0.18 percent on Thursday July 31, 2014 with the S&P ASX 200 up 10.0 points to 5,632.9 points.

Seven of the Biotech Daily Top 40 stocks were up, 18 fell, 10 traded unchanged and five were untraded. All three Big Caps were up.

Circadian was the best, up two cents or 11.4 percent to 19.5 cents with 56,150 shares traded.

Atcor and GI Dynamics climbed more than six percent; Acrux and Pharmaxis were up more than four percent; Patrys was up 3.6 percent; with Cochlear, CSL, Mesoblast and Resmed up by less than one percent.

Anteo led the falls, down 2.5 cents or 14.7 percent to 14.5 cents with 20.4 million shares traded.

Analytica lost 5.3 percent; Avita, Ellex and Neuren fell four percent or more; Antisense, Benitec, Bionomics, Cellmid and Living Cell were down more than three percent; Prima and Universal Biosensors shed more than two percent; Medical Developments, Nanosonics, Starpharma and Tissue Therapies were down more than one percent; with Alchemia and Sirtex down by less than one percent.

## CALZADA

Calzada says it has been granted generally recognized as safe (Gras) status for its AOD9604 peptide in the US, which it hopes to licence or spin-out.

The approval was provided by the private company Gras Associates under the US Food Drug and Cosmetics Act.

A 536-patient trial of AOD9604 for obesity in 2007 failed to meet its primary endpoint and since then the peptide has been reported to have been pirated in China to be used by body-builders as well as being at the centre of a controversy for the Melbourne-based Essendon Football Club as a non-approved fitness supplement (BD: Feb 21, 2007).

The co-inventor of AOD9604 Dr Woei-Jia Jiang has pleaded guilty to obtaining money by deception for his role in defrauding \$4.6 million from Phosphagenics (BD: Jun 11, 2014).

Today, Calzada said that AOD9604 received conditional Gras status in 2012, pending publication of safety related data in peer-reviewed scientific journals.

The company said that the published articles were 'Safety and Tolerability of the Hexadecapeptide AOD9604 in Humans' published in the Journal of Endocrinology & Metabolism in April 2013 and 'Safety and Metabolism of AOD9604, a Novel Nutraceutical [food additive] Ingredient for Improved Metabolic Health' also published in the Journal of Endocrinology & Metabolism published in June 2014.

Calzada said that Gras status allowed AOD9604 to be sold as a nutrient supplement in conventional and functional foods, drinks and dietary supplements in the US at the daily level of up to 1mg per person.

The company said that it was exempt for these designated food uses from further pre-market approval requirements of food and drink ingredients in the US.

Calzada said that its wholly-owned subsidiary Metabolic Pharmaceuticals had non-exclusive licences with two Australian compounding pharmacies for the use, manufacture and sale of AOD9604 in compounded medicine preparations that comply with Australian regulatory requirements.

The company said that revenue from the licences was "small, but assert the company's propriety rights".

Calzada chairman David Williams said that "Gras status for AOD9604 might make Metabolic's [intellectual property] an attractive target for supplement, ingredient and [food additive] companies" such as Abbott, GSK Consumer Health, DSM Nutritional Products, Nestle, Proctor & Gamble, Mead Johnson Nutritionals, Ceapro, Bactolac Pharmaceuticals, Natrol, Red Bull, Pepsico, Valensa International and Kerry Ingredients.

Calzada said it was reviewing its future commitment to Metabolic and was considering the alternatives, including licence, trade sale or as a separate listed entity, to best extract value from the AOD9604 peptide.

Calzada was unchanged at 12 cents.

## BIOTECH DAILY APPENDIX 4C REPORTS

Biotech Daily reports all major announcements to the ASX, but biotechnology companies bleeding money is not news, unless the company has less than two quarters cash.

When companies clearly explain that they have draw-down facilities or loans or are about to have a capital raising, Biotech Daily will not report their Appendix 4C statement.

Where there is no explanation or it is not clear and the company has less than six months of cash reserves, it will be reported, with companies reporting after the close of business reported in the following edition.

**David Langsam**  
**Editor**

### UNILIFE

Unilife says its net operating cash burn for the three months to June 30, 2014 was \$US20,009,000 (\$A21,478,380) with cash at the end of the quarter of \$US10,838,000. Unilife said it had access to an “at the market” facility of \$US12.8 million and had increased expenditure ahead of an expected increase in cash receipts and revenue in 2014-'15.

The company said it expected to have revenue of up to \$US15 million for the 12 months to June 30, 2014, but in its consolidated statement of cash flows recorded receipts from customers of \$US23,738,000, of which \$US1,142,000 was received in the three months to June 30, 2014.

Unilife was up 2.5 cents or 5.3 percent to 49.5 cents.

### GENERA BIOSYSTEMS

Genera says its net operating cash burn for the three months to June 30, 2014 was \$358,000 with cash at the end of the quarter of \$592,000.

Genera said it was expecting further increased sales and the completion of its proposed merger in the immediate future.

In June, Genera said it intended to merge with a larger molecular diagnostics business with “a highly compatible platform technology” (BD: Jun 30, 2014).

Genera was unchanged at 29.5 cents.

### GENETIC TECHNOLOGIES

Genetic Technologies says its net operating cash burn for the three months to June 30, 2014 was \$2,579,323, with cash at the end of the quarter of \$2,831,085.

Genetic Technologies chief financial officer Eutillio Buccilli told Biotech Daily that the company “is currently considering a number of pending transactions”.

Genetic Technologies was unchanged at 3.3 cents.