



# Biotech Daily

Wednesday December 19, 2012

*Daily news on ASX-listed biotechnology companies*

- \* **ASX, BIOTECH UP: COMPUMEDICS UP 24%, ALLIED HEALTH DOWN 5%**
- \* **CLINUVEL CLAIMS SCENESSE PHASE II VITILIGO SUCCESS**
- \* **PRANA COMPLETES PHASE IIa PBT2 HUNTINGTON'S RECRUITMENT**
- \* **HUNTER HALL TAKES MORE PROFIT FROM SIRTEX**
- \* **ALLAN GRAY TAKES 5% OF ACRUX**
- \* **UBS AG TAKES 5% OF ACRUX**
- \* **ACUVAX REQUESTS ACQUISITION TRADING HALT**
- \* **CALAMA TAKES 7% OF TYRIAN**

## MARKET REPORT

The Australian stock market was up 0.49 percent on Wednesday December 19, 2012 with the S&P ASX 200 up 22.6 points to 4,617.8 points.

Fourteen of the Biotech Daily Top 40 stocks were up, eight fell, 11 traded unchanged and seven were untraded. All three Big Caps were up.

Compumedics was the best, up 1.3 cents or 23.6 percent to 6.8 cents with 15,000 shares traded, followed by Viralytics up 14.3 percent to 36 cents with 301,746 shares traded.

Antisense climbed 8.3 percent to 1.3 cents with 8.4 million shares traded; Clinuvel was up 6.7 percent; Psivida and Starpharma were up more than five percent; Universal Biosensors was up 4.4 percent; Acrux, Pharmaxis and Prana rose more than two percent; Heartware, Genetic Technologies and Impedimed were up more than one percent; with Cochlear, CSL, Resmed and Sirtex up by less than one percent.

Allied Health led the falls, down 0.1 cents or 4.55 percent to 2.1 cents with 4.6 million shares traded, followed by Phylogica down four percent to 2.4 cents with 154,905 shares traded.

Circadian, Living Cell, Mesoblast, Nanosonics and QRX shed two percent or more; with Living Cell and Tissue Therapies down more than one percent.

## CLINUVEL PHARMACEUTICALS

Clinuvel says its US phase IIa trial of Scenesse with narrowband ultra-violet B light significantly improves repigmentation in vitiligo patients compared to monotherapy. Clinuvel said that Scenesse (afamelanotide 16mg implant) with narrowband ultra-violet B light was compared to narrowband ultra-violet B light alone and significantly improved repigmentation.

The company said that time to first repigmentation was not significant although there was a trend towards Scenesse treatment ( $p=0.086$ ) and there were no significant safety issues reported.

Clinuvel said that patients with darker skin types responded best to the Scenesse combination treatment.

The company said that vitiligo was a common skin disorder, affecting about 45 million people, in which pigment producing cells, melanocytes, appear to become dysfunctional and as a result, lighter depigmented patches of skin appear in different parts of the body due the loss of melanin.

The company said that vitiligo therapy was primarily intended to arrest depigmentation and to stimulate repigmentation of affected skin as a secondary action, but there was no known cure for vitiligo.

Clinuvel said the standard of care was treatment with narrowband ultra-violet B light therapy given in two to three sessions a week over the course of 12 to 18 months.

The company said that the response rate to narrowband ultra-violet B light (NB-UVB) was low and repigmentation was incomplete, with combination therapies often employed in an attempt to enhance repigmentation.

Clinuvel said the 54-patient open-label phase IIa study was conducted in three US centres and the primary endpoint was to compare the efficacy of Scenesse with NB-UVB in comparison to NB-UVB as a monotherapy.

The company said that the speed of repigmentation after drug administration and depth of repigmentation was evaluated, with a secondary endpoint of safety.

Clinuvel said patients were randomly assigned to two groups with the active group receiving one month of NB-UVB monotherapy, followed by monthly doses of Scenesse and combination NB-UVB for four months, then a final month of NB-UVB monotherapy, compared to the control group receiving NB-UVB monotherapy for six months.

The company said that 41 patients (75.9%) completed the treatment, with 13 withdrawing "due to their inability to comply with the demanding treatment protocol, or, in the case of five patients, due to the intensity of pigmentation experienced" and that overall the combined treatment was well tolerated with no serious drug-related adverse events.

The company said the primary endpoint of the extent of repigmentation between Day 0 and Day 168 showed that the extent of repigmentation in the Scenesse and NB-UVB group was significantly greater than observed in the NB-UVB alone group.

Clinuvel said that significantly better, more complete and deeper repigmentation was observed for those patients with the darkest skin complexion, who had received the combination therapy compared to those on monotherapy ( $p = 0.046$ ).

Clinuvel said that stability of the treatments would be evaluated at six months after treatment.

New York Mount Sinai Hospital chair of dermatology Prof Mark Lebwohl said that until now "all treatments had taken many years to achieve repigmentation in vitiligo and patients had great difficulty complying with the rigors of light treatment regimes".

"We finally have a treatment that allows us to repigment patients much more quickly," Prof Lebwohl said.

Clinuvel was up 12.5 cents or 6.7 percent to \$1.98.

### PRANA BIOTECHNOLOGY

Prana says it has completed recruitment of the 100 patients in its phase IIa trial of PBT2 for Huntington's disease.

Prana said the six-month double-blind, placebo-controlled trial of patients with early to mid-stage Huntington's disease met the enrolment target ahead of schedule and additional patients might be included, subject to final procedures this week.

The study's principal investigator, Johns Hopkins University Medical Center's Dr Ray Dorsey said that "interest in PBT2 is high in part because PBT2 offers a novel mechanistic approach to the treatment of [Huntington's disease]".

Prana was up half a cent or 2.4 percent to 21 cents.

### SIRTEX MEDICAL

Long term investor, Hunter Hall Investment Management has again reduced its substantial holding in Sirtex from 14,407,180 shares (25.83%) to 13,824,180 shares (24.79%).

Hunter Hall said that it sold the 583,000 shares between November 20 and December 14, 2012, for prices ranging from \$11.78 to \$11.97 a share.

In November, Hunter Hall sold 572,000 shares with the single largest sale 86,157 shares for \$874,934 or \$10.16 a share (BD: Nov 21, 2012).

In August, Hunter Hall also took profit on Sirtex shares, reducing its holding by 558,704 shares or one percent (BD: Aug 7, 2012).

Sirtex was up two cents or 0.2 percent to \$12.76 with 142,948 shares traded.

### ACRUX

Allan Gray Australia (formerly Orbis Investment Management) has returned to a substantial holding in Acrux with 8,419,845 shares or 5.06 percent.

Allan Gray director Simon Marais told Biotech Daily that the shares taking Allan Gray above the five percent substantial shareholder mark were acquired for about \$2.70 each.

In May, Allan Gray Australia reduced its substantial holding in Acrux from 10,059,941 shares (6.04%) to 8,088,453 shares (4.86%) selling 1,971,488 shares for \$8,181,675 or an average price of \$4.15 a share (BD: May 15, 2012).

Allan Gray had been reducing its holding and taking profit in Acrux since November 2010, when it sold 2,652,890 shares of its 29,731,141 share holding at an average price of \$3.06 a share (BD: Nov 4, 2010).

Prior to November 2010, Orbis last acquired 2,247,369 Acrux shares between July 18, 2008 and October 27, 2010 for \$2,037,837 or an average price of 90.7 cents a share.

Acrux was up six cents or 2.2 percent to \$2.79 with 571,550 shares traded.

### ACRUX

UBS AG and related bodies corporate have become a substantial shareholder in Acrux with 8,816,211 shares or 5.30 percent.

The Hong Kong-filed notice said that most of the shares were described as held with the "power to control disposal over shares pursuant to stock borrowing and lending activities".

In a 55-page filing, UBS said it borrowed, returned, bought and sold shares in trades as small as single shares for prices ranging from \$4.00 on August 15, to \$2.805 on December 14, 2012.

Acrux has been reported as one of the most heavily 'short-sold' stocks in the Australian biotechnology sector.

### ACUVAX

Acuvax has requested a trading halt “pending an announcement concerning an acquisition and the resultant company’s capital structure”.

Trading will resume on December 21, 2012 or on an earlier announcement.

Acuvax was untraded at 0.1 cents.

### TYRIAN DIAGNOSTICS

Calama Holdings acting for the Mambat Super Fund has increased its substantial shareholder in Tyrian from 58,153,834 shares (5.8%) to 72,389,206 shares (7.08%).

The substantial shareholder notice said the 14,235,352 shares were acquired \$15,235 or 0.1 cents a share.

The notice signed by Calama director David Whiting said that the holding was associated with David and Susan Whiting.

Tyrian was untraded at 0.1 cents.