



Biotech Daily

Thursday March 14, 2013

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH DOWN: CIRCADIAN UP 12%, ELLEX DOWN 9%**
- * **MONASH HOPES FOR 1st-IN-HUMAN BIONIC EYE IN 2014**
- * **MESOBLAST COMPLETES \$170m PLACEMENT**
- * **TISSUE THERAPIES REGULATORY TRADING HALT**
- * **FDA SETS AUGUST PDUFA DATE FOR QRX MOXDUO**
- * **CONSEGNA PLEADS SCHULTZ TO ASX 200% QUERY**
- * **SUNSHINE HEART APPOINTS JON SALVESON DIRECTOR**

MARKET REPORT

The Australian stock market fell 1.18 percent on Thursday March 14, 2013 with the S&P ASX 200 down 60.2 points to 5,032.2 points.

Nine of the Biotech Daily Top 40 stocks were up, 15 fell, 11 traded unchanged and five were untraded. All three Big Caps fell.

Circadian was the best, up three cents or 11.5 percent to 29 cents, with 10,000 shares traded.

Benitec climbed more than eight percent; Allied Health was up 7.1 percent; Medical Developments rose six percent; Avita was up four percent; Viralytics was up 3.6 percent; Heartware and Starpharma were up more than one percent; with Clinuvel up 0.4 percent.

Ellex led the falls, down two cents or 9.1 percent to 20 cents with 17,500 shares traded.

QRX lost eight percent; Patrys fell 7.1 percent; both Cellmid and GI Dynamics were down 6.7 percent; Atcor, Prana and Psivida fell more than four percent; Anteo and Phosphagenics were down more than three percent; Mesoblast shed 2.6 percent; Alchemia, Pharmaxis and Resmed were down more than one percent; with Acrux, Cochlear, CSL and Sirtex down by less than one percent.

MONASH UNIVERSITY, MONASH VISION GROUP

Monash University's Vision Group hopes to complete pre-clinical trials of its bionic eye this year with a first-in-human trial beginning in 2014.

The chairman of the Group's advisory board Prof David de Kretser told a Monash Vision Group Business Breakfast that the project was a collaboration with Alfred Hospital, Grey Innovation and Minifab and was driven with industry.

Prof de Kretser said that camera signals would be sent to a processor and then to electrodes on tiles implanted in the occipital lobe of the brain.

Grey director Jefferson Harcourt told the meeting that the architecture was being designed but the lead proposal was a camera stem worn over the ear connecting to an implant at the back of the head, controlled with a pocket sized processor and software system.

Mr Harcourt said that if the Cochlear hearing implant was radio, "then we are television, albeit black and white".

Mr Harcourt said the wearer would be able to use the controller to click through algorithms selecting image type from facial expressions to spatial landscape and supporting brightness and light levels as well as a zoom function.

Monash University's head of the Department of Surgery and Clinical Sciences Prof Jeffrey Rosenfeld said that work in rats had demonstrated the electrodes could activate specific neurons and sheep were being testing for bio-compatibility ensuring the equipment was not toxic to neurons as well as testing the surgery required to implant the tiles.

Prof Rosenfeld said that so far haemorrhaging had been "minimal".

He said that testing on Macaque monkeys was about to begin, which would indicate what the animals could see with the system.

Prof Rosenfeld said that the monkeys could be rewarded for responding to light flashes, which would indicate whether the system was providing an image.

Prof Rosenfeld said that the challenges ahead included surgical techniques, developing an insertion tool and training neurosurgeons, along with reducing risks to patients including infection control, preventing haemorrhages, tile dislodgement and seizures.

Prof Rosenfeld said that the existing Second Sight retinal device cost about EUR100,000 (\$A125,000) and he guessed that the bionic eye would be "in the same ballpark".

Prof Rosenfeld said there were 50,000 blind Australians and many millions of blind people world-wide.

He said that about 80 percent of people in the developed world could benefit from the Monash bionic eye device and about 15 percent could benefit from a retinal device.

Prof Rosenfeld said glaucoma, diabetic retinopathy trauma and tumors were not suitable indications for the retinal device but these patients could benefit from the Monash device, while neither device was suitable for congenital blindness.

Prof Rosenfeld said that engineering challenges included hermeticity and peri-electrode gliosis and once the device was fitted, the patient would require perception and device training.

"We don't know if the brain will construct images the way we want to," Prof Rosenfeld said. "We won't know until we do it."

"The holy grail is facial recognition. People want to see family members," he said.

He said the Group was not promising facial recognition in the first patient in 2014, but "a small amount of vision can have a huge impact".

Prof Rosenfeld said that the initial patients would be aged in their thirties to fifties, had been blind for less than five years and were physically and mentally fit.

He said the US Food and Drug Administration would require evidence on seven to 10 people and the Group required funding for a further three years, having expended most of the \$8 million Australian Research Council grant and other funding.

MESOBLAST

Mesoblast says it has raised \$170 million in its private placement at \$6.30 a share and has cash reserves of about \$332 million (BD: Mar 6, 2013).

Mesoblast said that 26,970,979 shares were issued under the placement at \$6.30 a share. Mesoblast fell 16 cents or 2.6 percent to \$6.02 with 417,091 shares traded.

TISSUE THERAPIES

Tissue Therapies has requested a trading halt "pending an announcement regarding regulatory approvals".

Trading will resume on March 18, 2013 or on an earlier announcement.

Tissue Therapies last traded at 24.5 cents.

QRX PHARMA

QRX says the US Food and Drug Administration has set August 26, 2013 as the Prescription Drug User Fee Act date for its resubmitted Moxduo new drug application. Last year, the FDA's complete response letter rejected the QRX application for the dual opioid pain relief drug Moxduo IR, requiring further data (BD: June 27, 2012).

In February, the company resubmitted the new drug application (BD: Feb 28, 2013).

QRX chief executive officer Dr John Holaday said the company was "pleased that the FDA has formally accepted our resubmitted Moxduo NDA".

"We expect the advisory committee meeting to be scheduled between late June and late July," Dr Holaday said.

QRX fell 10 cents or eight percent to \$1.15.

CONSEGNA GROUP

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

The ASX said the company's share price rose 200 percent from 0.4 cents on March 6, to 1.2 cents on March 14, 2013, and noted an increase in trading volume.

Consegna closed up 0.4 percent or 80 percent to 0.9 cents with 52.4 million shares traded.

SUNSHINE HEART

Sunshine Heart says that Jon Salveson has been appointed as a director.

Sunshine Heart said that Mr Salveson was Piper Jaffray's vice-chairman of investment banking and chairman of the healthcare investment banking group and was a director of device company Cryolife.

Sunshine Heart chairman John Erb said that Mr Salveson had corporate transaction and financing experience.

The company said that Mr Salveson joined Piper Jaffray in 1993 and was elected managing director in 1999.

Sunshine Heart fell 0.1 cents or 3.2 percent to three cents.