



# Biotech Daily

Tuesday February 25, 2014

*Daily news on ASX-listed biotechnology companies*

- \* **ASX DOWN, BIOTECH UP: BENITEC UP 21%, PHARMAXIS DOWN 4%**
- \* **SIRTEX FIRST-LINE TRIALS ON-TRACK**
- \* **AFT LAUNCHES MAXIGESIC DUAL O-T-C ANALGESIC**
- \* **BRAIN H1 REVENUE DOWN 24% TO \$1.4m, LOSS DOWN 30% TO \$812k**
- \* **ANTEO H1 REVENUE UP 39% TO \$1.8m, LOSS DOWN 16% TO \$620k**
- \* **BIOXYNE COMPLETES \$1.56m HUNTER SALE TO MARIPOSA**

## MARKET REPORT

The Australian stock market fell 0.12 percent on Tuesday February 25, 2014 with the S&P ASX 200 down 6.4 points to 5,433.8 points.

Sixteen of the Biotech Daily Top 40 stocks were up, 10 fell, 12 traded unchanged and two were untraded.

Benitec was the best for the second day in a row, up 39 cents or 21.1 percent to \$2.24 with 3.4 million shares traded, followed by Uscom up 18.4 percent to 22.5 cents with 158,559 shares traded and Circadian up 14.3 percent to 20 cents with 13,200 shares traded.

Antisense and Prana climbed more than six percent; Neuren was up 5.3 percent; Living Cell was up 4.9 percent; Anteo, Genetic Technologies and Viralytics were up three percent or more; Clinuvel, Patrys and Starpharma rose more than two percent; Mesoblast and Nanosonics were up more than one percent; with Alchemia and CSL up by less than one percent.

Pharmaxis led the falls, down 0.5 cents or 4.35 percent to 11 cents, with 592,356 shares traded.

Oncosil, Optiscan and QRX lost more than three percent; both Admedus and Universal Biosensors shed 2.9 percent; GI Dynamics, Psivida, Resmed and Reva were down more than one percent; with Cochlear and Sirtex down by less than one percent.

## SIRTEX MEDICAL

Sirtex is expecting definitive results in two major trials of its SIR-Spheres that investigators say could change treatment options for liver and colorectal cancer.

At an investor briefing in Melbourne, the lead investigator of the Sirflox study and Royal Melbourne Hospital medical oncologist Prof Peter Gibbs said that all 532 patients had been enrolled and treatment completed in the trial of SIR-Spheres secondary liver cancer from metastatic colorectal cancer, with final results expected in mid-2015.

The Sirflox study compares a combination of Oxaliplatin, Leucovorin and 5- Fluorouracil (Folfox) against Oxaliplatin, Leucovorin and 5- Fluorouracil with the administration of Sirtex Yttrium-active microspheres (BD: Apr 12, 2013).

Prof Gibbs said that the primary endpoint was progression free survival and an improvement of three months or more would warrant first-line use of SIR-Spheres.

Prof Gibbs said that secondary endpoints included overall survival, tumor response rate, quality of life and surgical resection rate.

Prof Gibbs said that oncologists were inherently conservative in their decision-making and would not take on the extra load of arranging and supervising the insertion of SIR-Spheres in patients without evidence from large randomized controlled trials.

Prof Gibbs said that if the Sirflox trial demonstrated three or four months of additional progression free survival the use of SIR-Spheres as a first line therapy would be "be very seriously hard to ignore".

He said that previous small trials had shown progression free survival, with a trial of 70 patients showing a mean increase 6.2 months for SIR-spheres with chemotherapy compared to chemotherapy alone, a 21-patient trial with a mean increase of 16.6 months for SIR-spheres with chemotherapy compared to chemotherapy alone and a 44-patient trial with a mean increase of 3.4 months for SIR-spheres with chemotherapy compared to chemotherapy alone.

Interventional radiologist at the Paris, France-based Hôpital Beaujon Prof Valérie Vilgrain said as lead investigator of the 400-patient Sarah trial she was comparing SIR-Spheres "head to head" with sorafenib for primary hepatocellular carcinoma or liver cancer.

Prof Vilgrain said that a trial in 2008 established Bayer's sorafenib as the standard-of-care with 299 patients on sorafenib reaching a mean overall survival of 10.7 months compared to 303 patients on placebo achieving overall survival of 7.9 months.

Prof Vilgrain said that an Asia-Pacific trial found treatment with sorafenib resulted in 6.2 months overall survival and controls had 4.1 months overall survival, but sorafenib had a large number of adverse effects.

Prof Vilgrain said that in parallel to her Sarah trial, an Asia-Pacific trial led by the Singapore-based Prof Pierce Chow was enrolling 360 patients and with similar protocols there would be a meta-analysis of the combined raw data.

She said the Sarah trial's primary endpoint was overall survival with secondary endpoints including safety, time to disease progression, quality of life and healthcare costs.

Prof Vilgrain said the trial had recruited 300 patients so far and she expected to complete the trial by the end of 2015, with results in 2016.

Prof Vilgrain said that there were 780,000 new cases of hepatocellular carcinoma diagnosed each year and 746,000 deaths per year.

Prof Vilgrain said that it was the third highest cause of mortality from cancer globally and increasing in incidence, with 90 percent developing on top of liver cirrhosis, often caused by alcohol or hepatitis B or C or a combination of the viruses and alcohol.

Sirtex fell two cents or 0.1 percent to \$15.14 with 264,283 shares traded.

### AFT PHARMACEUTICALS

AFT has launched its paracetamol and ibuprofen combination drug Maxigesic in Australia claiming it provides “32 percent more pain relief” than its component drugs.

A spokesperson for AFT said the company received Australian Therapeutic Goods Administration approval for Maxigesic on December 23, 2013.

A media release from AFT said that the Maxigesic combination of 500mg acetaminophen (paracetamol) and 150mg ibuprofen provided 32.3 percent lower pain scores than 500mg paracetamol alone and 35.8 percent lower pain scores than 150mg ibuprofen alone.

A study of 122 evaluable adults over the age of 16 years, funded by AFT, measured post-operative pain relief after removal of one to four wisdom teeth.

The study, entitled “Combined acetaminophen and ibuprofen for pain relief after oral surgery in adults: a randomized controlled trial” was published in the British Journal of Anaesthesia and is available at: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2791549>.

The study concluded that “Maxigesic tablets provide superior pain relief after oral surgery to acetaminophen or ibuprofen alone”.

AFT said its founder and managing director Dr Hartley Atkinson was the inventor and developer of Maxigesic, which was developed “while trying to find a more effective alternative to combination painkiller products”.

“Combination products traditionally use paracetamol or ibuprofen as the basic active ingredient then add codeine to amplify the effect,” Dr Atkinson said. “However, codeine is an opiate and there is growing concern over its potential for misuse.”

AFT said that Maxigesic would be available over-the-counter from Australian pharmacies in packs of 10, 16 and 30 tablets, but had been sold in New Zealand pharmacies since 2009, where it recently reached the milestone of 10 million tablets sold.

The company said that it had out-licenced the Maxigesic intellectual property to more than 40 countries and was “well-positioned to tap into the \$US4.1 billion global over-the-counter global painkiller market”.

AFT is a private company.

### BRAIN RESOURCE

Brain Resource says revenue for the six months to December 31, 2013 fell 24 percent to \$1,399,000 with net loss after tax reduced 30 percent to \$812,000.

Brain supplies cognitive testing and training tools to corporations and is involved in trials assessing biomarkers for depression and other conditions.

The company said its net tangible assets per share was up 5.5 percent to 18.4 cents and diluted loss per share fell 38.5 percent to 0.8 cents.

Brain said it had cash and cash equivalents of \$3,266,418 at December 31, 2013 compared to \$3,784,665 at June 30, 2013.

Brain fell 2.5 cents or 9.1 percent to 25 cents

### ANTEO DIAGNOSTICS

Anteo says revenue for the six months to December 31, 2013 was up 39 percent to \$1,848,872 with net loss after tax reduced 16 percent to \$620,457.

The company said its net tangible assets per share was up 0.01 cents from 0.00 cents at June 30, 2013 to 0.01 cents and diluted loss per share was unchanged at 0.1 cents.

Anteo said it had cash assets of \$7,475,786 at December 31, 2013 compared to \$2,621,072 at June 30, 2013.

Anteo was up half a cent or 3.1 percent to 16.5 cents with 7.2 million shares traded.

## BIOXYNE

Bioxyne says it has completed the sale of subsidiary Hunter Immunology to Mariposa Health founded by former chief executive officer Dr Phillip Comans (BD: Dec 2, 2013). Last year, Bioxyne said that Mariposa would pay \$175,000 in cash, assume a debt of \$60,000 and Bioxyne would acquire equity in Mariposa to the notional value of not less than \$325,000 at a deemed price of 16.5 cents a share, equivalent to five percent of Mariposa.

Bioxyne said at that time that Mariposa would provide deferred consideration of \$1 million on commercialization of HI-164OV for chronic obstructive pulmonary disease (COPD) pending clinical and financial milestones over five years, and on commercialization pay an ongoing royalty from 2.0 to 6.5 percent of gross revenue.

In 2012, a 320-patient phase II trial of HI-164OV for chronic obstructive pulmonary disease failed to meet its primary endpoints, triggering a board spill and management changes (BD: Jun 28, 2012).

Today, the company said that the total consideration of \$1.56 million in cash and equity had been completed.

Bioxyne said that with the divestment of the HI-164OV program, it would continue with its sales and distribution of probiotics products and research and development of its Intellectual Property in *Staphylococcus aureus* and *candida*.

The company said it was continuing with its acquisition strategy of advanced stage research projects to broaden the operational base of the Company.

Bioxyne chairman Tony Ho said that "as a substantial shareholder of [Mariposa], we will be working with Dr Phillip Comans and his team to support their endeavors to successfully commercialize HI-164OV".

Bioxyne said that Mariposa held a number of COPD related research and development programs and the acquisition of HI-164OV would complement its portfolio of COPD research programs.

Bioxyne was untraded at one cent.