



# Biotech Daily

Wednesday July 13, 2016

*Daily news on ASX-listed biotechnology companies*

- \* **ASX, BIOTECH UP: UNIVERSAL BIOSENSORS UP 15%  
- CELLMID, OSPREY DOWN 3%**
- \* **US, NZ PATENTS FOR ANTISENSE ATL1103 FOR ACROMEGALY**
- \* **RACE OPENS UP 42.5%**
- \* **RACE CEO PETER MOLLOY TAKES 7.6%, CHAIR DR BILL GARNER 28.5%**
- \* **RECCE ADDS VIRUSES TO BACTERIA, CANCER FOR RECCE-327**
- \* **UK OKAYS AVIRAGEN BTA585 RSV TRIAL, US CLINICAL HOLD**
- \* **SIMAVITA APPOINTS NATHAN BARTROP JOINT CO SEC**
- \* **MGC APPOINTS PROF URI KRAMER CONSULTANT, AUSTRALIAN TRIALS**

## MARKET REPORT

The Australian stock market was up 0.66 percent on Wednesday July 13, 2016 with the ASX200 up 35.3 points to 5,388.5 points.

Twenty-one of the Biotech Daily Top 40 stocks were up, eight fell, 10 traded unchanged and one was untraded.

Universal Biosensors was the best, up four cents or 14.8 percent to 31 cents with 108,000 shares traded, followed by Uscom up 12.2 percent to 27.5 cents with 186,876 shares traded.

Prana climbed five percent; Factor and Psivida were up more than four percent; Atcor, Biotron, Ellex and Oncosil were up more than three percent; Acrux, Anteo, Clinuvel, Nanosonics and Starpharma rose more than two percent; Actinogen, Bionomics, Opthea, Orthocell and Pharmaxis were up more than one percent; with Impedimed, Mesoblast and Resmed up by less than one percent.

Cellmid and Osprey led the falls, down 3.2 percent to three cents and 30 cents, respectively, with 934,000 shares and 150,349 shares traded, respectively.

Admedus, Living Cell and Neuren all lost three percent; Benitec shed two percent; CSL fell 1.2 percent; with Cochlear, Sirtex and Viralytics down by less than one percent.

## ANTISENSE THERAPEUTICS

Antisense says it has been granted separate US and New Zealand patents relating to ATL1103 for acromegaly.

Antisense said the US patent entitled 'Modulation of Growth Hormone Receptor Expression and insulin like growth factor expression' provided intellectual property coverage to December 2024.

The company said that the patent covered ATL1103 and other modified oligonucleotides, 12 to 35 nucleobases in length, that targeted the growth hormone receptor and all useful antisense oligonucleotide therapeutics to the growth hormone receptor capable of reducing serum levels of growth hormone binding protein, the extracellular portion of growth hormone receptor found in the blood.

Antisense said that the patent was generated as a block to other antisense approaches including small interfering RNA (siRNA) and locked nucleic acid (LNA) drugs to growth hormone receptor where their effect was to reduce growth hormone receptor and growth hormone binding protein expression.

The company said that the New Zealand patent was entitled 'Combination Therapy comprising a growth hormone variant and an oligonucleotide targeted to the growth hormone receptor' and provided coverage until February 2033.

Antisense said that the New Zealand patent covered ATL1103 and other oligonucleotides to the growth hormone receptor for use in combination with the growth hormone antagonist pegvisomant, which was marketed by Pfizer as Somavert, to prevent or treat disease associated with increased levels of serum levels of insulin-like growth factor-I (sIGF-I) such as acromegaly.

The company said that the patent was based on the synergistic effect observed in animal studies with the use of ATL1103 in combination with pegvisomant.

Antisense said that the New Zealand patent was the first of the related patent family applications covering the potential use of ATL1103 in combination with pegvisomant for enhanced efficacy in patients who do not have their sIGF-I normalized with monotherapies.

The company said that its phase II trial of ATL1103 in adult patients with acromegaly showed a decrease in growth hormone binding protein coinciding with a significant reduction in serum levels of sIGF-I.

Antisense said that the patents strengthened its intellectual property protecting ATL1103 and other antisense compounds as either monotherapy or use in combination for acromegaly and other sIGF-I related diseases.

Antisense was unchanged at 3.5 cents.

## RACE ONCOLOGY

Race Oncology opened at 27 cents at 12.12pm today, climbing to 28.5 cents in early trading, a 42.5 percent premium above its initial public offer price of 20 cents a share.

Earlier this week, Race said it raised \$4.3 million in an oversubscribed initial public offer at 20 cents a share to reinstate and commercialize Bisantrene for cancer.

Race chief executive officer Peter Molloy told Biotech Daily that Bisantrene was a phase II/III drug previously trialled in 44 clinical studies and more than 2,000 patients, which did not have the cardiac toxicities of other anthracycline drugs used as chemotherapy agents for cancer (BD: Aug 27, 2015; Jul 11, 2016).

Race closed up 6.5 cents or 32.5 percent at 26.5 cents with 2.5 million shares traded.

## RACE ONCOLOGY

Race chief executive officer Peter Molloy has become substantial in his company with 4,000,000 shares or 7.59 percent.

Mr Molloy said the shares were acquired at 20 cents each “under a share and loan offer”.

Race chairman Dr William Garner has become substantial in his company with 15,000,000 shares or 28.47 percent.

Dr Garner said the shares were issued “as consideration for acquisition of intellectual property”.

## RECCE

Recce says that its Recce-327 antibiotic shows in-vitro anti-viral activity against influenza viruses in monkey and dog cell lines.

Recce said that the tests were conducted by an unnamed independent US contract research organization.

The company said that Recce-327 was sequentially doubled to assess its activity against influenza A virus strain TX/36/91 or H1N1 influenza in Vero monkey cells:

Recce said that Recce-327 might be used to target viruses located external to cells, which were common when the invading virus was located between a parent cell and a new host-cell, thus preventing the virus from spreading.

The company said that there was a direct, linear relationship between the concentration of Recce-327 and inhibition of the virus

Recce said that inhibition or kill rate was anti-viral and not due to toxicity, which was demonstrated as dose-dependent inhibition of the influenza virus outside the range of any toxicity to the monkey cells.

The company said that Recce-327 was trialled in **Madin-Darby canine kidney** (MDCK) dog cells and the dose sequentially doubled, to assess the compound's activity against influenza A virus strain TX/36/91 or H1N1 influenza.

Recce said that Recce-327 might be used to target viruses in cells, the common location of invading viruses, preventing the virus from spreading

The company said that at low concentrations of 0.003125 percent, Recce-327 inhibited or killed 42 percent of the virus, even when ‘hidden’ within the cell, with a direct, linear relationship between concentration and inhibition of the virus.

Recce said that a 0.1 percent concentration showed 62 percent of the virus had been inhibited or killed, which was within the therapeutic dosing window

The company said that a trend towards 100 percent inhibition or kill rate was observed and if the test was continued, it might achieve the same result when the virus was hidden within a cell.

Recce said that the compound “did not exhibit any toxicity to the MDCK dog cells”.

The company said that it had lodged a patent application to include the data with the aim of securing the potentially significant opportunity.

Recce said it would continue the assessment of anti-viral capabilities with in-vivo testing and if successful, it would “take the opportunity of drawing the [US Food and Drug Administration] attention to this, as well as Recce's additional capabilities against cancers and/or bacteria – a very rare total capability”.

Recce executive chairman Dr Graham Melrose said the data was “an early, but very encouraging development”.

“Recce-327 may be the first drug in history to be purposefully targeted against bacteria, viruses and cancer,” Dr Melrose said.

Recce was up 4.5 cents or 19.6 percent to 27.5 cents.

### AVIRAGEN THERAPEUTICS (FORMERLY BIOTA PHARMACEUTICALS)

Aviragen says it has resumed enrolment in its phase IIa study of oral BTA585 for the treatment and prevention of respiratory syncytial virus infections.

In May, Aviragen said it had voluntarily decided to delay further enrolment in the UK phase IIa trial of the Melbourne-developed BTA585 for respiratory syncytial virus infections following a laboratory report from one subject showing an increase of a cardiac enzyme level coupled with transient electro-cardiogram (ECG) changes, which led to a hospitalization of less than 24 hours (BD: May 27, 2015)

Aviragen said at that time that the subject's ECGs were normal prior to hospitalization, the cardiac enzyme levels returned to baseline shortly thereafter and following a safety report the US Food and Drug Administration the investigational new drug application for BTA585 had been placed on clinical hold for US studies.

The company said there were no BTA585 trials being conducted under the application.

In April, the then Biota began its phase IIa challenge study of oral BTA585 for the treatment and prevention of respiratory syncytial virus infections (BD: Apr 12, 2016).

Aviragen chief executive officer Dr Joseph Patti said the company had been given approval by the UK Medicines and Healthcare Products Regulatory Agency to continue the study "based on our submission of all requested information and documentation and the subsequent review by the UK regulatory authority".

Dr Patti said he expected to complete the trial by the end of 2016.

Aviragen said it had received confirmation from the FDA of the clinical hold and expected to submit a complete response by March 2017.

On the Nasdaq last night, Aviragen was unchanged at \$US1.43 (\$A1.88 equivalent to 23.5 cents before departing the ASX) with 36,639 shares traded.

### MGC (MEDICAL GRADE CANNABIS) PHARMACEUTICALS

MGC says it has appointed Prof Uri Kramer as a consultant and member of its strategic advisory board.

MGC said Prof Kramer was the Tel Aviv, Israel-based Sourasky Medical Centre director of paediatric epilepsy and had led research on medical cannabis treatments for epilepsy.

The company said it had "commenced the process of stakeholder engagement, focusing on the benefits of medical cannabis for the treatment of severe epilepsy in children".

MGC said the process followed "the Victorian Government's recent approval of the use of medical cannabis for children with severe epilepsy, and the New South Wales Government pushing towards its own clinical trials".

"The two-stage engagement process with key stakeholders, including Federal and State governments, will lay the foundations for potential formal collaboration agreements and the commencement of Australian clinical trials," MGC said.

In April, Victoria Premier Daniel Andrews said a medicinal marijuana cultivation trial had begun and the State would supply paediatric epileptic patients directly (BD: Apr 20, 2016).

On April 15, 2016, the Federal Deputy Prime Minister and Agriculture Minister Barnaby Joyce visited a possible trial site farm near Tamworth, New South Wales and said Australian farmers had the expertise to be "at the forefront of this industry".

"I believe that it would be an absolute travesty ... if we find out that the fruits of our labor are only to be recognised in the importation of a product from another country ... so the beneficiary of this are farmers somewhere else," Mr Joyce said.

MGC said that "a key focus of the company's strategy [was] to undertake clinical trials in Australia and Europe, with the appropriate governmental support".

MGC was up 0.2 cents or 4.3 percent to 4.9 cents with 6.6 million shares traded.

## SIMAVITA

Simavita says that Nathan Bartrop has been appointed joint company secretary, working with joint company secretary Peta Jurd.

Simavita said that Mr Bartrop was a lawyer and chartered company secretary employed by the Sydney-based Company Matters Pty Ltd.

The company said that Mr Bartrop had experience with ASX-listed, dual-listed and unlisted entities and had been involved in several ASX listings and was formerly an ASX listings compliance adviser in Sydney and Perth.

Mr Bartrop holds a Bachelor of Laws from the University of Western Australia.

Simavita was up half a cent or 7.5 percent to 7.2 cents.