

# **Biotech Daily**

# Tuesday September 22, 2009

# Daily news on ASX-listed biotechnology companies

\* ASX DOWN, BIOTECH EVEN: BENITEC UP 20%; USCOM DOWN 14%

- \* INFECTION RISKS INCREASE NANOSONICS DISINFECTION DEMAND
- \* NANOSONICS PLEADS OLD NEWS TO ASX 22% PRICE QUERY
- \* MESOBLAST ENROLLS SECOND HEART FAILURE STEM CELL ARM
- \* \$14.5m HEART RESEARCH FACILITY FOR SYDNEY'S NEWTOWN
- \* VIRALYTICS COMPLETES 2<sup>nd</sup> PHASE I MELANOMA TRIAL TREATMENT
- \* STARPHARMA VIVAGEL PATENT PROTECTS TO 2024
- \* NEUREN PLEADS SCHULTZ TO ASX 46% PRICE JUMP QUERY

## MARKET REPORT

The Australian stock market fell 0.29 percent on Tuesday September 22, 2009 with the S&P ASX 200 down 13.7 points to 4653.7 points.

Fifteen of the Biotech Daily Top 40 stocks were up, 16 fell, seven traded unchanged and two were untraded.

Benitec was best, up 0.9 cents or 19.6 percent to 5.5 cents with 1.85 million shares traded, followed by Viralytics up 11.1 percent to three cents with 4.5 million shares traded.

Clinuvel and Psivida climbed more than eight percent; Alchemia, Antisense, Phosphagenics, Starpharma and Tissue Therapies were up four percent or more; Genetic Technologies rose two percent; Acrux, Bionomics, Novogen and Sirtex were up more than one percent; with Chemgenex, Cochlear and Resmed up by less than one percent.

Uscom led the falls, down 11 cents or 13.75 percent to 69 cents with 22,000 shares traded, followed by Nanosonics down 9.1 percent to 50 cents.

Cytopia lost 8.3 percent; Mesoblast fell 5.4 percent; Tyrian and Universal Biosensors fell more than four percent; Genera and Labtech were down more than three percent; Prana shed 2.4 percent; Biota, Cellestis, Pharmaxis, Progen and Sunshine Heart were down more than one percent; with Circadian, CSL and Peplin down by less than one percent.

#### **NANOSONICS**

Nanosonics says its disinfection systems are an alternative solution for the rising number of secondary infections acquired in healthcare institutions.

In a media release issued on September 18, 2009 Nanosonics said nosocomial infections, also known as hospital acquired infections, "are becoming a big issue for health authorities internationally".

The company said hospital acquired infections were often caused by environmental organisms and have been linked to contaminated healthcare equipment.

In May, Nanosonics submitted its 510(k) application to the US Food and Drug Administration for the Trophon EPR and its Nanonebulant consumable (BD: May 13,

2009) designed for the disinfection of ultrasound transducers.

Nanosonics chief executive officer David Radford said "the evidence was mounting daily about cross infection problems and this is going to mean more people turning to Nanosonics technology".

"Recent studies in Australia have identified that healthcare-acquired infections created an economic burden of close to \$1 billion a year and accounted for approximately five percent of all admissions," Mr Radford said.

"Recently a couple of hundred patients in a NSW regional hospital had to be tested for serious infection after uses of medical testing equipment that should have been thrown away after a single use," Mr Radford said.

"The cost of this, in terms of dollars and people's health, is too great and communities everywhere are entitled to want better standards of disinfection," he said.

A Hunter New England Health media release on September 17, 2009 said that 218 patients at the Inverell Hospital in northern New South Wales were believed to have been exposed to an infection control breach over seven-months.

A Hunter New England Health spokeswoman told Biotech Daily that syringe drivers had been used to deliver anaesthetic to successive colonoscopy and gastroscopy patients on surgery lists, but there was "a low risk of possible cross-infection" as it was unlikely blood would return though the tubing to the driver. The drivers were replaced at the end of each surgery list, the spokeswoman said.

Hunter New England Health said it would review Inverell's overall compliance with infection control policies and procedures within the entire hospital and expected the investigation would be completed by mid-November 2009.

"Any recommendations from the investigation or the subsequent review will be included as part of an action plan, which will be implemented as a high priority," the authority said. Nanosonics said that one of the issues with sophisticated medical instruments, such as ultrasound probes and endoscopes, was that they couldn't be sterilized in autoclaves, due to the heat sensitive nature of electronics and materials.

Nanosonics said alternative disinfection methods included alcohol wipes, soap and water, or toxic chemical solutions which create occupational health and safety issues

The company said its solution for ultrasound probes, based around nebulized particles of non-toxic hydrogen peroxide, was "generating strong commercial interest in Australia and globally", because it was able to kill the most resilient micro-organisms such as Methicillin resistant staphylococcus aureus (MRSA), Vancomycin resistant enterococci (VRE) and Clostridium difficile.

Nanosonics said future applications of its disinfection technology were for hard surface decontamination projects such as hospital wards or pandemic control as well as continued development of the Trophon EPR concept for use with other medical devices.

The company said it hoped to have FDA approval to market the Trophon EPR in 2010. Nanosonics fell five cents or 9.1 percent to 50 cents.

#### **NANOSONICS**

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

The ASX said the company's share price rose from 45 cents on September 18, 2009 to 55 cents, a 22.2 percent increase, on September 21, but did not note an increase in trading volume.

Nanosonics referred to its annual report issued on August 21, 2009 and presentation slides posted to the ASX on August 24, 2009 and said both referred to the commercialization of its disinfection technology and "on-going discussions with prospective business partners".

Nanosonics did not refer to the September 21, 2009 media release highlighting the opportunities for the company following the Inverell Hospital infection scare (see above).

#### MESOBLAST

Mesoblast has completed enrolment of the second group of 20 patients to receive an increased dose of its adult stem cell product Revascor for congestive heart failure. Mesoblast said the trial of the allogeneic, or off-the-shelf, adult stem cells was being run by its US sister company Angioblast Systems and will randomize up to 60 patients suffering from congestive heart failure to three groups receiving either a progressively increasing dose of the company's allogeneic adult stem cells or standard of care. The company said that the treated patients in the second group received a dose of Revascor three times higher than in the first group.

Mesoblast said no cell or procedure-related adverse events occurred in any of the 40 patients enrolled to date.

The company said interim and final efficacy results would be reported when all patients met the three and six-month endpoints.

Mesoblast said that meeting clinical trial enrolment milestones on schedule was "an important objective of Mesoblast's equity-based investment in Angioblast".

As a result of Angioblast's successful patient enrolment to date, in accordance with the terms of the Series B investment Mesoblast's equity holding in Angioblast has now converted into 38.4 percent common shares, Mesoblast said.

Mesoblast said that at Angioblast's next financing it might maintain or increase its shareholding.

Mesoblast fell six cents or 5.4 percent to \$1.06.

## NEW SOUTH WALES HEART RESEARCH INSTITUTE

New South Wales Minister for Science and Medical Research Jodi McKay has opened a \$14.5 million Heart Research Institute facility in Sydney's Newtown.

"The new facility will support research efforts into the prevention of atherosclerosis, thickening of the arteries," Ms McKay said in a New South Wales Government media release.

"Researchers will explore new techniques that will hopefully help lead to better detection and treatment of the condition," Ms McKay said.

The media release said the Heart Research Institute was established in 1989 through NSW and Federal Government support.

Ms McKay said her Government had committed \$4.5 million towards the facility with the Federal Government providing \$10 million.

#### **VIRALYTICS**

Viralytics says the last patient has been treated in its second phase I melanoma trial and a fully-integrated trial report is being prepared.

Viralytics managing director Bryan Dulhunty said the phase I trials using the company's Cavatak common cold virus were expected to show the treatment was well tolerated and there was sufficient biological activity for the company to proceed to phase II trials.

"Viralytics will now progress with a US investigational new drug application," he said. Mr Dulhunty said a clinical trial under the US Food and Drug Administration "adds significantly greater value to future licencing partners than a trial undertaken below this regulatory standard".

Viralytics said the move to phase II trials coincided "with growing international recognition of oncolytic virotherapy as a valid cancer treatment".

The company said a US oncolytic virus company working with another virus would begin two phase III intra-tumoral trials, one for melanoma and one for head and neck cancer. While this company is using a genetically altered herpes virus that is different to Cavatak, Mr Dulhunty said the success so far was further validation for the practice of oncolytic virotherapy.

Viralytics said oncolytic virotherapy, for the first time, was not only being recognized as a novel and interesting anti-cancer therapy, but had yielded anti-cancer activity on par or better than existing cancer treatment methods.

Viralytics said the potential of oncolytic virotherapy as a well tolerated treatment, with minimal side effects, compared to those observed in conventional chemotherapy, for a wide range of cancers may soon be realized.

Viralytics said its natural, non-genetically-altered common cold virus might possess some potentially superior biological attributes compared to other viruses being used by competitors in trials.

"It is interesting to note that Viralytics' two most advanced intra-tumoral clinical trials are also in late stage melanoma and head and neck cancer," Mr Dulhunty said.

Viralytics was up 0.3 cents or 11.1 percent to three cents with 4.5 million shares traded.

#### **STARPHARMA**

Starpharma says it has been granted a key US patent relating to the use of SPL7013 to protect against sexually transmitted infections.

Starpharma said the granting of the patent meant that any product presentation of SPL7013, the active ingredient in Vivagel, was protected in the US for an additional five years until 2024, with a possible further 12 month extension to 2025.

The company said that given the importance of genital herpes and other sexually transmitted infections in the US, this market was "clearly a major commercial opportunity for Vivagel products".

Starpharma said the composition of matter patent was the third US patent for Vivagel and added to the patent coverage for the product in 26 countries covering all major markets. The company said Vivagel was being developed as a condom coating in collaboration with SSL International, the world's leading condom company, which markets Durex and has about 40 percent of the global branded condom market.

Following a deal announced in 2008, SSL has exclusive marketing rights for the Vivagel coated condom (BD: Sep 9, 2008).

Starpharma said it was also developing Vivagel as a vaginal microbicide to prevent the transmission of sexually transmitted infections, including HIV and genital herpes. Starpharma was up two cents or 4.4 percent to 47 cents.

#### **NEUREN**

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

The ASX said the company's share price rose from 2.8 cents on September 18, 2009 to 4.3 cents, a 53.6 percent increase, on September 21 and noted an increase in trading volume.

Neuren fell half a cent or 13.2 percent to 3.3 cents with 1.75 million shares traded.