



# Biotech Daily

Friday May 20, 2016

*Daily news on ASX-listed biotechnology companies*

- \* **ASX, BIOTECH UP: ONCOSIL UP 11%, ATCOR DOWN 6%**
- \* **GREENS SCIENCE, RESEARCH, INNOVATION POLICY- 4% OF GDP**
- \* **OSPREY DYEVERT TRIAL SHOWS 47% CARDIAC DYE REDUCTION**
- \* **MGC 'OVERSUBSCRIBED PRIORITY OFFER' RAISES \$2.5m, TOTAL \$7.5m**
- \* **RHINOMED SHARE PLAN RAISES \$167k, TOTAL \$4.7m**
- \* **ANALYTICA: 'CASE STUDIES BACK PERICOACH PELVIC FLOOR SYSTEM'**
- \* **MESOBLAST RECEIVES \$6m FEDERAL R&D TAX REFUND**
- \* **TGA QUESTIONS GI DYNAMICS ENDOBARRIER COMPLIANCE**
- \* **MEDLAB PLEADS SCHULTZ TO ASX 50% QUERY**
- \* **INVITROCUE APPOINTS SCIENTIFIC ADVISORY BOARD**

## MARKET REPORT

The Australian stock market was up 0.53 percent on Friday May 20, 2016 with the ASX200 up 28.0 points to 5,351.3 points.

Twenty of the Biotech Daily Top 40 stocks were up, 12 fell, seven traded unchanged and one was untraded.

Oncosil was best, up 1.5 cents or 11.1 percent to 15 cents with 806,149 shares traded.

Antisense climbed seven percent; Genetic Technologies was up 5.3 percent; Polynovo improved four percent; Compumedics and Pro Medicus were up more than three percent; Ellex, Mesoblast and Starpharma rose more than two percent; Impedimed, Living Cell, Neuren, Opthea, Prana, Sirtex, Universal Biosensors and Viralytics were up one percent or more; with Clinuvel, Cochlear, Medical Developments and Psivida up by less than one percent.

Atcor led the falls, down one cent or 6.25 percent to 15 cents, with 305,103 shares traded. Admedus lost 5.8 percent; Benitec and Cellmid fell more than four percent; Bionomics was down 3.2 percent; Actinogen, Factor Therapeutics, Nanosonics, Orthocell and Reva shed more than two percent; Airxpanders and Biotron were down more than one percent; with CSL down by 0.3 percent.

## THE AUSTRALIAN GREENS

The Greens have launched their Federal Election science, research and innovation policy promising to increase spending on the sector to four percent of GDP by 2030.

The Greens said they would support commercialization through the Medical Research Future Fund and reverse the 1.5 percent cut to the R&D Tax Incentive, which was “yet to be legislated, but the Government has booked the saving in the Budget”.

Greens leader Senator Richard Di Natale and science and industry spokesperson Adam Bandt said the policy would make Australia “a world leader in investment in research and development”.

A media release from the Greens said that Australia currently spent 2.2 percent of gross domestic product (GDP) on science research and innovation and the Party would seek to lift that to 3.0 percent by 2025 and 4.0 percent by 2030.

The Greens said that the \$5 billion plan was costed by the Parliamentary Budget Office and would increase funding to the Commonwealth Scientific and Industrial Research Organisation to end job cuts, boost funding for the Australian Research Council, National Health and Medical Research Council, co-operative research centres and universities, would restore tax breaks for business research and development and would establish a new innovation fund with investments from the Future Fund.

“‘Innovation’ isn’t just a buzzword Malcolm Turnbull can use to sell his corporate tax cuts, it underpins Australia’s future prosperity,” Senator Di Natale said.

“The Greens’ research investment plan will help build a smarter, healthier, more prosperous Australia,” Senator Di Natale said.

“It will invest in building skills, research infrastructure and incentives for business to participate,” Senator Di Natale said.

“We will increase funding, improve access to information, foster national and international collaboration, protect our key research institutions and deliver the research and innovation Australia needs to remain competitive,” Senator Di Natale said.

“The industries and jobs of the 21st century will rely on our minds, not our mines,” Mr Bandt said. “The government’s ideological obsessions are harming science and research by ignoring the importance of both pure research and public good science.”

“The recent cuts to CSIRO have highlighted this problem and show the government doesn’t get it,” Mr Bandt said.

“We will fund and protect the CSIRO and our key research institutions,” Mr Bandt said.

“The Greens will invest in science & research and foster a culture where experimentation, invention and innovation can flourish in Australia,” Mr Bandt said.

“Our \$5 billion plan will make Australia one of the top investors in the world in research and development,” Mr Bandt said.

The Greens media release said that the plan included a ‘Protecting Science’ package, consisting of a \$847.9 million boost to the Australia Research Council, National Health and Medical Research Council, Cooperative Research Centres, restoring \$306.5 million to the CSIRO to prevent job cuts, \$201.2 million for indirect costs associated with research, steps towards default five-year grants from the ARC and NHMRC, reverse Government cuts to the Sustainable Research Excellence program and boost university research, costing \$1,306 million, a \$422.6 million investment in “critical infrastructure via Innovation and Science Australia”, a \$43.4 million investment in strategic opportunities for international collaboration, an additional \$297.2 million for the Future Fellowships scheme to attract and retain top research talents, \$197.7 million for open access publishing of Government-funded research, support for women in science costing \$213.7 million and \$171.9 million to support collaborative health research centres to translate research discoveries into clinical practice.

### OSPREY MEDICAL

Osprey says its 44-patient Dyevert pilot trial shows the contrast dye reduction system reduces dye for cardiac procedures by 47.4 percent with no loss of image quality. Osprey said that data from the prospective, non-randomized, single-arm trial, presented at the European Association of Percutaneous Cardiovascular Intervention's conference in Paris on May 19, 2016, showed a 50.3 percent reduction in percutaneous coronary intervention, or stenting, procedures and a 46.6 percent reduction in diagnostic procedures (BD: Oct 12, 2015).

The company said that the trial was conducted at the Lübeck, Germany-based Heart Centre and at Melbourne's Monash Medical Centre with Monash's Dr James Sapontis as the principal investigator and the Heart Centre's Prof Steffen Desch presenting the trial results.

Osprey said that the study found that Dyevert's dye savings benefit did not affect image quality and physicians reported that even though Dyevert reduced the amount of contrast dye dose delivered to the patient by nearly half in the study, fluoroscopic X-ray visualization was maintained throughout the procedures.

The company said that there were no device related adverse events reported in the trial, and physicians using Dyevert reported that the system was easy-to-use.

"The results of this trial are very promising for patients suffering from poor kidney function," Prof Desch said.

"We now have an easy-to-use, self-adjusting, next generation device that significantly reduces the amount of contrast volume delivered to the patient without compromising image quality," Prof Desch said.

"This allows us to protect the kidneys of those patients that are at highest risk of further damage," Prof Desch said.

Osprey chief executive officer Mike McCormick said that the Dyevert system had both Conformité Européenne (CE) mark and US Food and Drug Administration clearance.

"The product is currently in US commercialization where we are initially focusing on the southern states which have the highest incidence of chronic kidney disease," Mr McCormick said. "We look forward to using these results to accelerate our commercialization efforts."

Osprey was untraded at 25 cents.

### MGC (MEDICAL GRADE CANNABIS) PHARMACEUTICALS

MGC says its "priority offer" has closed early "due to being heavily over-subscribed", raising \$2,500,000 at 4.4 cents a share

MGC said that investors would receive one free attaching option for every three shares issued, exercisable at 6.5 cents by June 30, 2019, pending shareholder approval.

Earlier this month, MGC said it had raised \$5 million in an over-subscribed placement at the same price (BD: May 4, 2016).

MGC was up 0.8 cents or 18.2 percent to 5.2 cents with 25.3 million shares traded.

### RHINOMED

Rhinomed says its share plan at 2.4 cents a share has raised \$167,000, taking the total raised to \$4.682 million (BD: Mar 31, 2016).

Rhinomed said the funds would be used for working capital and to support the launch of its Mute snoring and sleep technology in the US and activities in the UK and Europe.

Rhinomed was unchanged at 2.2 cents with 2.3 million shares traded.

## ANALYTICA

Analytica says that two case studies have been published documenting benefit from its Pericoach intra-vaginal pelvic floor training system.

Analytica said that the two articles were published in the journal Urologic Nursing a publication by the US Society of Urologic Nurses and Associates.

The company said that in both cases studies, Pericoach was demonstrated to be easy-to-use, affordable and an effective non-surgical home training option for strengthening pelvic floor muscles and decreasing symptoms of urinary incontinence and pelvic organ prolapse.

The article co-authored by University of Missouri Healthcare nurse practitioner Julie Starr entitled 'Pelvic Floor Biofeedback via a Smart Phone App for Treatment Of Stress Urinary Incontinence' documented the experience of an athletic 37-year-old woman seeking treatment for symptoms of stress urinary incontinence.

Ms Starr said the patient's main complaint was "wetting my pants while running" and she was also bothered by leaking urine several times a day when talking, coughing, laughing, sneezing, lifting, and other forms of exercise.

Ms Starr's article said that the symptoms started after the birth of her first child about five years previously and the patients was "particularly frustrated because she felt she could improve with ... [pelvic floor] exercises, but she had difficulty remembering to perform them every day".

"Study results demonstrated that with use of the Pericoach, she was able to remember to perform [pelvic floor muscle] exercises twice a day and her symptoms markedly improved," the article reported.

"At her eight-week follow-up, she reported significant improvement in her [stress urinary incontinence] symptoms," the report said.

"She was able to complete her daily cardio workout and chores on the farm without leaking urine," the article said.

"She did report a rare occurrence of [urinary incontinence] when sneezing or coughing with a full bladder, but was otherwise dry," the article reported.

"She was very satisfied with her outcome," the report said.

The second article by physiotherapist Beth Shelly, entitled 'Pelvic Muscle Exercises Using A Home Trainer for Pelvic Muscle Dysfunction: A Case Report' described the experience of a 66-year-old woman with pelvic organ prolapse and urinary incontinence, "who initiated pelvic muscle exercises with the assistance of a novel, at-home trainer equipped with a vaginal sensor and accompanying smartphone app software, the Pericoach system".

Ms Shelly said that after eight weeks of training with the device, she showed "improvements in strength, endurance, and disability, as measured by manual muscle test, electromyography, and pelvic floor disability index scores".

"Older women can use biofeedback technology to improve pelvic floor muscle function successfully at home," Ms Shelly said.

Analytica chief executive officer Geoff Daly said that the publication of the case studies was "a great endorsement for Pericoach and is our greatest differentiator to other players in the incontinence market".

"It demonstrates that we are on the right path with our strategy in becoming the trusted solution for incontinence for clinicians and women," Mr Daly said.

Analytica said that Pericoach had regulatory clearance in Australia, had both Conformité Européenne (CE) mark and US Food and Drug Administration 510(k) clearance and was available for sale in Australia, New Zealand, the UK, Ireland and in the US by prescription. Analytica was untraded at 0.6 cents.

## MESOBLAST

Mesoblast says it has received \$6,161,879 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Mesoblast said the rebate related to research and development expenditure for the year to June 30, 2015 and it expected to receive further reimbursement of funds for ongoing research and development activities in the year to June 30, 2016.

Mesoblast was up five cents or 2.7 percent to \$1.90 with 877,687 shares traded.

## GI DYNAMICS

GI Dynamics says "there is a material risk of action by the Australian Therapeutic Goods Administration" relating to compliance for its Endobarrier therapy.

GI Dynamics did not specify the nature of the compliance issue for the Endobarrier, which was the subject of a major trial halt following a higher than expected number of liver abscesses, or bacterial infections (BD: Mar 5, Jul 30, 2015).

Data from the closed trial for obesity and type 2 diabetes showed that the Endobarrier failed to meet its primary safety and efficacy endpoints (BD: Mar 15, 2016).

In 2014, Europe stopped Endobarrier shipments pending a review of vigilance and reporting systems, allowing a restart later that year (BD: Oct 6, Dec 1, 2014).

Today, GI Dynamics said that the Endobarrier was listed on the Australian Register of Therapeutic Goods enabling sales in Australia in 2011.

The company said that it had been in communication with the TGA regarding compliance since January 2015.

"While the conclusion of these communications is not foregone, a material risk exists that the TGA may take action in regard to Endobarrier in the near future," GI Dynamics said.

The company said that the TGA had "raised a number of specific questions and has required that the company provide sufficient evidence to demonstrate compliance with the essential principles under the Act".

GI Dynamics said that the essential principles set out certain requirements that must be met with respect to a medical device in order for it to be supplied in Australia and the TGA gave the company until June 9, 2016 to submit its response addressing the TGA's concerns.

The company said that if the TGA was not satisfied with the response, it could suspend Endobarrier from the ARTG.

GI Dynamics said that suspension did not constitute cancellation.

The company said that it was preparing its response.

GI Dynamics chief executive officer Scott Schorer said the company "was focused on addressing the TGA's concerns as quickly and effectively as possible".

GI Dynamics fell 0.1 cents or 5.9 percent to 1.6 cents.

## MEDLAB CLINICAL

Medlab 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 50.0 percent from 2.6 cents on May 17, 2016 to 3.9 cents on May 19, 2016, and noted an increase in the trading volume.

Medlab requested a trading halt until May 24, 2016 but did not cite the reason for the halt.

Medlab last traded down 2.5 cents or 6.4 percent to 36.5 cents.

## INVITROCUE

Invitrocue says it has appointed the scientific and medical advisory board for its in-vitro cell-based assays, patient-derived organoids, digital pathology and medical imaging. Invitrocue said the board would comprise the Singapore-based Astar Experimental Therapeutics Centre and D3 chief executive officer Prof Alex Matter, the University of North Carolina's Prof Joseph King-Tak, the London School of Hygiene and Tropical Medicine's Prof Simon Croft, the UK's Leeds University Teaching Hospitals consultant vascular surgeon Prof Shervanthi Homer-Vanniasinkam, and National University of Singapore's Prof Soo Yong Tan.

Invitrocue listed on the ASX in February to develop and commercialize a range of diagnostics including the growth of cancer cells to test chemotherapy drugs, as well as a test for malaria (BD: May 13, 2016).

According to Commsec, Invitrocue traded unchanged at 10 cents with two shares traded.