



Biotech Daily

Wednesday March 29, 2023

Daily news on ASX-listed biotechnology companies

- * **ASX UP, BIOTECH DOWN: UNIVERSAL BIOSENSORS UP 6%;
- IMPEDIMED DOWN 16%**
- * **\$15b RECONSTRUCTION FUND CORP BILL APPROVED – ROYAL ASSENT**
- * **MICROBA MAP315 COLITIS TRIAL APPROVED**
- * **LTR TRIALS NASAL SPRAY SPONTAN FOR ERECTILE DYSFUNCTION**
- * **TELIX DIRECTOR DR ANDREAS KLUGE TAKES 6 MONTHS LEAVE**
- * **ORTHOCELL APPOINTS PROF DY, PROF BROGAN ADVISERS**

MARKET REPORT

The Australian stock market was up 0.23 percent on Wednesday March 29, 2023, with the ASX200 up 16.2 points to 7,050.3 points.

Eleven of the Biotech Daily Top 40 stocks were up, 13 fell, 13 traded unchanged and three were untraded. All three Big Caps fell.

Universal Biosensors was the best, up 1.5 cents or six percent to 26.5 cents, with 33,208 shares traded.

Cynata climbed 5.7 percent; both Alcidion and Orthocell improved 4.2 percent; Nova Eye was up 3.6 percent; Emvision and Proteomics rose more than two percent; Genetic Signatures, Mesoblast and Paradigm were up more than one percent; with Nanosonics up by 0.6 percent.

Monday's 111.9 percent best, Impedimed, led today's falls, down two cents or 16.0 percent to 10.5 cents (78.0 percent above the Friday close at 5.9 cents), with 20.8 million shares traded.

Medical Developments lost 6.25 percent; Dimerix, Polynovo and Prescient fell four percent or more; Starpharma was down 3.1 percent; Avita and Opthea shed more than two percent; Clinuvel, Next Science, Resmed and Telix were down more than one percent; with Cochlear, CSL, Neuren and Pro Medicus down by less than one percent.

FEDERAL GOVERNMENT

The Federal Government National Reconstruction Fund (NRF) Corporation Bill 2023 has passed both Houses of Parliament and is awaiting Royal Assent.

The Greens said that they won amendments in the Senate specifically excluding the direct funding of coal and gas projects.

A spokesperson for the Minister for Industry Ed Husic told Biotech Daily that the fund was never intended for those projects but rather Australian innovation and value adding. Australia Prime Minister Anthony Albanese told the House of Representatives that the \$15 billion National Reconstruction Fund was “one of the biggest ever investments in our nation’s manufacturing capability.”

“Throughout the election campaign I made it very clear that I wanted to see a future made in Australia. I want manufacturing jobs in Australia. I want value-adding here in Australia,” Mr Albanese said.

Mr Albanese said that the lesson from the Covid pandemic was that Australia “must do better” than sending raw materials off-shore to be repurchased from other countries as finished goods.

“While we are at the end of global supply chains our economy is vulnerable,” Mr Albanese said.

The Minister for Industry Ed Husic acknowledged that the Senate amendments included prohibitions on investment in coal and gas, as well as the inclusion of secure jobs, the impact of investments on First Nations people, a reduction of board terms from five years to four years and the first review of the Act by December 31, 2026.

Australian Greens leader Adam Bandt told the Parliament that the Greens supported manufacturing but needed to ensure that future Governments did not use the fund for inappropriate purposes.

Mr Bandt cited attempts by the previous Government to use the Clean Energy Fund for fossil fuel projects.

Mr Bandt said that the Greens wanted the Bill to go further and include the public ownership of manufacturing for the public good and noted the absence of a tax-payer owned vaccine manufacturer in the on-going Covid pandemic.

Deputy Opposition Leader Sussan Ley said that the Liberal and National Party Coalition opposed the Bill citing the exclusion of coal, gas and forestry projects.

The House of Representatives passed the Bill with 87 votes in favor and 55 votes against. The Bill will await the signature of the Governor-General David Hurley for Royal Assent to become an official Act of Parliament, expected within about one week.

Earlier this month, the Federal Government said the National Reconstruction Fund would invest \$15 billion across priority areas of the economy including medical science, renewables and low emissions technologies, transport, value-adding in resources, value-adding in agriculture, forestry and fisheries, defence capability and enabling technologies (BD: Mar 10, 2023).

Mr Husic said at that time that the Fund would “rebuild Australia’s industrial capability and support long-term sustainable economic growth”.

The Government said that the Fund would be “administered at arm’s length to Government by an independent board making independent investment decisions”.

More detail is at: <https://www.industry.gov.au/news/national-reconstruction-fund>.

Science & Technology Australia said it represented 139 organizations and 115,000 Australian scientists and technologists and welcomed the Fund “as a powerful new investment in the country’s future”.

The organization said the Fund would invest in next-generation materials development, value-adding and advanced manufacturing among its seven priority areas.

MICROBA LIFE SCIENCES

Microba says it has ethics approval for a first-in-human, 32-patient, double-blind, randomized, controlled, phase I trial of its MAP315 bacteria for ulcerative colitis. Microba said the trial would evaluate the safety, tolerability and pharmaco-kinetics of MAP315 in healthy adults, with Brisbane's Beyond Drug Development as the contract research organization to support the trial to be held at Melbourne's Nucleus Network. The company said ulcerative colitis was currently treated with anti-inflammatory and immune-modulatory drugs which control symptoms, but often lead to significant side effects and fail to achieve sustained remission in more than 50 percent of patients. Microba said MAP315 was identified from its databank and the previously unidentified bacterial species was "commonly observed in healthy individuals but consistently deficient in individuals with inflammatory bowel disease".

The company said that in-vitro and in-vivo studies showed that MAP315 promoted "epithelial restitution and mucosal healing, biological activities ... associated with disease remission but not adequately addressed through existing therapy".

Microba therapeutics head Prof Trent Munro said the ethics approval was "an important milestone as we take the next step in maturity for our therapeutic development activities". "Our ability to use human-data guided drug discovery sets us apart as a global leader in the microbiome sector," Prof Munro said.

Microba fell 0.75 cents or 2.1 percent to 34.25 cents.

LTR PHARMA

Brisbane's LTR says it will conduct an 18-volunteer pharmaco-kinetic study of 5mg Spontan nasal spray compared to a vardenafil 10mg tablet for erectile dysfunction. LTR said its Spontan vardenafil intranasal spray bypassed the digestive system and was designed to overcome the issues of oral tablets through a significantly reduced onset time of action to within five-to-15 minutes.

The company said that if the trial showed equivalent results for Spontan to 10mg vardenafil, it would pursue a US Food and Drug Administration 505(b)(2) regulatory process for a change of route in administration of an already approved drug, in this case vardenafil for erectile dysfunction.

LTR said that Adelaide's Bellberry human research ethics committee approved the trial, which would compare the pharma-cokinetics, safety and tolerability of vardenafil following administration of its Spontan nasal spray and Levitra tablets in healthy male adults. The company said it expected to begin patient recruitment this year, with trial sites to be opened in Sydney by October 2023.

LTR said the market for erectile dysfunction treatments was estimated to be worth \$US3.6 billion (\$A5.3 billion) worldwide.

LTR executive chair Lee Rodne, previously managing director of Admedus (now Anteris) said Spontan had the potential to revolutionize the way men manage erectile dysfunction. "Spontan is a truly innovative, fast-acting treatment, which is on track to disrupt the established blockbuster oral [phosphodiesterase-5] market," Mr Rodne said.

"Current oral tablets such as Viagra can take up to one hour to take effect, and many men are dissatisfied with the results as they don't always work or in the time desired," Mr Rodne said.

"We are thrilled to have received ethics approval for this pivotal clinical study – a crucial step in clinical validation and our expedited regulatory journey, as we prepare to market this product around the world," Mr Rodne said.

LTR Pharma is a private company.

TELIX PHARMACEUTICALS

Telix says non-executive director Dr Andreas Kluge had requested that he take about six months leave of absence “to enable him to deal with personal issues”.

Telix said Dr Kluge would return to the role on or around September 29, 2023.

The company said it extended its “support to Dr Kluge at this time, and [looked] forward to his return in September”.

Telix said that Dr Kluge had extensive experience in molecular imaging and clinical development and was the general-manager and medical director of Therapiea Verwaltungs-GmbH, a neuro-oncology development company acquired by Telix.

Telix fell eight cents or 1.2 percent to \$6.73 with 582,785 shares traded.

ORTHOCELL

Orthocell says it has appointed US orthopaedic surgeons Prof Christopher Dy and Prof David Brogan to its medical scientific advisory board.

Orthocell said Prof Dy and Prof David Brogan were hand and wrist surgeons based at Washington University in St Louis who specialized in nerve injuries.

The company said the addition of these surgeons to its advisory board meant it was “ideally positioned to drive its market leading nerve repair medical device into the US”.

Orthocell managing director Paul Anderson said the company was “delighted to be collaborating with Washington University, one of the leading centres for nerve reconstructive surgery in the US”.

Orthocell was up 1.5 cents or 4.2 percent to 37.5 cents.