

Biotech Daily

Tuesday April 27, 2021

Daily news on ASX-listed biotechnology companies

- * ASX, BIOTECH DOWN: NEXT SCIENCE UP 6.5%; MESOBLAST DOWN 8%
- * VICTORIA: 'FUNDING RETURNS 366% GSP, 454% INCOME IN 10 YEARS'
- * TELIX: GMS TO MANUFACTURE, SUPPLY RADIATION UNIT DOSES
- * EURO PATENT FOR OSTEOPORE MAGNESIUM COMPOSITE FILLER
- * INVION SELECTS INV-043 FOR PHOTO-DYNAMIC THERAPY FOR CANCER
- * ANTERIS COMPLETES 'COMMISSURAL ALIGNMENT' DESIGN CONCEPT
- * MEMPHASYS FELIX SPERM SEPARATOR FIX ON-TRACK
- * PHARMAUST MONEPANTEL DOG PLASMA LEVELS 'SUPPORTIVE'
- * GENETIC TECHNOLOGIES FILES US COVID-19 RISK TEST APPLICATION
- * BLACKROCK TAKES 7% OF COCHLEAR
- * CANN GROUP APPOINTS JOHN SHARMAN DIRECTOR

MARKET REPORT

The Australian stock market fell 0.17 percent on Tuesday April 27, 2021, with the ASX200 down 11.8 points to 7,033.8 points. Thirteen of the Biotech Daily Top 40 stocks were up, 19 fell and eight traded unchanged.

Next Science was the best, up 10.5 cents or 6.5 percent to \$1.73, with 1.4 million shares traded. Impedimed improved four percent; Alterity, Cyclopharm, Neuren and Uscom climbed more than three percent; Orthocell, Pharmaxis, Proteomics and Resonance rose two percent or more; Avita and Immutep were up more than one percent; with Kazia and Resmed up by less than one percent.

Mesoblast led the falls, down 16 cents or 7.8 percent to \$1.88, its first time below \$2.00 in more than 12 months, with 10.3 million shares traded. Optiscan lost 7.6 percent; Osprey and Paradigm were down more than five percent; Antisense fell 4.8 percent; Amplia, Medical Developments and Patrys were down more than three percent; Clinuvel and LBT shed more than two percent; Actinogen, CSL, Nanosonics, Opthea, Polynovo, Telix, Universal Biosensors and Volpara were down more than one percent; with Cochlear, Genetic Signatures and Pro Medicus down by less than one percent.

VICTORIA GOVERNMENT

Victoria says that every dollar of Government funding to biotechnology has generated an additional \$3.66 for gross state product and \$4.54 in additional income to Victoria. The Victoria Government released the report, titled 'Creating a Healthy Future The impact of Victorian Government investment in health and medical research' commissioned by lead scientist Dr Amanda Caples and the Department of Jobs, Precincts and Regions. The report said it examined the impact of investments made in the 2000 to 2010 period, and focused on the impact of: the \$620 million Science, Technology and Innovation (STI) Initiative, of which 50 percent of investments were biotechnology, the \$230 million Healthy Futures: Victoria's Life Sciences Statement in 2006 and the Operational Infrastructure Support (OIS) program, which began in 2001 and continues.

"Every dollar of Victorian Government funding invested to support the health and medical technologies and pharmaceuticals sectors has generated an additional gross state product (GSP) of \$3.66 and additional income of \$4.54 in Victoria," the report said. The report said that State biotechnology exports were worth more than \$2.4 billion a year, the sector spent \$1 billion a year on research and development, with Melbourne attracting more than 40 percent of Australia's medical research funding, and was "one of four cities in the world to have two universities in the global top 40 biomedicine rankings". The report said the three major programs "provided the investment to support the structure (bricks) and strength (mortar) of Victoria's health and medical research system and corresponding industry sectors".

Dr Caples said the report "provides an evidence base to inform and sustain government investment in health and medical research" with 11 case studies to describe the impact of more than 150 investments during the 'experimental period' between 2000 and 2010. "It answers three questions: what did we get for our investment; what lasting capability has it produced; and how has this helped us to respond to the coronavirus pandemic," Dr Caples said.

"We know from leading biotech hubs in the US and Europe that industry is attracted to excellence in science," Dr Caples said.

"Therefore, government investment to boost Victoria's medical research base through the creation and expansion of institutes, and support for our two leading biomedical universities, was important for biotech sector development," she said. "We are seeing the benefit of this strategy through the attraction of joint [research and development] facilities across our major precincts and the retention of CSL."

"Secondly, we know that research breakthroughs emerge when talented researchers have access to the latest tools and technologies ... [so] government has invested in research platform technologies with facilities ranging from large scale facilities like the Australian Synchrotron through to collaborative technology platforms [such as] imaging, genomics [and] metabolomics across Melbourne," Dr Caples said.

"Thirdly, discoveries need to be transformed into quality medicines and tested in the clinic to international regulatory standards ... [so] we invested in product development and commercialization capabilities such as the Centre for Drug Candidate Optimisation at Monash Institute of Pharmaceutical Sciences, in early-clinical trial capability at Nucleus Network at the Alfred, and commercialization activities through the Medical Research Commercialisation Fund," Dr Caples said.

"And finally, industry and academic networks are essential to create critical mass and the building of local, national, and international networks which is why the Victorian Government has supported the creation of Bio-Melbourne Network and Ausbiotech," Dr Caples said. "These investments provide a foundation for growth ... and they work together to make the whole greater than the sum of the parts."

TELIX PHARMACEUTICALS

Telix says Global Medical Solutions will manufacture and supply finished unit doses of its radiation products for clinical development programs.

Telix said that the Henderson, Nevada-based Global Medical Solutions initially would manufacture and deliver finished unit doses of its investigational prostate cancer therapy products TLX591 and TLX592 to sites in Australia for the planned Prostact phase III and Cupid phase I clinical trials, respectively.

The company said the agreement was structured to support its manufacturing needs for further products and incorporated potential future product distribution requirements in the Asia-Pacific region.

Telix chief executive officer Dr Christian Behrenbruch said that Global Medical Solutions (GMS) had "a well-deserved reputation for manufacturing diagnostic and therapeutic radio-pharmaceutical agents to rigorous quality standards".

"Our agreement also paves the way for a longer-term product relationship within the region, particularly in Asean countries where GMS is strongly positioned in terms of regulatory expertise and market access," Dr Behrenbruch said.

GMS head of operations and business development Shahe Bagerdjian said Telix had grown quickly into a diagnostics and therapeutics leader "with an impressive pipeline of investigational products".

"GMS is committed to expanding access to diagnostic and therapeutic radionuclides in Australia and more broadly in the Asia-Pacific region," Mr Bagerdjian said.

"We are well placed to support Telix to develop and ultimately deliver these products to patients with prostate cancer in need," Mr Bagerdjian said.

Telix fell seven cents or 1.8 percent to \$3.73 with 605,923 shares traded.

<u>OSTEOPORE</u>

Osteopore says the European Patent Office has issued a patent describing a method for forming a bio-composite comprised of a polymetric matrix and a magnesium filler. Osteopore said that the patent, titled 'Bioresorbable Magnesium Composite' would protect its intellectual property until November 13, 2035.

The company said that the patent described the process by which a magnesium filler comprised of a soluble magnesium salt - magnesium chloride, magnesium sulphate, or magnesium phosphate - was produced as a thin film, or when combined with a suitable polymer, was used to produce three-dimensional biomimetic scaffolds without requiring solvents or heat.

Osteopore said that soluble magnesium salts in combination with regenerative implants improved normal cellular function and were suited to regulating bone homeostasis, encouraging osteogenic differentiation and in the regeneration of host tissues without the negative side-effects caused by the production of gas near the implant's surface. Osteopore director Prof Teoh Swee Hin said that the company's process went further than traditional tissue engineering in building a scaffold for cells to produce an extracellular matrix, with the scaffolds dissolving over time leaving only the bone extracellular matrix. "In the next generation scaffolds, we design the scaffolds to provide nutrients and energize the bone cells with trace elements of metal, such as magnesium, which are known to be essential for healthy bone, as the scaffolds degrade," Prof Teoh said. Osteopore fell half a cent or one percent to 48.5 cents.

<u>INVION</u>

Invion says it has selected INV-043 as a new active pharmaceutical ingredient to progress its photo-dynamic light therapy for cancer.

Invion said that work with Melbourne's Hudson Institute on immune deficient mouse models of T-cell lymphoma, triple negative breast and pancreatic cancers had provided early indications that INV-043 had superior anti-cancer activity and cancer-targeting characteristics than previous compounds.

The company said that it would begin work on additional proof-of-concept studies using INV-043 on immune-competent animal models, and it had applied for provisional patents relating to the work and would finalize the research "in the coming weeks".

Invion executive chair Thian Chew said that having selected a new compound and overcome disruptions caused by Covid-19, "we will be moving to the next stages of development using our next-generation [photo-dynamic therapy] cancer technologies". Invion was up 0.1 cents or 12.5 percent to 0.9 cents with 3.3 million shares traded.

ANTERIS TECHNOLOGIES

Anteris says it has completed the concept for critical components of its Comasur transfemoral delivery system.

Anteris said it had a new "commissural alignment component" which gave the physician the ability to align the commissures, or the points of the join, of the replacement valve to the native valve was fully-functional.

The company said this aspect of transcatheter aortic valve replacement (TAVR) delivery was "not available with currently marketed products but is highly desired by physicians". Anteris said that animal studies showed the feasibility of its Duravr prosthetic aortic valve and its Comasur delivery system, using minimally invasive techniques and track through the aortic arch to the aortic valve where a Duravr was implanted.

The company said the studies showed "the deflection features of the Comasur delivery system as it traversed the anatomical features as well as the ability to align the Duravr [transcatheter heart valve] with the native commissures of the aortic valve prior to implantation", and echocardiography and computed tomography scans confirmed the functionality of the Duravr with stable positioning and good haemodynamic function. Anteris said the studies were part of the plans agreed with the US Food and Drug Administration as part of its approval process for a study planned later in the year. Anteris chief executive officer Wayne Paterson said the development of the commissural alignment component was a "milestone" and would "give physicians the ability to deliver Duravr accurately and consistently leading to better outcomes for patients". Anteris was up 87 cents or 10.2 percent to \$9.40.

MEMPHASYS

Memphasys says that clinical testing of the engineering fix for its Felix sperm separator has been "positive" in validating its performance.

In March, Memphasys said it found an engineering flaw during its validation process which would delay production and commercial sales (BD: Mar 8, 2021).

Today, the company said that verification work for the upgraded device was expected to be completed by June 30 and validation work by September 30, 2021

Memphasys said that initial commercial sales discussions in early access markets was expected to begin by September 30, subject to study results and Covid-19 conditions. Memphasys fell 0.5 cents or 7.1 percent to 6.5 cents with 3.2 million shares traded.

PHARMAUST

Pharmaust says it has "further supportive evidence of the monepantel blood plasma levels required to suppress B cell lymphoma growth in pet owners' dogs".

Pharmaust said it was "in a good position" to optimize treatment levels of monepantel for a further study, with monepantel showing "no material adverse events".

Pharmaust's chief scientific officer Dr Richard Mollard said that "a range of drug blood plasma levels was again observed in this lower dose trial, but this time all within a narrower spread".

"Examination of the blood plasma data in the context of the previous trial, while referencing side effects and efficacy, has reinforced our understanding of a target therapeutic window for monepantel's use in dogs with B cell lymphoma," Dr Mollard said. In March, Pharmaust said that six dogs, of an undisclosed number, with stage 4 to 5 B-cell lymphoma had completed assessment at five trial sites (BD: Mar 31, 2021).

In February, Pharmaust said it had begun recruitment of 'several' dogs in its second trial of monepantel for naïve B cell lymphoma (BD: Feb 15, 2021).

Last year, Pharmaust said that monepantel for naïve B cell lymphoma in dogs was successful, with one of seven dogs having a 60 percent reduction in tumor size after treatment (BD: May 12, 2020).

Pharmaust chair Dr Roger Aston said the data was "a material advance in optimizing the treatment regimen for canine patients with B-Cell lymphoma and may have applicability to other anticancer treatments in companion animals and in humans".

"Cancer therapy is all about optimizing efficacy and minimizing adverse events and this is particularly important with aggressive late-stage cancers such a stage 4/5 B-Cell lymphoma," Dr Aston said.

Dr Aston said the next dog trial would "also examine how monepantel can be integrated into the current standard of care".

Pharmaust was up 0.2 cents or 2.1 percent to 9.6 cents.

GENETIC TECHNOLOGIES

Genetic Technologies says that it has submitted an application to US regulators for its Covid-19 risk test.

Genetic Technologies said that the application was made through the Piscataway, New Jersey-based Infinity Biologix LLC.

The company said that the final steps in the technical interface were being built with additional capabilities for the telehealth platform to enable sales of the test and further products outside the US.

Genetic Technologies said that the commercial release of the covi-d19 risk test was expected by June 2021 "once the technical interface for the United States telehealth platform is completed by [Infinity's] telehealth partners".

Genetic Technologies chief executive officer Simon Morriss said the company was "excited to be at the precipice of the commercial release of our Covid-19 risk test".

Mr Morriss said that Infinity was performing about 100,000 severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2) tests each day and his company's test would inform individuals of their risk of developing a serious case of Covid-19.

Genetic Technologies was up 0.05 cents or 6.25 percent to 0.85 cents with 22.7 million shares traded.

COCHLEAR

Blackrock Investment Management says it has increased its substantial shareholding in Cochlear from 4,025,947 shares (6.12%) to 4,688,252 shares (7.13%).

The New York-based Blackrock said that between August 26, 2020 and April 23, 2021 it bought, sold and transferred shares in more than 4,500 transactions at prices ranging from \$178.21 to \$238.52.

Cochlear fell \$1.40 or 0.6 percent to \$222.37 with 108,162 shares traded.

CANN GROUP

Cann Group says it has appointed Universal Biosensors chief executive officer John Sharman as a director, effective from today.

Cann Group said that Mr Sharman had experience as a managing-director, chief executive officer, chief financial officer and non-executive director with public and private companies, along with an understanding of the medical manufacturing industry as well as the pharmaceutical and food additive sectors.

The company said that prior to Universal Biosensors, Mr Sharman was Medical Developments chief executive officer, and the managing-director of CVC Venture Managers, Vita Life Sciences and Cyclopharm.

Cann Group said that previously Mr Sharman worked for Pricewaterhousecoopers, National Australia Bank and KPMG in London and Melbourne.

The company said that Mr Sharman held a Bachelor of Economics from Monash University and a Master of Applied Finance from Macquarie University. Cann Group fell one cent or two percent to 50 cents.