# Biotech Daily

Wednesday June 28, 2023

*Daily news on ASX-listed biotechnology companies*

*** ASX, BIOTECH UP: COMPUMEDICS UP 12.5%; AMPLIA DOWN 7%**

*** FEDERAL $392m INDUSTRY PROGRAM DESIGN DISCUSSION PAPER**

*** TELIX TLX250-CDX 'DETECTS EXTRA-RENAL LESIONS'**

*** SERVATUS: BIOTHERAPEUTICS FOR INSOMNIA 'EXTREMELY PROMISING'**

*** NEUREN STARTS US PHASE II PRADER-WILLI SYNDROME TRIAL**

*** QIMR RESEARCH 'COULD LEAD TO COVID TREATMENT', IN HAMSTERS**

*** ANTISENSE: UK OKAYS ATL1102 DUCHENNE MUSCULAR DYSTROPHY TRIAL**

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*** IMAGION EXTENDS SIEMENS HER2 BREAST CANCER IMAGING TO US**

*** ALLEGRA, ROBINWOOD TAKE $2m LOAN TO END 2024**

*** CLARITY OPENS IDAHO 'CENTRE OF EXCELLENCE'**

*** INVEX: 'PHASE III PRESENDIN TRIAL SLOW; OBESITY POTENTIAL'**

*** CORRECTION: MICROBA**

*** IMPEDIMED DR MICHAEL SEIDEN, DANIEL SHARP IN; ROBERT GRAHAM OUT**

*** ANTEOTECH LOSES EX-CEO, DIRECTOR CHRISTOPHER PARKER**

*** VOLPARA WINS MICROSOFT PARTNER OF THE YEAR GONG**

## MARKET REPORT

The Australian stock market was up 1.1 percent on Wednesday June 28, 2023, with the ASX200 up 78.3 points to 7,196.5 points. Twenty-two of the Biotech Daily Top 40 stocks were up, nine fell, eight traded unchanged and one was untraded.

Compumedics was the best, up two cents or 12.5 percent to 18 cents, with 117,683 shares traded. Micro-X climbed 9.1 percent; Imugene improved 8.3 percent; Polynovo was up 7.1 percent; 4D Medical climbed 6.9 percent; Dimerix was up 5.3 percent; Cynata and Universal Biosensors were up more than four percent; Alcidion and Genetic Signatures improved more than three percent; Avita rose two percent; Antisense, Clinuvel, Cochlear, Cyclopharm, Immutep, Neuren, Nova Eye, Paradigm, Resmed and Volpara were up one percent or more; with Nanosonics, Pro Medicus and Telix up by less than one percent.

Amplia led the falls, down 0.6 cents or 7.4 percent to 7.5 cents, with 29,500 shares traded. Next Science lost 5.9 percent; Starpharma was down 3.45 percent; Actinogen and Impedimed shed more than two percent; Emvision, Orthocell and Prescient were down by more than one percent; with CSL and Opthea down by less than one percent.

## FEDERAL GOVERNMENT

The Federal Government says it has launched a discussion paper on the design and operation of the proposed $392 million Industry Growth Program

A media release from the Federal Minister for Industry and Science Ed Husic said the program was intended “to support small businesses get their great ideas to market and overcome barriers to scale”.

The media release said that the discussion would ask how the program should be designed and operated for the best outcomes.

The Government said that the program would target priority areas under the $15 billion National Reconstruction Fund including: medical science; renewables and low emission technologies; value-add in agriculture, forestry and fisheries; value-add in resources; transport; defence capability; and enabling capabilities.

Mr Husic’s media release said that the program would “help transform industry in Australia by providing expert business advice and matched grant funding to support enterprises to increase revenue, grow their workforce and attract investment”.

The media release said that an independent committee with expertise in commercialization and industry growth would be established to provide program oversight and recommendations to the Department of Industry, Science and Resources on projects to receive grant funding.

Mr Husic said the program was intended to support companies “to navigate the difficult aspects of getting ideas to market”.

“We’re particularly keen to help bridge the ‘valley of death’, where great ideas, often backed by solid research, are hamstrung only by a lack of funding and expertise,” Mr Husic said. “This consultation is about creating the right conditions to ensure brilliant Australian entrepreneurs can grow and thrive here at home.”

The Government said consultations would close on July 30, 2023 and the discussion paper was available at: https://consult.industry.gov.au/industry-growth-program.

## TELIX PHARMACEUTICALS

Telix says TLX250-CDx can detect extra-renal lesions, supporting potential clinical use for metastatic or recurrent cancers and for staging and informing treatment.

In an email not released to the ASX, Telix said the data came from its 300-patient, phase III Zircon study of TLX250-CDx (89Zr-DFO-girentuximab) in clear cell renal cell carcinoma.

Last year, Telix said the pivotal trial for imaging clear-cell renal cancer met its primary endpoints, with 86 percent sensitivity and 87 percent specificity (BD: Nov 7, 2022).

The company said TLX250-CDx positron emission tomography and/or computed tomography (PET/CT) detected more lesions in liver and bone than CT imaging alone and the results reinforced the performance of the imaging agent across all analyses.

The company said the data was featured in an oral presentation on June 26, 2023 at the Society of Nuclear Medicine and Molecular Imaging meeting in Chicago, by the University of California, Los Angeles’ Dr Jeremie Calais, a principal investigator in the Zircon study.

Telix said that 25 patients had one or more extra-renal lesions detected by whole body PET/CT (n=10), abdominal PET/CT (n=17), or both modalities (n=2), with the extra-renal lesions mostly localized in bone, liver, lung, adrenal glands and lymph nodes.

Dr Calais said the data showed “potential utility of TLX250-CDx for staging and monitoring high risk patients where there is a great deal of interest from the clinician community”.

Telix said it was in the process of implementing an expanded access program in the US and establishing named patient programs for TLX250-CDx in Europe.

Telix was up three cents or 0.3 percent to $11.35 with 546,985 shares traded.

## SERVATUS LTD

Servatus says it will expand its 50-patient, randomized, blinded, controlled, phase I/II trial based on preliminary evidence that its live biotherapeutic is promising for insomnia.
Servatus said the trial at Brisbane's Prince Charles Hospital sleep disorders centre examined safety and efficacy of 35 days treatment.
Servatus chief executive officer Dr Wayne Finlayson told Biotech Daily that the trial would be expanded to up to 125 patients.
"With the trial still underway and expanding we have to re-blind the data," Dr Finlayson said.
"But I can say that the preliminary look was extremely promising," Dr Finlayson said.
In a media release, the company said the expanded trial would "look to further verify the results seen in the phase I/II2 trial as the treatment moves towards commercialization".
The director of the Prince Charles Hospital sleep centre Dr Deanne Curtin said that insomnia and other sleep disorders "impact the majority of the population, with close to 60 percent of Australians suffering from at least one chronic sleep symptom".
"People often turn to over-the-counter medications and do not seek professional treatment for their sleep disorders, so the need for effective, long-term insomnia treatments are clear," Dr Curtin said.
"Servatus' live biotherapeutic treatment explores the role of the microbiome in sleep health and our preliminary results for the trial have been extremely promising," Dr Curtin said.
"By expanding our trial with a dose-ranging study we expect to produce more substantial data to demonstrate the effectiveness of this treatment option," Dr Curtin said.
Dr Finlayson said that "the strong preliminary results from our insomnia treatment trial indicate that there is indeed a link between the microbiome-gut-brain axis and its impact on sleep".
"With the trial expanding we are confident that we are moving closer to being able to provide an effective new treatment option for those suffering from insomnia," he said.
Servatus is a public unlisted company.

## NEUREN PHARMACEUTICALS

Neuren says it has opened its first US site for its up-to 20-paediatric patient, phase II trial of twice daily, oral NNZ-2591 for Prader-Willi syndrome.
Earlier this year, Neuren said the US Food and Drug Administration had approved its investigational new drug application for the paediatric trial (BD: Jan 23, 2023).
Today, the company said the trial would examine safety, tolerability, pharmaco-kinetics and efficacy of NNZ-2591 in children aged four-to-12 years, over 13 weeks of treatment and would generate the data needed to design a further registration trial.
Neuren said Prader-Willi syndrome was a neuro-developmental disorder that led to low muscle tone and feeding difficulties in infants, as well as an unregulated appetite and weight gain in the later stages, which could lead to morbid obesity.
The company said it had three more phase II trials of NNZ-2591 in other neurological disorders including Phelan-McDermid, Pitt Hopkins and Angelman syndromes.
Neuren chief executive officer Jon Pilcher said the company was "very excited to be working with the community to complete this important first study of NNZ-2591 in young children with Prader-Willi syndrome".
"We are eager to assess the potential impact of NNZ-2591, having observed highly encouraging effects in the preclinical model," Mr Pilcher said.
Neuren was up 13 cents or 1.1 percent to $12.25 with 281,716 shares traded.

QUEENSLAND INSTITUTE FOR MEDICAL RESEARCH BERGHOFER

The Queensland Institute for Medical Research says a peptide-based drug it has developed and tested on hamsters “could transform the treatment of Covid-19”.

The Institute said that the inhibition of nuclear ACE2 translocation potentially protected against infection by any severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2) variant and reversed “the persistent inflammation that is a major driver of debilitating long Covid” in golden Syrian hamsters.

QIMR said that a second study showed the pre-clinical effectiveness of the peptide-based drug, NACE2i.

The research article, titled ‘In-vivo inhibition of nuclear ACE2 translocation protects against SARS-CoV-2 replication and lung damage through epigenetic imprinting’, was published in Nature Communications, with the full article available at: https://www.nature.com/articles/s41467-023-39341-4.

The research article said that ACE2 translocated to the nucleus to induce Sars-Cov-2 replication and using digital spatial profiling of lung tissues from Sars-Cov-2-infected hamsters, the researchers showed that a specific and selective peptide inhibitor of nuclear ACE2 (NACE2i) inhibited viral replication two days after infection.

The article said that the peptide prevented inflammation and macrophage infiltration and increases natural killer cell infiltration in bronchioles.

The article said that NACE2i treatment increased the levels of the active histone mark, H3K27ac, restored host translation in infected hamster bronchiolar cells and led to an enrichment in methylated ACE2 in hamster bronchioles and lung macrophages, a signature associated with virus protection.

The article said that ACE2 methylation was increased in myeloid cells from vaccinated patients and associated with reduced Sars-Cov-2 spike protein expression in monocytes from individuals who have recovered from infection and the “protective epigenetic scarring of ACE2 [was] associated with a reduced latent viral reservoir in monocytes/macrophages and enhanced immune protection against Sars-Cov-2”.

The article said that nuclear ACE2 might be “a therapeutic target independent of the variant and strain of viruses that use the ACE2 receptor for host cell entry”.

QIMR co-lead author Prof Sudha Rao said the drug was tested repeatedly by independent laboratories using a variety of pre-clinical models.

“The results of this second major study are really exciting,” Prof Rao said.

“It shows our drug, NACE2i, stops the virus replicating and protects against re-infection,” Prof Rao said.

“We believe it could be a highly promising adjuvant to boost the effectiveness of existing vaccines providing long-lasting protection against any variant of the virus that tries to enter the cells,” Prof Rao said.

“The other major discovery is that we uncovered the pathway that the virus uses to induce the persistent inflammation which causes organ damage found in long Covid,” Prof Rao said.

“This study shows our drug prevents that inflammation and even repairs damaged lung tissue in pre-clinical models,” Prof Rao said.

“It is both a prevention and a treatment,” Prof Rao said

## ANTISENSE THERAPEUTICS

Antisense says the UK has approved its 45-patient, double-blind, placebo controlled, phase IIb trial of ATL1102 in non-ambulant boys with Duchenne muscular dystrophy.
Earlier this month, Antisense said it had dosed the first patients in the trial in Istanbul, Turkey (BD: Jun 8, 2023).
Today, the company said the trial had been approved in all four countries intended to conduct the trials including Turkey, the UK, Bulgaria and Australia, with contracts expected to be finalized for opening trial sites by October 2023.
Antisense chair Dr Charmaine Gittleson said the company looked forward to starting activities in the UK where it intended to open multiple sites to advance patient enrolment.
“We are further encouraged by the fact that three patients have already received their first dose,” Dr Gittleson said.
Antisense was up 0.1 cents or 1.6 percent to 6.5 cents with one million shares traded.

## MICROBA LIFE SCIENCES

Microba says it has dosed the first of 32-participants in its randomized, double-blind, placebo-controlled phase I study of MAP315 for inflammatory bowel disease.
Microba said the trial of its live biotherapeutic MAP315 was being conducted in healthy adult participants by the Nucleus Network in Melbourne to evaluate the safety, tolerability and pharmaco-kinetics of the drug.
The company said participants were enrolled in two cohorts of 16, with the study randomized at a three-to-one ratio of those receiving MAP315 or a matching placebo daily over a two-week period.
Microba said the milestone brought its drug candidate into clinical development as a potential treatment option for the millions of people suffering from ulcerative colitis.
Microba was up two cents or 6.8 percent to 31.5 cents.

## IMAGION BIOSYSTEMS

Imagion says it has extended its agreement with Australia’s Siemens Healthcare Pty Ltd to work on its Magsense HER2 breast cancer imaging agent by two years and in the US.
Imagion said that Siemens Medical Solutions US would work with its clinical advisors and investigators to optimize the magnetic resonance imaging (MRI) protocols used in its multi-site, phase II trial of its Magsense human epidermal growth factor receptor2 (HER2) imaging agent.
The company said the existing collaboration in the Magsense phase I study in Australia had been “very valuable and is expected to continue now in this expanded capacity in the US”.
Imagion chair Bob Proulx said Siemens “was instrumental in the early stages to help establish the initial MRI protocols that were implemented” in its study and had contributed to ongoing evaluation and optimization to achieve the best data possible for Magsense.
“This collaboration creates a win-win situation in which Imagion benefits from having access to the Siemens Healthineers MRI research team’s knowledge and expertise, while providing Siemens Healthineers direct visibility to our work to make molecular MRI a reality,” Mr Proulx said.
Imagion was up 0.2 cents or 16.7 percent to 1.4 cents with 23.7 million shares traded.

## ALLEGRA ORTHOPAEDICS

Allegra says Robinwood Investments Pty Ltd (RIPL) has agree to extend the $2 million convertible loan agreement until December 31, 2024.
In 2021, Allegra said it had a $2 million loan at 13 percent per annum from an undisclosed lender to fund its strontium-hardystonite-Gahnite bone substitute, which it could draw down in tranches of $300,000 for up-to 24 months (BD: Apr 28, 2021).
Today, the company said Robinwood was a substantial shareholder of the company and an associated party of Allegra director Dr Nicholas Hartnell.
Allegra was untraded at 5.8 cents.

## CLARITY PHARMACEUTICALS

Clarity says it will establish a “centre of excellence” for copper diagnostics and therapeutics at Idaho State University’s Accelerator Centre.
The company said the centre would allow it to “efficiently execute several strategically important projects, support commercial readiness of products currently in clinical development and enable the expansion of [targeted copper diagnostics and therapeutics] as a platform uniquely positioned to take the radiopharmaceutical sector into large global markets”.
Clarity executive chair Dr Alan Taylor said the Idaho centre’s “in-house production of copper-67, combined with a team of world class researchers … made the decision of establishing centre of excellence here a logical step for both organizations to benefit from academic-industry collaboration”.
Clarity was unchanged at 72 cents.

## INVEX THERAPEUTICS

Invex says enrolment has slowed for its phase III clinical trial of GLP-1 receptor agonist Presendin for patients with idiopathic intracranial hypertension.
Invex said it had undertaken a strategic evaluation of the study after slower than expected site activations and patient enrolments as well as the rapidly evolving market uptake of GLP-1 receptor antagonists for the treatment of obesity.
Last year, the company said it had a target enrolment of 240 patients in 24 months at a hoped-for 40 clinical sites by June 30, 2023, but currently had 13 patients enrolled and 12 sites activated (BD: Nov 21, 2022).
Invex said slowed enrolment was due to a significantly higher patient screening failure rate than initially expected.
Invex said it would seek feedback and ethics committee approvals for a revised protocol and intended to make changes including the reordering of the trial’s secondary endpoints and a reduced sample size of 130 patients.
The company said it had been monitoring the use of approved GLP-1 receptor agonists, specifically semaglutide, currently sold under the brand names Ozempic, Wegovy and Rybelsus.
Invex said it considered “the use of these agents in the management of obesity particularly as a potential future risk to the acceptability of Presendin as an orphan treatment in [idiopathic intracranial hypertension]”.
Invex fell 24 cents or 52.2 percent to 22 cents with 6.4 million shares traded.

## MICROBA LIFE SCIENCES

Last night's edition incorrectly said Microba and the University of Queensland had received $2.92 million from the Federal Government for a microbiome biobank.
In fact, Microba received the funds in partnership with the Queensland University of Technology.
The Tuesday sub-editor – a graduate of the University of Melbourne, ranked Number 1 in Australia and 14 in the world - should have known the difference and has been dismissed.
It is so hard to get good hired help these days.

## IMPEDIMED

Impedimed says it has appointed Dr Michael Seiden and Daniel Sharp as independent non-executive directors, replacing Dr Robert Graham, effective from July 1, 2023.
Impedimed said Dr Seiden was a certified medical oncologist and was previously US Oncology Network president and Fox Chase Cancer Center chief executive officer.
The company said Mr Sharp was currently a director of Alcidion and Botanix and previously worked for Canaccord Genuity Australia.
Impedimed said Dr Graham had been a director since 2017 and his resignation was effective from June 30, 2023.
Impedimed fell half a cent or 2.7 percent to 18 cents with 18.1 million shares traded.

## ANTEOTECH

Anteotech says director and previous chief executive officer Christopher Parker has retired from the board of the company, effective from June 27, 2023.
Anteotech said Mr Parker was its chief executive officer from April 2018 and was appointed a director on April 23 2019.
The company said Mr Parker's "dedication and unwavering commitment to the company's vision have been instrumental in shaping [its] current standing".
Anteotech chair Ewen Crouch thanked for Mr Parker for his "dedicated service and leadership during a pivotal period".
Anteotech was up 0.3 cents or 7.7 percent to 4.2 cents with three million shares traded.

## VOLPARA HEALTH TECHNOLOGIES

Volpara says it has won the Microsoft Healthcare and Life Sciences Partner of the Year Award for its breast cancer screening software, based on Microsoft technology.
Volpara said the award acknowledged "outstanding successes and innovations by partners in more than 100 countries and in a wide variety of categories and industries".
The company said its product suite used the Microsoft Azure Internet of Things platform to enable rapid deployment and reliable operation at scale.
Last year, Volpara said that with the Redmond, Washington-based Microsoft, it would develop a product to detect and quantify breast arterial calcifications which were shown to be associated with cardio-vascular disease outcomes (BD: Jun 21, 2022).
Volpara was up one cent or 1.45 percent to 70 cents.