# Biotech Daily

Monday February 7, 2022

*Daily news on ASX-listed biotechnology companies*

*** ASX, BIOTECH DOWN: RESONANCE UP 17%; PRESCIENT DOWN 7%**

*** MCRI, PROTA: DESENSITIZATION FOR PEANUT ALLERGY; PROBIOTIC**

*** PROTEOMICS: BIOMARKERS FOR OBSTRUCTIVE AIRWAY DISEASE**

*** QIMR EXOSOME BLOOD TEST FOR CANCER TREATMENT**

*** RESONANCE: 'ELIGIBLE FOR LIVERSMART IMAGING CPT CODES'**

*** TELIX EU ILLUCCIX REVIEW EXTENSION; REVENUE DELAY**

*** CLARITY: FDA APPROVES PROSTATE CANCER IMAGING TRIAL**

*** RESPIRI 2nd ACCESS US DISTRIBUTION DEAL**

*** MEDLAB CLOSER TO UK NANABIS MARIJUANA CANCER PAIN TRIAL**

*** ALTHEA: DR REDDY'S TO ACQUIRE DISTRIBUTOR NIMBUS HEALTH**

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*** BILAL AHMAD TAKES 6.25% OF DORSAVI**

*** DIMERIX APPOINTS DR ASH SOMAN CMO**

*** ROBYN SLAUGHTER REPLACES ALLEGRA CO SEC JUSTYN STEDWELL**

## MARKET REPORT

The Australian stock market fell 0.13 percent on Monday February 7, 2022, with the ASX200 down 9.4 points to 7,110.8 points. Sixteen of the Biotech Daily Top 40 stocks were up, 18 fell and six traded unchanged. All three Big Caps were down.

Resonance was the best, up 2.5 cents or 16.7 percent to 17.5 cents, with 1.45 million shares traded. Neuren climbed 13 percent; Paradigm improved 4.9 percent; Amplia, Clinuvel and Emvision were up more than three percent; Oncosil rose 2.4 percent; Compumedics, Cynata, Orthocell and Uscom were up more than one percent; with Avita, Genetic Signatures, Opthea and Universal Biosensors up by less than one percent.

Prescient led the falls, down 1.5 cents or 7.1 percent to 19.5 cents, with 2.6 million shares traded. Micro-X lost six percent; Kazia and Nova Eye were down five percent or more; Actinogen and Pharmaxis fell more than four percent; Imugene, Patrys and Polynovo were down more than three percent; Antisense, Atomo and Medical Developments shed more than two percent; CSL, Cyclopharm, Next Science, Starpharma and Volpara were down one percent or more; with Cochlear, Nanosonics, Pro Medicus and Resmed down by less than one percent.

## MURDOCH CHILDREN'S RESEARCH INSTITUTE, PROTA THERAPETICS

Murdoch Children's Research Institute and Prota say that a 201-patient trial shows that an immunotherapy significantly reduces peanut allergy in children.

In a media release, the MCRI said that about half of the children achieved remission, allowing them to stop treatment and safely eat peanuts freely.

The Institute said that children were randomly assigned (2:2:1) to receive probiotic and peanut oral immunotherapy (PPOIT), placebo probiotic and peanut oral immunotherapy (OIT), or placebo probiotic and placebo OIT (placebo) for 18 months, and were followed up until 12 months after completion of treatment.

The Institute said that oral immunotherapy consisted of increasing doses of peanut protein, until a 2000mg daily maintenance dose was reached.

MCRI said that the probiotic adjuvant was a daily dose of $2 \times 10^{10}$ colony-forming units of the probiotic Lactobacillus rhamnosus ATCC 53103.

The Institute said that the placebo immunotherapy comprised maltodextrin, brown food colouring and peanut essence, while the placebo probiotic was maltodextrin.

MCRI said that 36 of 79 children (46%) in the PPOIT group ($p < 0.0001$) and 42 of 83 children (51%) in the OIT group ($p < 0.0001$) "achieved sustained unresponsiveness compared with two of 39 children (5%) in the placebo group".

The Institute said there was no significant difference between the PPOIT and OIT groups.

MCRI said that treatment-related adverse events were reported in 72 of 79 children (91%) in the PPOIT group, 73 of 83 children (88%) in the OIT group and 28 of 39 children (72%) in the placebo group; and that during the 12-month post-treatment period, 60 of 71 children (85%) in the PPOIT group, 60 of 70 children (86%) in the OIT group, and six of 34 children (18%) in the placebo group were eating peanut; with rescue epinephrine use infrequent - two of 71 (3%) in the PPOIT group, four of 70 (6%) in the OIT group, and none in the placebo group.

The research article, titled 'Probiotic peanut oral immunotherapy versus oral immunotherapy and placebo in children with peanut allergy in Australia (PPOIT-003): a multi-centre, randomized, phase IIb trial' was published in the journal The Lancet Child & Adolescent Health, and is available at: https://bit.ly/3ov8YHx.

The article concluded that "PPOIT and OIT were similarly effective and both superior to placebo at inducing eight-week sustained unresponsiveness in children aged one to 10 years with peanut allergy".

"The addition of a probiotic adjuvant to peanut OIT in this study did not improve efficacy of OIT … [but] might provide a meaningful safety benefit, particularly for children aged one to five years, by reducing the burden of gastro-intestinal symptoms and systemic reactions," the article concluded.

The team, led by Prota chief executive officer and MCRI researcher Prof Mimi Tang, previously showed the combination treatment resulted in 74 percent achieving remission after 18 months of treatment, and 70 percent of those initial responders remained in remission and were safely eating peanuts four years later (BD: May 23, 2018).

The next step was to test whether adding a probiotic gave a benefit over and above oral immunotherapy on its own and to compare long-term outcomes following treatment.

"The results show that high dose peanut oral immunotherapy provides meaningful benefit to treated children," Prof Tang said.

"Addition of a probiotic did not significantly improve effectiveness compared to oral immunotherapy, however, it appeared to enhance tolerability of the treatment, with fewer gastrointestinal symptoms, especially in children between one and five years of age," Prof Tang said.

Prota is a private company.

## PROTEOMICS INTERNATIONAL LABORATORIES

Proteomics says its 75-patient proof-of-concept study has identified “multiple novel protein biomarkers for obstructive airway disease”.
Proteomics said that once validated, the biomarkers had the potential to “deliver a new diagnostic test for asthma and chronic obstructive pulmonary disease (COPD)”.
Proteomics said it worked with Western Australia’s Busselton Population Medical Research Institute to study the plasma samples of 75 patients with symptoms ranging from airway obstruction, atopy or an exaggerated immune response, bronchial hyper-responsiveness and healthy controls.
The company said that it would file a patent application covering the screening, diagnostic and prognostic methods of using these biomarkers.
The company said that the study, titled ‘Protein Biomarkers of Obstructive Airway Disease’, was presented at the Lorne Proteomics Symposium February 3 to 6, 2022.
Proteomics said that the study showed “multiple protein biomarkers were statistically significant in identifying specific types of airway disease”.
Busselton Institute chair Prof Alan James said that “doctors currently use physiological tests to diagnose and assess severity of airway disease”.
“These tests of lung function and structure are useful in investigating common symptoms such as cough and breathlessness,” Prof James said. “They do not necessarily reflect the various underlying pathologies which cause abnormal structure and function and which may respond differently to different treatments.”
Proteomics said that after the disease had advanced, interventions were less effective because damage to the lungs from COPD “cannot be reversed with current treatments”.
“Accurate and early identification of these common conditions and differentiation of phenotypes of airway disease can allow early intervention with directed therapy, resulting in improved patient outcomes,” Prof James said.
The company said it would validate the biomarkers in larger clinical cohorts and refine the panel of biomarkers into a working diagnostic test for obstructive airway disease, over the next 12 to 18 months.
Proteomics was up half a cent or 0.5 percent to $1.085.

## QUEENSLAND INSTITUTE FOR MEDICAL RESEARCH BERGHOFER

The Queensland Institute for Medical Research Berghofer says it is co-developing an exosome-based blood test to improve cancer treatment.
The Institute said it was working with the Lausanne, Switzerland-based Biopsomic SA to develop the blood test to analyze exosomes to guide cancer treatment.
QIMR said that the test would “read the content of exosomes” which were fluid-filled sacs shed by tumor cells into the blood of patients.
“They are essentially miniature blueprints of what is contained in the cancer cells,” the Institute said.
QIMR’s head of tumor micro-environment research Prof Andreas Möller said that clinicians had “no reliable way of predicting whether a particular patient will respond better to chemotherapy, immunotherapy, or any other therapy”.
“This blood test could quickly and accurately indicate the most effective treatment for an individual patient,” Prof Möller said.
“These exosomes offer insight into how cancer cells will likely behave,” Prof Möller said.
“If their contents suggest a person’s cancer cells will not respond to a given therapy, then their clinician can explore more effective alternatives,” Prof Möller said.
QIMR said that the terms of the agreement were commercial-in-confidence.

## RESONANCE HEALTH

Resonance says that its Liversmart liver-iron and fat imaging device is eligible for two new US current procedural terminology (CPT) codes.
Resonance said that Karen Zupko & Associates reviewed the Liversmart user guide and other materials and said that CPT code 0648T applied when Liversmart was performed without other documented diagnostic liver imaging; and CPT code 0649T applied when additional diagnostic liver imaging was performed in the same scanning session.
The company said that the magnetic resonance imaging (MRI) based Liversmart would be classified as category III codes, with the potential for conversion to Category I.
Resonance said CPT codes described medical procedures and services for reimbursement by government and private payers.
Resonance managing-director, Mitchell Wells said that “the confirmation of applicability of two new CPT codes represents a major milestone in the pathway to more widespread reimbursement of Liversmart in the US”.
Resonance was up 2.5 cents or 16.7 percent to 17.5 cents with 1.45 million shares traded.

## TELIX PHARMACEUTICALS

Telix says that the Danish Medicines Agency has extended the review period for its prostate imagining test Illuccix, which will delay revenue of about $1.7 million.
Telix said it requested the extension to provide sufficient time to respond to information requests in relation to product manufacturing and pharmaceutical characterization of its Illuccix prostate cancer imaging test.
The company said the original March 23 deadline could not be met due to “unexpected process delays and vendor outages that have arisen from the rapid onset of the ‘omicron’ Covid variant”.
The company said it had until August 9 to provide responses, but said it intended to respond by May 10, 2022.
Telix said that the delay was expected to have about a $1.5 million to $1.9 million adverse impact on revenue expectations for the year October 1, 2021 to September 30, 2022.
Telix said that it was not providing financial guidance on Illuccix sales but expected the majority of sales for the year to December 31, 2022 to be generated from the US, and delays for the EU had “no impact on the US product launch of Illuccix”.
Telix was unchanged at $6.81 with 1.1 million shares traded.

## CLARITY PHARMACEUTICALS

Clarity says the US Food and Drug Administration has approved its up-to 50-patients, copper-64 SAR-bis-PSMA prostate cancer imaging trial.
Clarity executive chair Dr Alan Taylor said the company was “excited to be progressing this stand-alone diagnostic trial … as we head towards registering this product in the US.
Dr Taylor said the company was planning for recruitment to begin by July 2022 for the copper-64 sarcophagene-bis-prostate specific membrane antigen (SAR-bis-PSMA) in biochemically recurrent prostate cancer (Cobra) trial.
Clarity said that the phase I/II positron emission tomography (PET) trial of participants with biochemical recurrence of prostate cancer following definitive therapy was a multi-centre, single arm, non-randomized, open-label trial of 64Cu-labelled SAR-bis-PSMA.
The company said the primary objectives were to investigate safety and tolerability of 64Cu-SAR-bis-PSMA and its ability to correctly detect recurrence of prostate cancer.
Clarity was up one cent or 1.4 percent to 73 cents.

## RESPIRI

Respiri says it has its second, five-year, non-exclusive distribution and marketing agreement with Access Telehealth for the US.
Respiri said its second partnership with Access for remote patient monitoring had no associated upfront payments, with small minimum order quantities.
The company said it was “unable to reliably quantify the future revenue potential through this agreement by way of device sales and subscription revenues; however, the agreement does increase potential accessibility to additional patients in the key US market”.
Respiri said that in addition to device sales Access would share the product-as-a-service monthly fees generated by the Wheezo remote patient monitoring device that would be charged to physicians and other healthcare professionals.
Respiri fell 0.1 cents or 1.9 percent to 5.1 cents.

## MEDLAB CLINICAL

Medlab says it has received the receipt of ‘favorable opinion’ status from the UK research ethics committee for its phase III marijuana Nanabis for cancer pain trial.
Last year, Medlab says the Australian Therapeutic Goods Administration had approved its 360-participant, randomized, blinded, phase III trial of synthetic marijuana-based Nanabis for cancer bone pain (BD: Jul 12, Aug 25, 2021)
The company said at that time the trial aimed to show the analgesic efficacy of Nanabis as a monotherapy in cancer patients by proving that the analgesic was significantly better than the placebo and that the magnitude of improvement was clinically important.
Today, Medlab managing-director Dr Sean Hall said that “UK ethics approval is an important step towards our Nanabis [phase III] trial and we are very happy with the result”.
“We can now move forward with final UK clinical trials approval, at which point we will announce the UK hospitals and principal investigators,” Dr Hall said.
The company said that it would apply for approval from the UK Medicines and Healthcare Products Regulatory Agency and it planned to conduct phase III trials with about 120 patients each in Australia, the UK and the US.
Medlab was up half a cent or four percent to 13 cents.

## ALTHEA GROUP

Althea says that Dr Reddy’s Laboratories will acquire its German medicinal marijuana distribution partner Nimbus Health GmbH.
Althea said that the Hyderabad, India-based Dr Reddy’s Laboratories would acquire Nimbus Health for an upfront payment as well as performance and milestone-based payments throughout the next four years, but did not disclose the amounts.
In 2019, Althea said it had appointed Frankfurt’s Nimbus Health as its sales and distribution partner for Germany (BD: Nov 12, 2019).
said that it would receive payment for products supplied to Nimbus health, along with 50 percent of the net profit of sale.
Today, Dr Reddy’s head of European generics, Patrick Aghanian said that “medical cannabis is increasingly used to address and treat high unmet medical needs, especially in pain management and [the central nervous system]”.
“With numerous studies being conducted to leverage and introduce medical cannabis, we believe this is a must-be field for future healthcare delivery,” Mr Aghanian said.
Althea was unchanged at 21 cents.

## EMYRIA

Emyria says 100,097,478 shares will be released from ASX escrow on February 12, 2022, along with 10,500,000 unlisted options exercisable at 45 cents by June 13, 2023.
According to Emyria's most recent filing, following the release of shares, the company would have 275,002,469 shares available for trading.
Emyria was unchanged at 34.

## DORSAVI

The Perth, Western Australia-based Bilal Ahmad has become a substantial share-holder in Dorsavi with 22,109,490 shares or 6.25 percent.
Mr Ahmad said that he bought the shares between September 9, 2020 and February 1, 2022 for about $585,983 or an average of 2.65 cents a share.
Dorsavi was up 0.2 cents or 10.5 percent to 2.1 cents.

## DIMERIX

Dimerix says it has appointed Dr Ash Soman as its chief medical officer, effective from today, February 7, 2022.
Dimerix said that Dr Soman would lead its clinical development programs and medical affairs.
The company said that Dr Soman had more than 30 years' experience in hospital clinical practice, clinical study design and medical affairs, for pharmaceutical and biotechnology companies as well as clinical research organizations.
Dimerix said that Dr Soman previously worked as the Iqvia's medical-director and before that Astrazeneca, Sanofi-Aventis Australia-New Zealand, Oncosil and Roche.
The company said that Dr Soman held a Bachelor of Medicine and a Bachelor of Surgery from the University of London, and a Master of Business Administration from the Imperial College London.
Dimerix was unchanged at 25 cents.

## ALLEGRA ORTHOPAEDICS

Allegra Orthopaedics says that it has appointed Robyn Slaughter from the Automic Group to replace Justyn Stedwell as co. secretary, effective immediately.
Allegra said that Ms Slaughter had worked for ASX-listed and unlisted companies in industries including biotechnology, healthcare, financial services, cyber security and manufacturing.
The company said Ms Slaughter held a Bachelor of Arts from the University of Lincoln and a Master of Science from London's South Bank University.
Allegra was untraded at 17 cents.