



# Biotech Daily

Thursday April 8, 2021

*Daily news on ASX-listed biotechnology companies*

- \* **ASX, BIOTECH UP: IMMUTEP UP 12.5%; LBT, ONCOSIL DOWN 5%**
- \* **IMPEDIMED: SOZO BIS INDICATES HEART RISK**
- \* **VISIONEERING 'OVERSUBSCRIBED' SHARE PLAN RAISES \$1.2m**
- \* **FDA GRANTS IMMUTEP IMP321 FAST-TRACK STATUS FOR HNSCC**
- \* **PHARMAUST RECEIVES \$756k R&D TAX INCENTIVE**
- \* **RESAPP REQUESTS 'CAPITAL RAISING' HALT**
- \* **UNIVERSAL BIOSENSORS REQUESTS 'AGREEMENTS' HALT**
- \* **CREDIT SUISSE BELOW 5% IN IDT**
- \* **NICK ALLAN REPLACES RESONANCE CFO, CO SEC AGHA SHAHZAD**
- \* **BIONOMICS APPOINTS SUZANNE IRWIN CO SEC**

## MARKET REPORT

The Australian stock market was up 1.02 percent on Thursday April 8, 2021, with the ASX200 up 70.8 points to 6,998.8 points. Twenty-three of the Biotech Daily Top 40 stocks were up, eight fell, seven traded unchanged and two were untraded.

Immutep was the best, up 5.5 cents or 12.5 percent to 49.5 cents with 13.6 million shares traded. Kazia climbed 11.9 percent; Actinogen was up 10 percent; Nova Eye rose 7.6 percent; Osprey was up 5.6 percent; Clinuvel and Orthocell improved more than four percent; Alterity, Imugene, Medical Developments, Optiscan, Pro Medicus, Proteomics, Starpharma and Volpara were up three percent or more; Amplia, Mesoblast, Next Science and Paradigm rose two percent or more; Avita, CSL and Polynovo were up more than one percent; with Cochlear, Cynata and Nanosonics up by less than one percent.

LBT and Oncosil led the falls, both down 0.5 cents or 4.76 percent to 10 cents, with 287,964 shares and 289,598 shares traded, respectively. Antisense lost 4.1 percent; Patrys was down 3.3 percent; Neuren and Pharmaxis shed more than two percent; with Cyclopharm, Opthea and Resmed down by less than one percent.

## IMPEDIMED

Impedimed says a 133-patient study shows its Sozo bioimpedance spectroscopy is an indicator for heart failure risk and has outlined risk parameters for clinical settings. Impedimed said that its Sozo heart failure diagnostic (HF-Dex) measured extracellular fluid as a percentage of total body water.

Last year, the company said 172 patients, including 103 patients with heart failure and 69 control subjects, showed a statistically significant ( $p < 0.05$ ) difference in median HF-Dex for patients readmitted for heart failure (52.1%) compared to patients not readmitted for heart failure (49.0%) and healthy subjects (44.8%) (BD: Oct 1, 2020).

Today, Impedimed said that a controlled study of 133 subjects by the San Diego, California-based Scripps Health identified that Sozo measured HF-Dex values between 41.5 percent and 46.3 percent to be normal; 46.4 percent and 50.9 percent to be elevated; and 51.0 percent and 56.5 percent to be fluid overload, with 51 percent a marker for heart failure hospital readmission.

The data was published by Frontiers in Cardiovascular Medicine in an article titled 'Clinical Utility of Fluid Volume Assessment in Heart Failure Patients Using Bioimpedance Spectroscopy', and is available at: <https://bit.ly/2OtBHOb>.

Impedimed said the study showed that 64 patients with heart failure had significantly higher HF-Dex values compared to 69 control subjects without heart failure ( $p < 0.001$ ).

The article concluded that "BIS-measured [extracellular fluid as a percentage of total body water] values were significantly higher in [heart failure] patients as compared to adults without [heart failure]".

The article concluded that describing three strata of extracellular fluid as a percentage of total body water - normal, elevated, fluid overload - might aid in clinical risk stratification and fluid volume monitoring.

Impedimed said that the interquartile ranges of HF-Dex values between the heart failure and control groups did not overlap with a range of 46.7 percent to 51 percent and 43.8 percent to 46.4 percent, respectively ( $p < 0.001$ ); and the HF-Dex values correlated with the size of the inferior vena cava, the largest vein in the human body.

Impedimed said that Sozo bioimpedance spectroscopy (BIS) could be used beyond fluid changes in heart failure patients, with other uses including emergency departments, risk stratification in heart failure patients at discharge from hospital, longitudinal management in clinics, and larger-scale assessment of at-risk heart failure populations.

The article's lead author, Dr Andrew Accardi, said that "while BIS technology has been validated for fluid monitoring, the lack of established reference ranges in heart failure has limited its effectiveness for workflow implementation".

Dr Accardi said the study showed the use of an HF-Dex scale differentiating normal from abnormal extracellular fluid and "identifying sub-clinical fluid overload would be valuable in risk factor stratification for heart failure patients in the acute and chronic settings".

Impedimed was unchanged at 12 cents with 3.4 million shares traded.

## VISIONEERING TECHNOLOGIES

Visioneering says it has raised \$1.174 million in an 'oversubscribed' share plan at 1.7 cents per Chess depository interest (CDI).

Last month, Visioneering said it hoped to raise \$1,000,000 in a share plan, following its \$22.1 million placement at 1.7 cents per CDI (BD: Feb 17, Mar 18, 2021).

Today, the company said investors in the share plan would receive one free attaching option for every two CDIs purchased, exercisable at 3.0 cents each by February 28, 2024.

Visioneering was up 0.1 cents or 6.7 percent to 1.6 cents with 7.1 million shares traded.

## IMMUTEP

Immutep says the US Food and Drug Administration has granted fast-track status for IMP321 for head and neck squamous cell carcinoma (HNSCC).

Immutep said the FDA granted fast track designation was based on “promising data” including from part C of its up-to 196-patient Tacti-002 trial of IMP321, or eftilagimod alpha, combined with Keytruda for cancers.

Last year, the company said part C of the Tacti-002 trial had treated 18 second-line HNSCC patients in stage one and 17 of 19 patients in stage two, with three patients showing complete responses and all lesions gone (BD: Nov 10, 2020).

Today, Immutep said the overall response rate for the 28 HNSCC patients in the Tacti-002 trial was about 36 percent, or about 44 percent in evaluable patients.

The company said the fast-track designation covered its development program for IMP321 for recurrent or metastatic HNSCC due to its potential to address an unmet medical need.

Immutep said fast-track status would provide access to more frequent communications with the FDA, potentially rolling review of its biologic licence application once submitted, and possible eligibility for accelerated approval and priority review for IMP321 for HNSCC.

The company said it planned to begin a phase IIb ‘Tacti-003’ trial of IMP321 and Keytruda for HNSCC in “mid-2021”.

Immutep was up 5.5 cents or 12.5 percent to 49.5 cents with 13.6 million shares traded.

## PHARMAUST

Pharmaust says it has received \$755,595 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Pharmaust said the rebate related to expenditure for the year to June 30, 2020.

Pharmaust was unchanged at 10.5 cents.

## UNIVERSAL BIOSENSORS

Universal Biosensors has requested a trading halt “pending [the] execution of certain definitive agreements”.

Trading will resume on April 9, 2021 or on an earlier announcement.

Universal Biosensors last traded at 47.5 cents.

## RESAPP HEALTH

Resapp has requested a trading halt “pending the release of an announcement regarding a capital raising”.

Trading will resume on April 12, 2021 or on an earlier announcement.

Resapp last traded at 6.8 cents.

## IDT AUSTRALIA

Sydney’s Credit Suisse Holdings says it has ceased its substantial shareholder in IDT, having become substantial, last month.

In March, Credit Suisse said it become substantial in IDT with 14,535,683 shares or 6.05 percent of the company, later reducing to 12,032,052 shares (5.01%) (BD: Mar 26, 2021).

Today, Credit Suisse said it bought and sold shares between March 29 and April 1, 2021, with the single largest sale 761,234 shares for \$374,348 or 49.2 cents a share.

IDT fell 5.5 cents or 13.1 percent to 36.5 cents with five million shares traded.

## RESONANCE HEALTH

Resonance says it has appointed Nick Allan to replace chief financial officer and company secretary Agha Shahzad, effective from May 31, 2021.

Resonance said that Mr Shahzad would resign after 12 years with the company, including more than three years as chief financial officer and company secretary.

The company said that previously Mr Allan was the chief financial officer and company secretary at Schrole Group, and an analyst for JP Morgan and a corporate advisor for Ernst & Young and Deloitte Corporate Finance.

Resonance said director Mitchell Wells had been appointed company secretary for the transitional period to May 31, 2021, after which he would return to his board position.

Resonance was unchanged at 19.5 cents.

## BIONOMICS

Bionomics says it has appointed Suzanne Irwin to replace interim company secretary Adrian Hinton, effective immediately.

Bionomics said Mr Hinton would continue with the company as acting chief financial officer, having assumed the interim company secretary position following the death of legal counsel and company secretary Jack Moschakis (BD: Mar 24, 2021).

The company said Ms Irwin had 13 years of company secretary experience with EQ Resources and ERM Power and had previously worked for BHP mining.

Bionomics fell half a cent or 2.4 percent to 20 cents.