



In this edition of the Pharma & Biotech Movers & Shakers, we highlight 5 stocks that were on the move in September.

## **Biotron Limited (ASX: BIT)**

Bitron shares were the best performing shares in the Pharma & Biotech coverage universe in September, with the share price up 134.5% for the month after the company announced that it was in the final stage of its phase-2 trials for HIV-1 and COVID-19 in a shareholder letter on 26 September 2023.

The Company stated - "Biotron expects to have data from three such trials available in the very near term, which puts the Company in a very strong position. These data, if positive, will be central to successfully negotiating and completing a commercial transaction for the Company's HIV-1 and COVID-19 clinical programs."

The Company currently has a number of different pharmaceuticals in trials. Its leading candidate is BIT225, which is a unique anti-viral drug combining different anti-viral activities to improve immunity. The two HIV-1 Phase 2 trials were designed to assess the impact of BIT225 on immune biomarkers in two groups of HIV-positive individuals. The HIV drug market is significant, estimated to be ~US\$30 billion in 2021 with the market expected to grow to around US\$50 billion by 2030.

The drug also has further implications, with initial assessments showing that the drug has anti-viral activity against COVID-19. BIT225 reduced levels of SARS-CoV-2 in mice with treated mice not developing any signs of disease and remained healthy throughout the studies that were conducted.

The market is feeling positive regarding the outcomes for the trials with the share price significantly strengthening in the days post the announcement and that momentum has continued into October. The release of the results from the trials will no doubt be a catalyst for the share price.

## **Neurotech International Limited (ASX: NTI)**

Neurotech International shares rallied through September as patient recruitment was completed for the Phase I/II clinical trial of NTI164 in the treatment of Rett Syndrome. Rett Syndrome is a rare genetic neurological and developmental disorder and is almost exclusively the result of a mutation(s) in the methyl CpG binding protein 2 (MECP2) gene located on the X chromosome, which is required for normal brain development and function. Rett Syndrome occurs almost exclusively in girls, with incidence of one in 10,000 female live births. Approximately 15,000 girls and women in the US and 350,000 globally have Rett Syndrome. According to the Company, there is currently no cure for Rett Syndrome and no approved therapies. Current treatments only address symptoms and provide support that may improve movement, communication and social participation into adulthood. The Company expects the results will be available in 1Q'CY2024.

The Company has a number of trials in progress for the use of NTI164 including a Phase II/III trial in Autism Spectrum Disorder (ASD) and a Phase I/II trial in Paediatric Autoimmune Neuropsychiatric Disorders Associated with

Streptococcal Infections (PANDAS) and Paediatric Acute-Onset Neuropsychiatric Syndrome (PANS).

During the month, the Company held a webcast and presentation which provided an update to investors regarding the trials in PANDAS/PANS. The stock rallied on the back of the presentation, finishing the month up 34%.

In the presentation the Company stated that all patients had voluntarily elected to move into the extension phase, which will last for 52 weeks. If positive, it would represent the first ever broad-spectrum cannabinoid therapy to show an effect in this population. Post month-end, the Company announced that the Phase I/II trial had met its primary endpoints with the trial drug proving to be safe with the treatment showing a 30% improvement in the overall symptoms of anxiety and depression. With regards to the severity of illness, all but one patient that were deemed markedly ill at baseline were reclassified as moderately ill at 12 weeks with an 18% improvement in the mean severity illness rating.

## **Proteomics International Laboratories Ltd (ASX: PIQ)**

Proteomics International is a medical technology company at the forefront of predictive diagnostics and bioanalytics. The Company specialises in the area of proteomics, the industrial-scale study of the structure and function of proteins. The share price was up 28% in September after the Company announced the Centres for Medicare & Medicaid Services (CMS) in the US had listed the PromarkerD predictive test for diabetic kidney disease and assigned a payment rate of US\$390.75.

Despite the listing in the US, the Australian Therapeutic Goods Administration (TGA) has decided not to include the test in the Australian register. This decision temporarily impacts the ability of the Company to sell its test in Australia but does not impact the international activities. The Company advised the decision by the TGA was due to there not being adequate clinical and analytical data from the new manufacturing facility. The Company is now considering its alternatives to address the items the TGA raised.

The news was well received by the market with a number of brokers increasing their price targets post the announcement.

## **Antisense Therapeutics Limited (ASX: ANP)**

Antisense Therapeutics is a pharmaceutical and drug company that is involved in the research and development of antisense pharmaceuticals in Australia. Its product pipeline comprises ATL1102, an antisense inhibitor of CD49d, which is in a Phase IIa clinical trial for the treatment of multiple sclerosis, Duchenne muscular dystrophy, asthma, and other inflammatory indications. The positive momentum from the end of August continued into September, with ANP's shares continuing to rise throughout the month with the share price up 13.3% in September.

During the month, the Company shared new data from a research collaboration investigating ATL1102 in the treatment of limb girdle muscular dystrophy R2. In a mouse model of LGMDR2, treatment with ATL1102 partially normalised the function and physiology of the calf muscles to those of healthy animals. "This promising work adds to the growing body of

data supporting a role for ATL1102 in muscular dystrophies,” commented Antisense CEO, Dr. James Garner.

Antisense Therapeutics also provided an update for the use of ATL1102 in the treatment of Long COVID. The Company has reported promising data that identified potential biomarkers of COVID and suggested the ability of ATL1102 to modulate aberrant immune cytokine responses in the patient group. The work is now subject to an international patent application for the treatment regarding the diagnosis and use of ATL1102 to treat subjects with cognitive deficits. The Company noted that the achievement concluded their work in the disease area for the time being as the Company focuses on the ongoing Phase IIb study in Duchenne muscular dystrophy, however the data and the intellectual property that has been created may create some opportunities for further work in this area at a future date.

### **Universal Biosensors Inc. (ASX: UBI)**

Universal Biosensors designs and develops electrochemical cells (strips) used in conjunction with point of use devices used in a range of industries including, healthcare, wine, food, and agriculture in Australia, the Americas, Europe, and internationally. Its primary products are Xprecia Prime and Xprecia Stride, which allow for the testing of various substances, including glucose, malic acid, SO<sub>2</sub>, and the next-generation blood coagulation analyser.

In recent months, the Company has announced a number of contract wins and approvals. In August, the Company announced it had won a tender to supply Xprecia Prime in Italy. The tender is for an initial two year period commencing Q4'23. The order includes more than a hundred Xprecia Prime devices and 130,000 strips. The sale paves the way for the product to be sold in other European countries, which bodes well for the Company.

In September, Indian drug administrators approved Xprecia Prime to be sold, with the first sales expected in CY23. The first order remains a small one, but hopefully proves to be a stepping stone to what is a relatively large market.

Post the month-end, the Company received finalisation of its Xprecia Prime 4U product, which is a self testing device to be sold by regulators in Europe. CEO John Sharman said – “The Patient Self-Testing market is the fastest growing PT/INR market in Europe and when combined with the use of PT/INR devices and test strips in hospitals and clinic, we estimate the market is worth \$365m pa. More importantly, many of the hospitals and governments will only award tender ‘wins’ to products that have the approval for patients to take the device home and test themselves.”

All of this paves the way for market penetration, and should see the Company through the next fiscal year, where it will continue to look to expand its sales channels.

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