INDEPENDENT INVESTMENT RESEARCH

Movers & Shakers - Pharma & Biotech

9 November 2023

It was a tough month for the Pharma & Biotech coverage universe with 73.2% of share prices for companies in the universe either flat or negative for the month of October. There were however a few shining lights. We highlight 5 stocks that experienced positive moves in October.

Dimerix Limited (ASX: DXB)

Dimerix shares leapt out of a trading halt on the news that Advanz Pharma had acquired the exclusive rights to register and commercialise DMX-200 for the treatment of Focal Segmental Glomerulosclerosis (FSGS) kidney disease in the European Economic Area, the UK, Switzerland, Canada, Australia, and New Zealand, following regulatory approval. Dimerix retains the rights in all other territories, providing the potential for further partnership agreements. Dimerix was the best performer of the coverage universe in October, with the share price finishing up 195.1% for the month.

Under the terms of the agreement, Dimerix will receive up to €138.5 million (AUD$230 million) in upfront and milestone payments, including (i) €6.5 million in an upfront payment; (ii) up to €132 million in potential milestone payments and (iii) tiered, escalating royalties of mid-teen to 20% on sales of DMX-200. Under the agreement Dimerix will continue to fund and execute the Phase III study and Advanz will be responsible for submission and maintenance of the regulatory dossier in licensed territories as well as sales and marketing activities.

FSGS is a rare disease that attacks the kidney's filtering units causing irreversible scarring that can lead to permanent kidney damage and eventual end-stage kidney failure, requiring dialysis or a transplant. FSGS affects adults and children as young as two years old with the average time from diagnosis of FSGS to the onset of complete kidney failure being five years. For those who receive a kidney transplant, ~60% will get re-occurring FSGS in the transplanted kidney. According to Insight Market Research, the number of people with FSGS in the US is ~80,000 and approximately 220,00 globally, with over 5,400 new cases diagnosed in the US each year. DMX-200 is an adjunct therapy, administered to patients already receiving an angiotensin II type I receptor blocker, which is the standard of care for hypertension and kidney disease. Dimerix has received Orphan Drug Designation for DMX-200 in both the US and Europe reflecting the limited treatment options available.

DMX-200 is currently in a Phase III study. The study is a multi-centre, randomised, double-blind, placebo-controlled study to determine the efficacy and safety of DMX-200 in patients with FSGS who are receiving a stable dose of an angiotensin II receptor blocker. The study is expected to involve a total of 286 patients over a period of 104 weeks in three parts with two analysis points. The first analysis is expected in March 2024. In the event the study shows a statistical meaningful improvement versus the placebo the trial will progress to Part 2 in which the Company may be able to potentially submit for conditional marketing approval in between the fist and final analysis release.

Noxopharm Limited (ASX: NOX)

Noxopharm shares were up 156.4% in October with the market reacting positively to the news that the FDA had granted Orphan Drug Designation (ODD) status to Noxopharm's CRO-67 drug candidate for the treatment of pancreatic cancer. ODD status may be provided to drug candidates that are being developed to specifically treat a rare disease, which is considered to be a disease that affects less than 200,000 in the US. ODD provides many potential benefits to pharmaceutical companies developing these drugs including:

- The potential for 7 years of market exclusivity in the United States following approval, or exemption from the application user fee if this is not needed;
- An exemption from FDA importation rules;
- Access to federal grants and tax credits for clinical research costs;
- The possibility of accelerated approval;
- Fee waivers, depending on the nature of the drug.

CRO-67 targets pancreatic cancer in a different way. The disease is especially difficult to treat because the tumours are surrounded by a dense barrier of cells that protects them from anti-cancer drugs, as well as from the body's immune system. CRO-67 seeks to kill cancer cells as well as barrier cells to improve outcomes.

The ODD comes after the Company presented the results from a study that involved human pancreatic cancer tumour cells implanted under the skin of mice. The mice were treated with CRO-67 for 21 days. At the end of the drug treatment, there was an average tumour reduction of 56.7% in the mice treated with CRO-67 versus the untreated mice. In addition to this, the rate at which the tumours grew was reduced by 48% in those mice treated with CRO-67 with the median doubling time for the tumours treated being 8.5 days in mice treated with CRO-67 compared to 4.4 days for untreated mice.

With pancreatic cancer expected to become the second leading cause of death in the US by 2040, and a 5 year survival rate of just 9% from the time of diagnosis, there is a significant need for novel treatments.

Biotron Limited (ASX: BIT)

The strong momentum for Biotron continued into October with the share price rising 47% after increasing 134.5% in September.

As reported in our previous edition of the Pharma & Biotech Movers & Shakers newsletter, the positive share price reaction was a result of the Company announcing to shareholders that it is in the final stages of its phase 2 trials for the use of its lead candidate (BIT225) for the treatment of HIV-1 and COVID-19.

In an investor presentation in October, the Company reiterated that the headline results were due in coming weeks with all patients recruited and dosing completed. The results of the trials are considered key to positioning of BIT225 for partnerships by the Company and therefore positive results will be a significant milestone for the Company.

The release of the results will be a catalyst for the share price with positive results likely to send the share price higher. Positive results may also offer the Company the potential to strengthen the balance sheet with the cash runway looking stretched at current cash levels.

Arovella Therapeutics Limited (ASX: ALA)

Arovella shares continued their positive momentum in October with the share price up 30.9% for the month. Arovella is the best performer of the coverage universe over the 12-months to 31 October 2023, with the share price up 196.7%.

During the month, Arovella announced the Company had entered into a global, exclusive license with Sparx Group to develop a world first iNKT cell therapy targeting a validated candidate, Claudin 18.2 (CLDN18.2) which is expressed in gastric cancers, gastroesophageal cancers and pancreatic cancer.

There are a number of products currently in clinical development for CLDN18.2. However, Arovella's CLDN18.2-iNKT cells will be the only CAR-iNKT product in development, providing a significant opportunity for the Company in the event the treatment provides improvement to the treatment of the targeted cancers.

The most advanced product in development is Zolbetuximab, which is expected to be the first available therapy targeting CLDN18.2 for the treatment of gastric and gastroesophageal cancers. Zolbetuximab is a monoclonal antibody that is expected to receive FDA approval in early 2024. Astellas Pharma acquired Zolbetuximab as part of its takeover of Ganymead Pharmaceuticals in 2016. Astellas Pharma has forecast peak sales of US$0.6 - 1.3 billion for Zolbetuximab.

The license payments include an upfront fee of AUD$300,000, payable in equity with shares issued subject to a 12-month escrow period. 4.35 million shares at $0.069 per share will be issued as compensation for the upfront payment. Arovella will also pay milestone payments in cash and equity for pre-agreed development milestones. The potential cash milestone payments total US$14 million, US$12.5 million of which is contingent of FDA approval.

The technology acquired by Arovella is still in the pre-clinical stages and therefore is a long way from approval, however early stage success of the products could result in the Company receiving some attractive offers given the unmet need associated with novel treatments for the targeted cancers.

Imricor Medical Systems Inc (ASX: IMR)

Imricor's share price increased 22.8% for the month albeit being a volatile month. Volatility was partially driven by the capital raising with the Company raising AUD$4.3 million through a share placement.

Investors outside the US purchased a total of 7,126,000 shares at A$0.50. These investors also received 10 year warrants to purchase a total of 1,781,500 additional shares at A$0.95 per shares. US investors purchased a total of 1,406,250 shares of Class A Common Stock at US$0.32 per share. US investors also received 10 year warrants to purchase a total of 351,563 additional shares of Class A Common Stock at US$0.60 per share.

In addition to the placement, the Company made a draw from the security subscription facility with GEM Global Yield SCS that was announced in July 2023. The funding facility is for up to AUD$30 million over the next three years which can be drawn in tranches at Imricor's discretion in consideration for new CDIs. The facility satisfies funding requirements that Imricor expects as it achieves milestones over the next three years.

Imricor is seeking to provide faster, safer and more effective treatments of cardiac arrhythmias through its products that allow for real-time MRI's for cardiac ablations, a procedure to stop abnormal electrical signals in the heart. The conventional treatment uses x-ray fluoroscopy. MRI provides the ability to provide real-time functional imaging in multiple views without ionizing radiation exposure. The Company has developed patented technology that allows it to be used while the patient is being scanned in the iCMR.

In late September, Imricor received approval to commence VISABL-VT trial in Germany. The Company expects patient enrolment will commence in 1Q'CY2024. The VISABL-VT trial is a prospective, single-arm, multi-centre investigation of the safety and efficacy of radio frequency ablation of VT associated with ischemic cardiomyopathy performed with the Vision-MR Ablation Catheter 2.0 in the iCMR environment. The study seeks to treat 64 patients and includes a six-month follow-up for each patient. The study is intended to support CE mark certification of the Vision-MR Ablation Catheter 2.0 for treating VT.

The global cardiac ablation market is valued at US$8 billion. The Company is seeking to progress sales of its products and progress the FDA approval process to enable it to be a meaningful participant in the market. Given the American College of Cardiology recommends that all catheterization laboratories adopt the principle of "ALARA", radiation doses to be used are "As Low as Reasonably Achievable", there is certainly a market for the Imricor technology.

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