

Movers & Shakers - Pharma & Biotech

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There were more negative performers than positive performers during the month of June in the Australian pharmaceuticals and biotech market, however there were still a number of companies that experienced significant share price movements. Below we take a look at a selection of companies, some that rallied strongly, while others experienced extreme volatility as news flow sent some stocks on the biotech roller coaster ride.

InvexTherapeutics Ltd (ASX: IXC)

IXC shares were up over 60% during the month of June, before finishing the month down 48%. The share price spiked on the news the company had received orphan drug designation by the European Medical Authority for Presendin in the treatment of moderate to severe Traumatic Brain Injury (TBI), however plummeted just days after when the company announced there was lower than expected enrolments for the IIH EVOLVE Phase 3 trial due to higher screening failures and slower site activations than expected. The trial is seeking to determined the efficacy of the company's primary drug candidate, Presendin, for the treatment of Idiopathic Intracranial Hypertension (IIH). The trial was initially targeting a total of 240 patients across 40 sites globally, with recruitment expected to take up to 24 months, however after seven months the company had enrolled just 13 patients with a total of 12 sites activated. The company had initially targeted to have the majority of the 40 sites activated and open to enrol by 30 June 2023. A total of 25 patients with IIH have been screened for potential enrolment, however there has been a higher than anticipated failure rate.

As a result of the delays, the company will seek to amend the trial design and is seeking the necessary approvals for the revised protocol. The revisions to the protocol are expected to require less patients (130 instead of 240), however will include a six month open label extension for patients, in which all patients will receive Presendin. The company is expecting the cost of the trial to remain unchanged, even with the change of protocol, with recruitment under the new protocol expected to accelerate due to an expected reduction in screen failures.

The company anticipated a cash balance of \$22.6 million as a 30 June 2023, with the company previously stating that it was fully funded to completed the Phase 3 trial through to registration, however further delays could impact the capital position of the company and require an additional capital raise, which is not optimal when the share price is trading near all-time lows.

Traumatic brain injuries and IIH, which the drug Presendin is primarily targeting, is around a \$1.5 billion market and is expected to grow to \$2.5 billion by 2030, growing at around 7% CAGR. The drug primarily acts to reduce the pressure around the brain of patients.

Vitura Health Limited (ASX: VIT)

Vitura Health, which recently changed its name from Cronos Australia (ASX: CAU), was one of the best performers for the month with the share price up 51.5%.

The company, which sells medicinal cannabis products, sold its 1.5 millionth unit through CanView, a distributor network, which is a part of Vitura's overall operations, and currently acts Vitura's distributor for its plant-based therapies. CanView primarily deals in prescribing, ordering, and dispensing solutions to Australian healthcare professionals, wanting to access plant-based therapies.

The Australian medicinal cannabis market according to Grand View Research, is expected to grow at around 30% a year, through 2030 to around \$400 million. Vitura currently has a significant market share in the industry, and its first-mover advantage should help it to maintain that advantage moving forward.

Beyond Australian shores, there remains significant opportunity in New Zealand, and Asian markets, with the likes of Thailand legalising cannabis increasingly. There are also prospects to expand into the U.S. and Canada, but it remains to be seen whether Vitura can capture those markets, which stands in the billions, with significant saturation already in the North American medical cannabis market.

Austco Healthcare Limited (ASX: AHC)

Austco, which is an IP-based nurse call system, was awarded multiple contracts through May and June, totalling \$11.4 million. Shares rose by 21.4% in June after the news came out of the latest contract. The contract is to supply Austco's Tacera alarm management and clinical workflow solution for the new 548-bed St. Pauls Hospital, to be built in Vancouver. The contract is the largest contract awarded to Austco and includes 1,110 full IP patient stations,1,200 clinical workflow terminals and Webservices interfaces for EMR and RTLS systems integrations. The share price is now up 70% over the 12-months to 30 June 2023.

Austco currently has four main products including Nurse Call, Mobile, Clinical Workflow, and Enterprise reporting. These products allow for cost-effective nurse calling solutions, emergency solutions, metric capture and reports under one system.

Revenue from customers grew by 15% in FY22 and EBIT came in at \$2 million. The momentum continued in the 1H'FY23, with the company delivering revenue from customer growth of 29% to \$20.5 million and software and services revenue growth of 47% to \$3.6 million. In late May, the company entered into an agreement to acquire Teknocorp, a communications hardware and software solutions provider and a certified reseller of Austco Nurse Call. The acquisition is expected to fast-tack the company's plan to build a direct sales capability in Australia. Teknocorp is expected to be EPS accretive with forecast revenues of \$9 million and \$1.1 million in earnings in FY23. New contracts secured, combined with the easing of supply chain issues and the Tecknocorp acquisition should see the company continue to deliver revenue growth in FY23 and beyond.

Oneview Healthcare PLC (ASX: ONE)

Shares of OneView continued their positive momentum, as news of further contracts came through. Shares were up 28.4% in June after the company signed a re-selling agreement with Baxter International to resell OneView's Care Experience Platform in the US market. Baxter International is an American healthcare company, that deals in acute, renal, hospital, and surgical care products.

The agreement is expected to add an additional 3,000-5,000 beds per annum to OneView's existing contracted book of ~15,000 beds. The agreement is for an initial two year period and provides OneView access to Baxter's network of beds, which currently constitutes around 75% of the 920,000 total beds in the United States.

The agreement with Baxter presents a significant opportunity for OneView, with Baxter having global sales of \$15.1 billion in 2022 with products sold across 100 companies.

The addressable market for electronic health records (EHR) and clinical information is substantial at \$47 billion, and the current addressable market for its main product 'BYOD' (bring your own device) standing at \$1 billion, OneView could realise significant gains in the market going forward, provided it maintains momentum.

Osteopore Limited (ASX: OSX)

Osteopore's shares were up over 60% during the month before declining sharply to finish the month up just 7.7%. The share price rallied on the back of the news of a collaboration, clinical research and implementation partnership with CellHeal with the primary objective to complete the necessary clinical trials required to secure Chinese regulatory approvals and proceed to commercialisation of Osteopore's regenerative technology in the Chinese market. The collaboration will focus on two projects utilising Osteopore's implant technology: (1) stem cells for dental applications; and (2) develop applications for tendon and cartilage regeneration. CellHeal will pay its own costs in connection with the research and development of the technologies, with the initial total cost estimated to be at least AUD\$4 million. Osteopore will own the IP rights developed in connection with the Dental Project, while the IP developed in connection with the Tendon and Cartilage Project will be jointly owned by Osteopore and CellHeal. If the necessary regulatory approvals are obtained, the technology will be distributed through CellHeal's distribution and pharmaceutical networks in China, Hong Kong, Macau and Taiwan.

After the exuberance from the announcement, the share price dropped sharply after news that the company had secured commitments for the shortfall from the recent non-renounceable entitlement offer, shares of which were offered at \$0.085, was released. A total of 10.69 million new shares were issued through the entitlement offer at \$0.085, which included 1 free attaching listed option for every 1 share subscribed for. The options are listed on the ASX with an exercise price of \$0.225 and an expiry of 24 April 2026. The capital raised will be used to facilitate expansion into international markets, bolster R&D initiatives and drive the production of 3D printed implants.

Osteopore is primarily involved in In-Situ Tissue engineering technology. Osteopore's technology harnesses the body's own regenerative capacity to regain lost tissue. The biodegradable implants used in a range of injuries break down by themselves over a term of 18-24 months and are replaced by the patient's tissue and bones.

Avita Medical Inc (ASX: AVH)

Avita Medical's shares jumped in June on the back of multiple news events. Avita's shares ended up 50.9% for the month, with the company being the best performer of the 156 companies in the coverage universe over the 12-months to 30 June 2023.

Avita Medical is a regenerative medicine company leading the development and commercialization of first-in-class devices and autologous cellular therapies for skin restoration. The US FDA approved the company's premarket approval (PMA) supplement for use of the RECELL system to treat full-thickness skin defects. The PMA supplement is on top of the original PMA approval of the RECELL System for the skin-graft treatment in September 2018.

Soon after the approval of the RECELL system for treatment of full-thickness skin defects, the FDA also approved RECELL for the treatment of Vitiligo, a disease that causes loss of skin colour in patches. The approval was based upon the company's trial, that evaluated the safety aspects of the drug for repigmentation of Vitiligo. According to Databridge, the Vitiligo market currently stands at around USD\$1.1 billion.

The CEO of AVH, Jim Corbett, commented that "RECELL represents first-in-class treatment for repigmentation through the delivery of normal, healthy skin cells. This is a breakthrough approval for AVITA Medical, significantly expanding the clinical applications for RECELL, and demonstrates our continued commitment to patient care. We look forward to offering a meaningful one-time treatment option for patients with stable vitiligo across the U.S."

In further news, the company was reinstated into the Russell 3000 index. The index measures the performance of the largest 3,000 companies in the US and should help the company gain exposure to investment managers, many of whom invest passively in the index.

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