INDEPENDENT INVESTMENT RESEARCH

Movers & Shakers - Pharma & Biotech

9 May 2024

Markets were more subdued in April after the strong start to the year. The S&P/ASX 200 Accumulation Index was down 2.9% and the S&P/ASX Small Ordinaries Accumulation Index was down 3.1%. The Healthcare sector was not immune with the S&P/ASX 300 Healthcare Accumulation Index down 2.3% in April. Despite the subdued markets there was a few companies in the Pharma & Biotech sector that experienced strong share price moves. Below we take a look at four companies whose share prices rallied during the month.

Mesoblast Limited (ASX: MSB)

Mesoblast was the best performer in the coverage universe in April, with the share price rising a further 78.4% after surging 88.1% in March.

The positive momentum in the share price is being driven by the meetings with the FDA which has reinvigorated the approval process for the pediatric use of Mesoblast's Remestemcel-L steroid-refractory acute graft versus host disease treatment. As was published in the previous edition of the Movers & Shakers - Pharma & Biotech newsletter, the company intends to file a resubmission for a Biologics License Application (BLA) in the June quarter which paves the way for potentially receiving approval in the 2H'CY24.

Remestemcel-L is being developed for the treatment for inflammatory diseases in children and adults including the treatment of acute graft versus host disease (aGVHD). aGVHD is a complication of an allogenic bone marrow transplant (BMT) that can potentially be life threatening. According to the Center for International Blood and Marrow Transplant Research, there are approximately 30,000 allogeneic BMTs globally per year for diseases including hematological cancers, with 25% of all cases in the pediatric population. Nearly 50% of all allogeneic BMT patients develop aGVHD. Liver or gastrointestinal involvement occur in up to 40% of all patients with aGVHD and are associated with the greatest risk of death, with mortality rates of up to 85%. There is limited treatment availability meaning there is an unmet need for a treatment for this designation.

During the March quarter, the company shored up its balance sheet, completing the Placement and Accelerated Entitlement Offer that was announced on 4 December 2023. The company raised a total of $97 million under the offer with the company having cash of AUD$117 million (USD$76.4 million) as at 31 March 2024. In its quarterly cash flow report released in April, the company stated that the cost containment strategies and payroll reductions have been enacted enabling the continuation of Phase 3 programs while still achieving reductions in net operating cash spend. In the March quarter, the company had net operating cash spend of USD$11.7 million, down 28% on the pcp. The company is targeting a 23% ($15 million) reduction in net operating spend in FY24 compared to the pcp.

The market will now be eagerly awaiting the results from the BLA submission with the results likely to drive significant volatility in the share price. Mesoblast need a win on the board with regards to approvals, with the repayment of a $50 million debt facility commencing in November 2024 and being required to be paid back by November 2026.

EZZ Life Science Holdings Limited (ASX: EZZ)

EZZ"s share price was on the march in April with the share price rising 53.4%.

EZZ formulates, produces, markets and distributes health supplements under the EZZ brand and is an exclusive distributor of skin care products under the EAORON brand in Australia and New Zealand.

During the month, EZZ completed a private placement raising $854,100 with a strategic investor, Kingstone Capital Pty Ltd. The funds raised will be used to enhance distribution channels, targeting expansion into new markets including Korea, Japan and Southeast Asia. Shares in the placement were issued at $0.50, a discount to the share price prior to the announcement. The dilutive offering did not have a negative impact on the share price with the share price finishing the month at $0.89.

Revenues in 1H'FY24 were up 42.4% on the pcp to $21.7 million with the company reporting a Net Profit of $1.1 million, down 12.1% on the pcp. EZZ branded products represented 88% of revenue for the period. Gross margins declined marginally on the pcp but the main driver of the NPAT decline was from the increase in advertising and marketing expense which was up 51% on the 1H'FY23 period. The increase was attributed to the newly established social commerce distribution channels, such as Kuaishou and Pindodo, with the company expecting costs to reduce once the revenue from these channels stabilises.

The company expects revenue growth to continue with total sales from the three main marketplaces expected to be up more than 75% in 3Q'FY24 compared to the pcp and new products launched in this financial year are expected to contribute to revenue growth. Further to organic growth, the company is on the lookout for acquisition opportunities. With no debt and $12.1 million cash as at 31 December 2024, the company is well placed to take advantage of opportunities as they arise.

Recce Pharmaceuticals Ltd (ASX: RCE)

There was plenty of newsflow for Recce Pharmaceuticals during the month including a business update from the company. The share price saw a 50% increase closing the month at $0.66.

Recce Pharmaceuticals is a clinical-stage biotech company developing a new class of Synthetic Anti-Infectives to address the urgent global health problems of antibiotic-resistant superbugs and emerging viral pathogens. The main product candidate, RECCE327 (R327) is the worlds only synthetic polymer sepsis drug candidate in development.

The company is seeking to submit an investigational new drug (IND) application with the FDA in 2H'CY24 for the use of R327 to treat Urinary Tract Infections (UTIs). Completion of the Phase 1 clinical trial provided valuable data on the safety and tolerability of R327 that will be used as part of the IND application.

The FDA has awarded R327 Qualified Infectious Disease Product designation under the Generating Antibiotic Initiatives Now (GAIN) Act, providing Fast Track designation and 10 years of market exclusivity post approval.

In February the company announced it had signed an MOU with Indonesian biomedical company PT Etna Biotechnologies. The agreement is designed to facilitate late-stage clinical trials in Indonesia. More than 10% of Indonesia's adult population (19.5 million) have diabetes, a disease that can lead to higher probabilities of foot infections, urinary tract infections, and surgical site infections. A recent study showed that 15% of sepsis patients in Indonesian hospitals had suffered from Diabetes.

During the March quarter, the company received an R&D Advance of $11.18 million from Endpoints Capital. This comes after the company received an Advanced Overseas Finding awarded by the Australia government of $54.9 million of applicable R&D expenditure in December 2023, extending the R&D rebate to cover R&D activities undertaken anywhere in the world for a period of three years (1 July 2022 to 30 June 2025). The funding provided by Endpoints Capital is non-dilutive and extends the financial runway and facilitates the acceleration of the clinical programs.

PYC Therapeutics Limited (ASX: PYC)

PYC's share price was up 18.3% in April. PYC Therapeutics is a clinical-stage biotechnology company creating a new generation of RNA therapies to change the lives of patients with genetic diseases. The company utilises its proprietary drug delivery platform to enhance the potency of precision medicines within the rapidly growing and commercially proven RNA therapeutic class.

PYC Therapeutics is progressing 3 first-in-class drug candidates with the company seeking to provide clinical proof of concept for all candidates within 18 months.

During the month, the company announced the drug candidate for the treatment of Polycystic Kidney Disease (PKD) is progressing to human clinical trials after completion of the preclinical trials. GLP studies will commence in 3Q'CY24 with a regulatory submission expected to be made in 4Q'CY24 and human trials to commence in early 2025, subject to GLP studies and regulatory engagement. The company believes the product may be able to receive approval from the Phase 2 clinical trials depending on the data readouts.

PKD affects ~1 in every 1,000 people and is characterised by large numbers of cysts forming in patient kidneys. These cysts increase in size over time and ultimately destroy the kidney tissue resulting in renal failure with the majority of PKD patients requiring a kidney transplant as a consequence of the disease. ~95% of patients with PKD have no treatment options available. As a result, the FDA has outlined a pathway for a New Drug Application (NDA) to be submitted for the treatment of PKD following a Phase 2 clinical trial based on a surrogate endpoint. PKD represents a significant market, with an estimated market value of $USD10 billion.

During the March quarter, the company completed dosing in the third cohort of patients enrolled in the ongoing Single Ascending Dosing (SAD) study for Rentinitis Pigmentosa type 11 (RP11), a blinding eye disease in children. In April, the company announced the Safety Review Committee determined all 3 doses to be safe and tolerable opening up a pathway for the company to initiate a Multiple Ascending Dosing (MAD) study in 2Q'CY24 and continue escalating dosing in the SAD study to identify the dose at which RP11 patients derive maximum benefit from the drug candidate. Successful results from the trial are expected to lead to the initiation of a registrational trial in 2025 aimed at supporting a NDA in 2027, subject to endpoints being met.

During the month, the company received binding commitments for the full $74.6 million under the Accelerated Non-Renounceable Entitlement Offer announced on 14 March 2024. The funds raised will allow the company to deliver on the clinical program over the next 18 months.

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