Movers & Shakers - Pharma & Biotech

8 April 2024

The Pharma and Biotech market was relatively buoyant in March with 49% of share prices in the coverage universe increasing for the month. There was some significant news flow which resulted in a strong uplift in share prices for some companies. Below we take a look at four companies whose share prices rallied strongly during the month.

Osteopore Limited (ASX: OSX)

There has been a lot going on for Osteopore shareholders. In early March 2024, the company completed a share consolidation on a 15-for-1 basis which saw the shares on issue decline from 154.9 million to 10.3 million. The share consolidation was implemented to streamline the company's capital structure and to maximise growth opportunities and shareholder value.

Shortly after the share consolidation was complete the company announced a 10-for-1 Entitlement Offer to raise approximately $3 million. Shares were issued at $0.029 per share, a 94.4% discount to the closing price prior to the announcement with shareholders receiving one free attaching option for every 5 shares subscribed to. The Offer closed on 2 April 2024 with 97% take-up of the Offer resulting in 100.2 million new shares being issued raising $2.9 million (before costs). Funds raised will be used for working capital and sales and marketing activities. The funds provided a much need cash injection to the company.

The strength of the take-up of the Offer was unsurprising given on 27 March 2024, the share price rose 361.5% on the back of the company announcing that it had secured market approvals in Singapore and Vietnam to supply its orthopaedic products. Osteopore received regulatory clearance in these two markets for aXOpore, which includes a suite of off-the-shelf and customisable orthopaedic products for use in High Tibial Osteotomy (HTO) as well as general bone grafting procedures.

According to the company, more than 10% of adults in Singapore are impacted by knee osteoarthritis with the prevalence on the rise amongst 40-60 year olds.

The HTO market is expected to grow at a CAGR of 9.2% with procedures expected to reach 35,000 per annum in the Asia Pacific region by 2025. Further to this, bone grafting market procedures are expected to increase to 250,000 per annum in the region by 2025.

During the month, Osteopore also provided an interim update on the single-arm feasibility clinical trials being conducted in Australia for cranial and long bone reconstruction using polycaprolactone-tricalcium phosphate customised scaffolds. Each study aimed to recruit 5-10 patients, however the long bone construction trial has now been closed with the recruitment of only 2 patients with patient recruitment proving difficult. The cranial reconstruction trial is now complete with 9 patients participating. 3 patients have reached the post-surgery milestone of 24 months, 1 is at 18 months and 5 are between 1 and 9 months. The study has shown that the custom-made device is capable of restoring vascularity within the scaffold while directing bone regeneration when combined with the surgical technique of Regenerative Matching Axial Vascularisation (RMAV). The company will be using this data to apply for regulatory clearance as a custom made medical device by the TGA for use in Australia.

Osteopore reported revenue of $2.2 million for FY23 (December year-end), a 31% increase on the previous year, however continues to operate at a loss with a Net Loss of $4.9 million. With Operating Cashflow of -$3.7 million for FY23, the company will need to improve revenues or be required to undertake a further capital raising. Clinical trials continue in China with commercialisation in this market likely to get the market excited.

Mesoblast Limited (ASX: MSB)

Mesoblast shares surged in March finishing the month up 88.1%. The positive momentum has continued in early April with the share price up a further 55.9% to begin the month. The enthusiasm was driven by the announcement that the FDA has informed the company that available clinical data from the Phase 3 study appears sufficient to support submission of the proposed Biologics License Application (BLA) for remestemcel-L for the treatment of pediatric patients with steroid-refractory acute graft versus host disease. The company stated that on the back this advice from the FDA, the company intends to file the resubmission for the BLA in the June quarter.

It has been a long road to this point with the company burning through a mountain of cash to get here. There is no guarantee that the company's application will be successful, however the market appears optimistic that the chances are improved compared to previous submissions.

During the month the FDA also supported an accelerated approval pathway for rexlemestrocel-L for patients with end-stage ischemic heart failure with reduced ejection fraction and a left ventricular assist device. The feedback from the FDA followed the Type B meeting in February, in which the company presented results from the pivotal study.

The company completed the Placement and Accelerated Entitlement Offer that was announced on 4 December 2023 in March. The Entitlement Offer originally closed in December 2023, with the company raising $60.3 million through the Placement and the Entitlement Offer, falling short of the $97 million it was seeking to raise. In March, the company secured commitments for a further $36.7 million, primarily from existing shareholders, taking the total funds raised under the Placement and Entitlement Offer to $97 million. The company's directors, including the CEO and Chief Medical Officer, showed their support for the company subscribing for a large parcel of shares. Shares under the Placement and Entitlement Offer were issued at $0.30 per share, providing subscribers a sizeable return since the issue.

The capital raised shores up the balance sheet and comes amidst cost reduction and operational streamline strategies to support the clinical program and reduce cash outflows, which were $12.3 million in the December quarter. 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.

Race Oncology Limited (ASX: RAC)

Race Oncology shares experienced a significant uplift in March, with the share price up 67.1%. The uplift was driven by the announcement that the pre-clinical trials exploring the use of Bisantrene, both as a single drug and in combination with decitabine, as a treatment for acute myeloid leukemia (AML) had demonstrated anticancer activity in mouse models. Anticancer activity was shown in use of Bisantrene as a single agent in patient-derived AML cancer cells, with the drug showing significantly higher anticancer activity when used in combination with decitabine, the standard of care drug. The combination of bisantrene and decitabine showed significantly higher efficacy than either drug alone.

During the month, the company also announced the first current Good Manufacturing Practice (cGMP) batch of the bisantrene formulation, RC220, was complete and met the quality specifications for use in humans. The new formulation allows for the administration of bisantrene via peripheral vein (arm and leg) IV, improving the commercial viability of the drug. Once the remaining studies are complete, the company will be able to progress with the new formulation for in-human clinical trials, with trials expected to be able to commence in 2H'CY24.

In late 2023, the company provided an updated corporate strategy with a focus on clinical development in Australia and an expanded clinical program designed to establish the anthracycline cardioprotection and clinical effects of the m^6A RNA pathway using the new formulation (RC220) in a range of solid tumours. The company undertook a Bonus Options issue and Piggy Back Options issue to fund the expanded clinical program. One Bonus Option was issued for every twenty shares held. Bonus Options have an exercise price of $0.75 and expire on 4 June 2024. For every one Bonus Option exercised shareholders will receive three Piggy Back Options. Piggy Back Options have an exercise price of $1.25 and an expiry date of 29 May 2026. The options program seeks to raise up to $36 million. Approximately 2 million of the 8.15 million Bonus Options issued have been exercised with the options currently trading in-the-money, suggesting more options will be exercised. In the event the required capital is not raised from the options program, the company will likely have to come to market to fund the program.

Immuron Limited (ASX: IMC)

Immuron shares jumped sharply in March, after the company announced it will be seeking to progress Travelan to a Phase 3 trial on the back of the results from the Phase 2 trial. Interim topline results from the Phase 2 trial confirmed that a single daily dose of Travelan is effective in the prevention of Enterotoxigenic Escherichia coli (ETEC) induced moderate to severe diarrhea.

The Phase 2 trial demonstrated protective efficacy however the attack rate was much lower than planned. The intended attack rate for the study was 70%, with an actual attack rate of only 37% for the Placebo group. This means the study does not have sufficient evidence to appropriately detect a significant difference in moderate to severe ETEC-induced diarrhea in the Placebo group compared to the Treatment group.

The Phase 2 trial was funded by the US Department of Defence with the aim of evaluating a dosing regimen most suited to deployed US troops visiting developing countries. 60 subjects have completed the inpatient challenge component with last patient visits anticipated to commence in April with a final clinical report to be completed in 2H'CY24.

The interim results from the 60 subjects (30 patients in each group) included:

- ETEC-induced moderate to severe diarrhea was reduced by 36.4% in the Treatment group vs the Placebo group;
- There was a 55.6% reduction in the number of subjects with an adverse event in the Treatment group vs the Placebo group;
- An 83.3% reduction in the subjects in the Treatment group requiring early antibiotic treatment post challenge compared to the Placebo group; and
- No subject in the Treatment group required intravenous rehydration post challenge compared to 3 in the Placebo group.

Despite the low attack rate, the company believes the data set is sufficient and will proceed to hold an end of Phase 2 meeting with the FDA to discuss the pivotal Phase 3 registration strategy and planned clinical trials including recommended dosing to support a Biologics License Application (BLA) for Travelan as a prophylactic medicine for Travelers' Diarrhea.

Immuron is currently exploring non-dilutive funding opportunities for the proposed Phase 3 clinical trial, which is expected to involve two randomised, double-blind, parallel-group, placebo-controlled, studies with approximately 1,200 healthy adult subjects (600 subjects in each study) travelling to regions with high traveler's diarrhea risk, with subjects to receive either Travelan or placebo. In a recent presentation at the Coffee Microcaps conference, the company provided a base case annual revenue estimate of US$102 million in the US for Travelan.

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