Movers & Shakers - Pharma & Biotech

11 September 2024

Market were up slightly in August with the ASX All Ordinaries Accumulation Index up 0.4%, however the story was mixed between sectors. Energy was the worst performing sector with the ASX 300 Energy Accumulation Index down 6.2% for the month, while Financials was the best performer with the ASX 300 Financial Accumulation Index up 7.2% largely driven by the banks. The ASX 300 Health Care Accumulation Index was down 0.9% with the largest stock in the index, CSL, falling 0.8%.

For the Pharma & Biotech coverage universe, there were some significant gainers with 11 stocks in the universe increasing by more than 30% in August and 57 of the 149 stocks delivering a positive share price performance. Below we take a look at 5 Pharma & Biotech companies whose share prices rallied in August.

LTR Pharma Limited (ASX: LTP)

LTR Pharma was the best performer in the Pharma & Biotech coverage universe in August with the share price rising 145.8%. Since listing on the ASX in December 2023 to 31 August 2024, the Company has delivered a return of 840% on the offer price of $0.20 per share.

LTR Pharma is developing SPONTAN, a nasal spray treatment for Erectile Dysfunction (ED). The company is repurposing an existing drug that has been approved for the treatment of ED, Vardenafil.

The company intends to commercialise and sell SPONTAN in Australia and the United States initially, before expanding globally. The company also intends to develop a range of new nasal spray products both for the treatment of ED and new indications.

SPONTAN changes the route of administration of Vardenafil from oral delivery to intranasal delivery. In June 2024, the company reported interim results from the pivotal pharmacokinetic clinical study to evaluate the relative bioavailability of SPONTAN (5 mg) compared to Vardenafil tablets (10 mg) in 18 healthy males. Initial results showed SPONTAN achieved more rapid absorption and faster onset of action than Vardenafil and demonstrated a similar peak drug concentration at half the dose of the oral tablet.

In August, the company announced SPONTAN had been prescribed to its first patients under the TGA special access scheme, which allows health practitioners to access unapproved therapeutic goods for patients on a case-by-case basis. The use of SPONTAN under the scheme allows the company to introduce the product and gather real-world data.

The company also announced during the month that it had entered into a co-development agreement with Aptar Pharma for the commercialisation of SPONTAN in global markets. The agreement will combine LTR Pharma's development capabilities with Aptar Pharma's expertise in nasal spray technology and expertise with the US regulatory pathway. The terms of the agreement were not disclosed.

Phosphodiesterase type 5 inhibitors (PDE5-Is) are the most commonly prescribed first-line treatment for ED, however there is a high percentage of patients who are unresponsive and drop out of treatments. In a recent investor presentation, the company stated that PDE5-Is do not work for 30% to 35% of patients, providing an opportunity for new treatments in a market that is forecast to grow to ~US6 billion globally by 2028.

There are a number of milestones expected in FY25 including the clinical trial data from the pivotal trial in 1Q'FY25 and Pre-submission meetings with the TGA and FDA in 2Q'FY25. The outcome from these milestones will be catalysts for the share price.

PYC Therapeutics Limited (ASX: PYC)

PYC Therapeutics share price was up 48.9% in August. During the month, the company provided an update on the clinical trials for its drug candidate VP-001 for the treatment of patients with a blinding eye disease called Retinitis Pigmentosa type 11 (RP11). The trials include a Single Ascending Dose (SAD) clinical trial with an open-label repeat dose extension arm and a Multiple Ascending Dose (MAD). The clinical trials are designed to establish a proof of concept for VP-001 to progress to a registrational study in 2025.

The company has completed dosing in the SAD trial in 4 cohorts of patients with an SDA trial extension at the two higher doses and commenced the MAD trial. To date, the drug has been safe and well tolerated in the small cohort of patients treated in the Phase 1 trials with improvement reported in the vision in 2 out of the 3 patients after a singe dose of VP-001 at 30 microgram dose and 75 microgram dose was received providing the company confidence to move forward with planning for the registrational study.

RP11 is a childhood disease affecting 1 in 100,000 people which is caused by a mutation in 1 copy of the PRPF31 gene leading to a protein insufficiency in photoreceptor and Retinal Pigment Epithelial cells. VP-001 is designed to increase expression of PRPF31 back to unaffected levels.

VP-001 is the first drug candidate to progress to human clinical trials for RP11 and has been grated fast track status by the FDA. With an addressable market of more than $1 billion and no available treatment means success of the clinical trials and progress to approval would be significant for the company.

During the month, the company also announced that the FDA had granted Rare Pediatric Disease (RPD) designation for its drug candidate PYC-001, which seeks to treat a blinding eye disease called Autosomal Dominant Optic Atrophy (ADOA). ADOA affects 1 in 35,000 people and there is currently no treatment option available for patients with ADOA. The RPD designation means that if the drug is approved the company would be eligible for a Priority Review Voucher (PRV) providing the potential for additional value to the company.

The company had $66.9 million in cash as at 30 June 2024 providing over 4 quarters of cash runway at the current quarterly run rate with positive results from the clinical trials likely to trigger a capital raise.

EZZ Life Science Holdings Limited (ASX: EZZ)

EZZ's share price continued its positive momentum in August with the share price rising 43.0%, taking the 12-month share price rise to 325.6% to 31 August 2024, the third best performer over the 12-month period in the universe. This momentum has continued in September, with the share price continuing its march hitting new all-time highs.

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.

In August, the company announced it had launched four new products marking the entry into the functional foods category. The products are designed to meet the nutritional needs of both children and adults. The company will leverage its established omnichannel distribution network to launch the new products, specifically in China. The company stated that the functional foods category has seen significant growth in China, driven by increasing consumer awareness regarding the importance of nutrition.

In its FY24 results reported during the month, the company report record revenue of $66.4 million, up 78.9% on the pcp, and NPAT of $6.9 million, up 91.8% on the pcp. While no guidance for FY25 was provided by the company, further growth is expected from the recently launched new products as well as the expected launch of other new products in FY25. Further to this, the company expects to commence sales in the US in 2Q'FY25 after approval from the FDA for the distribution of its products. With $19 million cash, no debt and positive and growing operating cashflow, the company is well positioned to continue its growth aspirations.

Beamtree Holdings Limited (ASX: BMT)

Beamtree's share price rose 40% in August driven by the FY24 results released during the month and the FY25 outlook provided by the company.

Beamtree is a provider of AI decision support and data insights solutions for the healthcare sector. Annual recurring revenue (ARR) continued its positive trajectory with the company reporting ARR of $25.5 million for FY24, up 12% on the pcp. The company reported revenue of $27.6 million, up 21% on the pcp, with international revenue being a key driver of revenue growth. Management stated on the results call that there had been a step change in the size and scale of contracts, which IIR views as significant for the earnings growth of the company.

During the year, the company invested in product development aimed at enhancing the return on investment, product relevance and increased customer stickiness. The benefits of this and the leg work already done is expected to see the ARR accelerate in coming years with the company reaffirming its ARR target of $60 million in FY26.

For the upcoming financial year, the company will seek to continue revenue growth of 20%+ and improve margins by keeping a focus on making sure the cost growth is less than revenue growth. The company will continue to develop its operations in Australia, however growth is expected to be driven by the key international markets of Canada, UK and Saudi Arabia. A key market will be the UK with the company announcing it is working with the NHS Confederation to explore the formation of an NHS analytics and knowledge network to drive efficiencies.

If the company can deliver on its revenue growth aspirations and control costs, we would expect the company to continue to find support from the market.

Opthea Limited (ASX: OPT and NASDAQ: OPT)

Opthea's share price was up 36% in August with the company attending the H.C Wainwirght virtual conference during the month and the company set to be added to the S&P/ASX 300 Index in the September quarterly rebalance.

Opthea is a clinical-stage biopharmaceutical company developing novel therapies to treat highly prevalent and progressive retinal diseases, including wet age-related macular degeneration (wet AMD), the leading cause of vision loss in the elderly. The lead drug candidate, sozinibercept (OPT-302), is a VEGF-C/D inhibitor to be used in combination with standard-of-care anti-VEGF-A therapies to improve vision in wet AMD patients.

The company has progressed to full enrolment in its two Phase 3 trials with 998 patients enrolled in the COAST trial and 986 patients enrolled in the ShORe trial. The topline data readout from the COAST trial is expected in 2Q'CY2025 and for ShORe by mid CY2025. These readouts will be significant news for the company.

The current standard-of-care for wet AMD is monotherapy administration of anti-VEGF-A therapies, including ranibizumab, aflibercept and faricimab, as well as off-label use of bevacizumab. Despite offering vision benefits, many patients fail to achieve sufficient vision gains to resume daily activities such as driving and reading, and may experience further vision loss.

The company bolstered the balance sheet throughout the FY24 period with a number of capital raisings with US$207 million cash post the recent retail entitlement offer. The capital is expected to extend the cash runway through to the topline data readouts for the Phase 3 trials.

If the trial results are positive there is the potential for a significant market with the current treatments having multi-billion dollar markets.

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