Movers & Shakers - Pharma & Biotech

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In this edition of the Pharma & Biotech Movers & Shakers, we highlight 5 stocks that experienced significant share price moves, both positive and negative, through the month of August.

Lumos Diagnostics Holdings Limited (ASX: LDX)

After increasing 418% in the prior month, Lumos Diagnostics continued its positive momentum in August with the share price rising 75.4%. In July, the Company raised $5.4 million through an Institutional Placement and Share Purchase Plan (SPP), although only $0.69 million was raised from the SPP. 77.7 million new shares were issued at $0.07 per share. The capital raised was used to buy back the remaining Convertible Notes that were issued to Lind Global Fund II, LP (Lind) and SBC Global Investment Fund (SBC) and to provide additional working capital as Lumos prepares for the US commercial launch of FebriDx after the Company received FDA approval in July.

Lind had $1.05 million Convertible Notes and SBC had $825,000 Convertible Notes. Lumos Diagnostics made a cash payment of $825,000 to SBC and a cash payment of $750,000 combined with the conversion on 300,000 Convertible Notes resulting in the issue of 6,382,979 ordinary shares in Lumos at $0.047 per share.

During the month the company announced that it had received a core patent for its camera technology titled "Device for reading an IVD Assay". These readers are a critical component of new POC tests, as the company looks to automate, readings and quantification of results. The patent covers the use of the company's reader technology in the European and Japanese markets until 2036 and has already been granted in the United States and Australia. Additionally, the company signed an agreement to further expand the distribution of the FebriDx POC tests with Henri Schein's Medical business in the Netherlands. Henry Schein B.V. in the Netherlands, which is part of Henry Schein, Inc. (Nasdaq: HSIC), the world's largest provider of healthcare solutions to office-based dental and medical practitioners, will sell the FebriDx test to the company's customers throughout the Netherlands.

Firebrick Pharma Limited (ASX: FRE)

Firebrick Pharma was the second best performer in August, behind Lumos Diagnostics, with the share price rising 73.0%. Firebrick Pharma is a pharmaceutical company founded in 2012, with the mission of developing commercial nasal spray therapies for the common cold.

During the month, the Company announced Nasodine, the company's lead candidate, had reached its primary end-point for its Phase 2 COVID-19 trial, with the treatment achieving a reduction in viral load, of SARS-COV-2 over 4 days, and achieving 100% reduction by day 4 compared to 48% for the placebo. The study was conducted in South Africa and recruited 39 subjects, 23 of whom were culture-positive, and qualified for primary treatment.

Executive Chairman, Dr. Peter Molloy said "To put this in perspective, the treatment regimen ran over two and a half days and then on the fourth day, 100% of the Nasodine subjects were clear of virus."

The company is not planning further COVID-19 studies or intending to pursue regulatory approval for Nasodine use in COVID-19. However, it expects to continue to undertake research that extends the evidence for Nasodine as a therapeutic intervention for upper respiratory infections, especially the common cold.

The company reached a key milestone during the month for its Phase 3 trial of Nasodine as a treatment for the common cold. The company closed the trial having recruited 500 subjects. Results are expected to be delivered by the end of September, the release of which will no doubt be a catalyst for the share price, either positive or negative.

The Phase 3 trial commenced in May 2022 and is intended to support registration of Nasodine in Europe but could also allow existing licensees in New Zealand, South Africa and Philippines, to file for approval in their markets. Positive results may also help with the expansion of international partnering. The EU registration dossier is scheduled to be filed in January 2024.

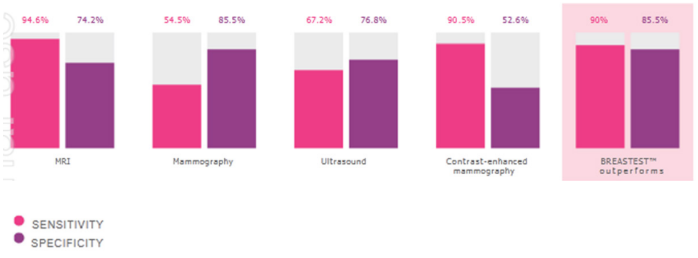
BCAL Diagnostics Limited (ASX: BDX)

BCAL Diagnostics is a cancer diagnostics company providing physicians and customers with proprietary detection and rule-out tests for Breast Cancer (BREASTEST). BCAL's shares experienced significant volatility in August, with the share price rising as much as 162.5% before finishing the month up 25%.

The share price reacted positively to the announcement of a breakthrough in diagnostic results from a Precion US study. The results showed a significant breakthrough and a path to commercialisation for the BCAL test, with a sensitivity of 90% and specificity of 85%. The results enables blood samples to be analysed in many commercial laboratories worldwide (using the BCAL test) fast-tracking market access and penetration. The US-based study was consistent with findings from earlier studies conducted in Australia, which used different mass spectrometry platforms.

There is currently no completely effective detection or rule out test available for breast cancer. The below shows how BREASTEST performed compared to current detection methodologies.

BREASTEST Results Compared to Existing Standards of Care



Source: BCAL Diagnostics Investor Education Presentation, 8 August 2023.

Jayne Shaw, Executive Chair of BCAL, commented - "These results are a major step towards making our test broadly available to patients and clinicians. We will continue to work closely with leading scientists and doctors as our science team further optimises the test to make it more cost-effective when it

is launched as a patient-friendly blood test for detecting breast cancer".

During the month, the company raised $2.4 million through a Placement issue of 24 million new fully paid ordinary shares at a price of 10 cents per share. In addition to the Placement, the company is also undertaking a Share Purchase Plan (SPP) at the same price as the Placement, to raise to $0.5 million (subject to the Board's discretion to accept SPP applications over $0.5 million). The proceeds raised will be used to progress BREASTEST towards commercialisation. The company is seeking to commercialise the product in 2H'CY24 with the initial roll out planned in Australia, followed by US, Europe and the broader Asia Pacific region.

Specifically, capital raised will be used for: (1) Clinical studies specifically directed to further strengthening data on the intended use of the test with the help of an international contract research organisation; (2) Building out BCAL's clinical services laboratory with equipment and staff to gain NATA certification of ISO15189 and NPAAC (National Pathology Accreditation Advisory Council), which is a prerequisite for BCAL's laboratory to undertake commercial testing; and (3) general working capital.

Botanix Pharmaceuticals Ltd (ASX: BOT)

Botanix Pharmaceuticals is a cannabinoid company committed to the treatment of novel dermatological and antimicrobial treatments. The company's share price continued its positive momentum, up 40.7% in August. The share price has risen over 137% over the 12-months to 31 August 2023.

The company has made significant progress throughout the year with the company continuing progress towards FDA approval of Sofpironium Bromide with approval targeted by the end of September.

In July 2023, Botanix Pharmaceuticals completed an agreement with Fresh Tracks Therapeutics, a clinical-stage therapeutics company that currently has several autoimmune and autoinflammatory drugs in its pipeline, to acquire the royalty and milestone payments for SB gel for US$8.25 million, resulting in all future financial obligations to be extinguished.

Botanix was obliged to pay Fresh Tracks US$4M on FDA approval of SB gel, US$4M if approval is extended to another indication (such as for personal use only palmar or plantar hyperhidrosis) and US$4M for approval in the UK or Europe. The Company was also obliged to pay sales milestones of up to US$160M which commence upon reaching the first US$75M of Net Sales, as well as royalties ranging from 12% to 20% on Net Sales from initiation.

The company raised $12.5 million in July, the proceeds of which will primarily be used to extinguish the future milestone and royalty payments to Fresh Track Therapeutics.

With the FDA review of SB gel expected to be completed in late September 2023, the company is positioning itself for the commercial launch of the product.

Mesoblast Limited (ASX: MSB)

Mesoblast is developing allogeneic (off-the-shelf) cellular medicines for the treatment of severe and life-threatening inflammatory conditions. Mesoblast share were among the worst performers in the month of August with the share price falling 55.5%. Shares sold off heavily after it was revealed the company failed to win the approval of the FDA on the second attempt. The company had attempted to get the FDA to reconsider its submission in February, of remestemcel-L, for children with steroid-refractory acute graft-versus-host disease (SR-aGVHD).

During the latest trial, the single-arm Phase III clinical trial (NCT02336230) for remestemcel-L in the paediatric population had met its primary endpoints, with an overall survival rate of 74% at 100 days and 68% at 180 days. The reworked information had substantial new information according to Mesoblast, including efficacy and biomarker information, but the FDA told Mesoblast it would require more data before proceeding. And, with the FDA previously requesting an additional trial, likely played an important part in the latest rejection.

Mesoblast's chief executive Silviu Itescu said: "FDA's inspection of our manufacturing process resulted in no observed concerns, the Agency raised no safety issues across more than 1,300 patients who have received remestemcel-L to date, and acknowledged improvements to our potency assay."

Since then, Mesoblast has clearly understood it will likely need a further trial to get approval. The company had $71 million in cash at June-end with an additional $40 million available to be drawn from a cash facility subject to certain milestones. The company raised US$88 million throughout the FY23 period. With no revenue and operating cash outflows of US$63.3 million in FY23, it will be interesting to see whether investors are prepared to stump up more cash if required.

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