Movers & Shakers - Pharma & Biotech

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In the July edition of Movers & Shakers, we highlight six stocks that experienced significant share price moves through the month, as important news flow came through.

Lumos Diagnostics Holdings Limited (ASX: LDX)

Shares of Lumos surged 1,490% early in July, as the company reported it had received approval from the FDA for its FebriDX system. Lumos Diagnostics is a medical technology company that deals in point-of-care (POC) diagnostic technologies. The stock ended up 418% for the month.

FebriDX is a point-of-care test to aid the diagnosis of acute bacterial respiratory infection and differentiation from non-bacterial etiology in patients presenting in urgent care or emergency care settings. The FDA determined that FebriDX had demonstrated substantial equivalence to the predicate device, and as a result cleared it for marketing in the US. In its investor presentation, the company stated that the device was cleared for sale in Europe, the UK, Brazil, Australia, and other markets as well. It should be noted the device had been initially rejected by the FDA, as it had not initially shown 'substantial' equivalence. On the back of the FDA approval, Lumos has commenced preparation for the launch of FebriDx in the US market. The company believes it will be in a position to received the first US commercial orders by the end of CY2023.

Following the announcement, the company proceeded to raise capital to buy back outstanding convertible notes and provide general working capital..The Company raised $4.75 million from an Institutional Placement through the issue of 67.9 million new shares at $0.07 per share. The Company was seeking to raise a further $4.75 million through a Share Purchase Plan (SPP) to eligible shareholders on the same terms as the Institutional Placement, however there was limited interest from shareholders with just $0.69 million raised from the SPP. The issue price of $0.07 per share was at an 18.6% discount to the closing price on the day prior to the capital raising announcement.

Lumos has a limited history as an ASX-listed company, listing in July 2021. While the shares surged in July, we note that at the July closing price of $0.057, the share price is still significantly below the $1.25 listing price.

Pacific Edge Limited (ASX: PEB)

Pacific Edge is a diagnostic company that offers a genetic biomarker-based suite of bladder cancer diagnostic tools. Pacific Edge shares increased sharply during the month after a delay in the implementation of the Local Coverage Decision (LCD). was announced. After rising as much as 188%, the stock ended up 68.8% in July.

In June it was announced that Medicare coverage for Cxbladder tests was to cease from 17 July 2023. This comes after it was determined Cxbladder tests are 'not considered medically reasonable and necessary', the threshold required for coverage under the US Social Security Act. Several other companies are also affected by the LCD. Should the LCD decision be implemented, the company expects that revenue will be significantly reduced. Medicare tests represented 60% of US commercial tests in the year ended March 2023 (FY23) and generated $15.3 million or 77% of total operating revenue for the FY23 period. The Company will now have the chance to put forward its case for the use of the tests during a 45-day notice and comment period, scheduled to close on 9 September, which will include an Open Public Meeting. The outcome of this process will no doubt result in some share price volatility.

As a result of the LCD, the company updated its billing policies for US testing. The Chief Executive Officer, Dr Peter Meintjes commented - "While the impact on demand for our tests in the US is uncertain, we expect the new approach to improve collections in the event of denial from any non-contracted insurer, including Medicare, and make some contribution to revenues after 17 July."

Invion Limited (ASX: IVX)

Invion is an Australian life-sciences company focused on transforming Photodynamic Therapy (PDT) for the treatment of cancers, atherosclerosis and infectious diseases. Invion shares doubled at one stage in July, before finishing the month up 50%, after a new patent was granted, for its Photosoft technology.

Photosoft is a PDT therapy, that works through photosensitising agents, activated by a specific wavelength, which in turn determines how far the light can travel into the body to address specific cancer types. The specific wavelength is shone on the cancer area, which then activates the reaction in the tumour. When exposed to specific wavelengths of light, photosensitising agents produce a form of oxygen that destroys cancer cells without damaging nearby tissue.

"The success in securing the patent in Australia is yet another key milestone for Invion ahead of our human trials later this year. It not only gives us an important edge in developing Photosoft™ as a standalone therapy but also in negotiating partnerships with global pharmaceutical groups to use the technology in combination therapies." "Importantly, the new Australian patent will support the international patent application that is currently being progressed through the other major markets globally, including the European Patent Office." – Invion CEO, Than Chiew

Invion is progressing towards clinical trials for its lead compound, INV043. The drug discovery work on both topical and intravenous (IV) formulations of INV043 have been completed, which will be used in the skin cancer and anogenital cancer trials. The company is progressing with the pre-clinical studies for the IV product that will be used in future solid tumour clinical trials. In addition to this, the studies are continuing using Photosoft on infection diseases and atherosclerosis with research partners.

In April, the company announced the expansion of exclusive rights to treat infectious diseases and atherosclerosis to the USA, Canada, and Hong Kong. The company paid RMW Cho Group (RMW), the licensor of Photosoft technology, $2.5 million for the expanded rights for infectious disease with an option to acquire further rights for atherosclerosis. Early studies have shown activity against a range of viruses, bacteria and fungi.

Mach7 Technologies Limited (ASX: M7T)

Mach7 specialises in innovative imaging software solutions, including providing solutions for enterprise diagnostics viewing, enterprise data management, enterprise PACS (picture archiving and communication system), and Teleradiology. Mach7 shares rose 33%, in July on the back of the news the company was selected for the Veteran's Health Administration's (VHA's) National Teleradiology Program (NTP). The company is set to provide VNA, eUnity, and Professional Services to VHA's NTP.

The VHA NTP is an in-house teleradiology service, which provides 24x7 service to VHA. The NTP services 125 sites across all 18 Veterans Integrated Services Networks (VISNs), and is projected to interpret between 1.0 and 1.5 million studies annually.

As it transitions off current contracts, the NTP is seeking the next generation of PACS that is designed, deployed, and optimised for its teleradiology. The NextGen PACS program involves two major phases. Phase I will see Mach7's VNA and eUnity viewer solutions form the core of NTP's NextGen PACS. Phase I has a 12-month implementation/professional service fee period then a fee per study subscription license over a three year term and has a potential total contract value (TCV) of $11.7 million. Phase II, which is contingent on Phase I, involves the expansion into the Veteran's Affairs hospital network adding a potential TCV of $47.9 million over a five year term.

The company reported its 4Q results on 31 July. The company received sales orders for the quarter of $3.2 million, taking sales orders for FY23 to $40.3 million, up 21% on FY22 and exceeding its target of $36 million. Meanwhile, the company is generating annual recurring revenue (ARR) of $17 million, slightly down on the March quarter ARR of $17.2 million. Management stated that the company had received $15 million in orders in the first month of the FY24. The company expects sales order growth of 20% in FY24.

Neurotech International Limited (ASX: NTI)

Neurotech International's share price rallied through the month of July finishing the month 40% higher. The company made a number of key announcements during the month. Neurotech International, a clinical-stage biopharmaceutical development company focused predominately on paediatric neurological disorders, received clearance for the commencement of the clinical trial for investigating the use of NTI164 in female Rett Syndrome.

As of 1 August, clinical trials had begun and the first patient was treated. Dr.Thomas Duthy, Executive Director of Neurotech International said - "On behalf of Neurotech we warmly congratulate our Principal Investigator Associate Professor Carolyn Ellaway, on commencing this important trial in Rett Syndrome which seeks to provide initial evidence on the safety and efficacy of NTI164 in this patient population." The trials are being held across 3 centres in Australia.

Rett Syndrome is a leading cause of intellectual disability, and there is an urgent need to provide safe therapies for the treatment of the disease. Rett Syndrome is a rare genetic neurological and developmental disorder and is almost exclusively the result of a mutation(s) in the methyl CpG binding protein 2 (MECP2) gene located on the X chromosome, which is required for normal brain development and function patients. It currently affects around 350,000 people globally.

NTI64 is a proprietary formulation derived from a cannabis strain and a novel combination of cannabinoids, including, BDA, CBC, CBDP, CBDB and CBN. Pre-clinical studies have shown the formula to have anti-proliferative, anti-oxidative, anti-inflammatory and neuro-protective effects in human neuronal and microglial cells.

The company had A$1.589 million in gross operating costs during the June quarter and had $5 million in cash as June end. It was not made clear what the cost of the trial might be, and it remains to be seen if cash is adequate to get the company through stage I/II of trials.

Doctor Care Anywhere Group PLC (ASX: DOC)

Shares of DOC finished up 27% in July, with the share price reacting to the June quarterly report. We note this comes after the company was trading at all time lows in June. DOC provides GP appointments, and other medical facilities such as prescriptions, through the telehealth model.

The company reported it had provided 190,000 consultations in the June quarter, up 32% YoY, and a 3% increase on a quarter-on-quarter (QoQ) basis. The company reported it had achieved its annualised revenue guidance of £43-£46 million for the year ending in June with the company targeting positive EBITDA and cash generation in 1Q'2024. The company recently sold off its Australian subsidiary GP2U making, the UK its main core market for the product.

DOC's shares have continued to slide from their high's in 2021. Downgrades to guidance and the CEO and founders resignation have added to the woes. Consensus estimates expect the company to generate a positive net income in FY24 with revenue expected to continue to grow over the coming financial years. The achievement of profitability will be a key milestone for the company and will no doubt be welcomed by shareholders.

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