

Movers & Shakers - Pharma & Biotech

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March witnessed plenty of movers and shakers in the biotech industry, with a number of key successes in trials, and others showing strong results, leading strong rallies from a number of biotech stocks. The biotech industry continues to perform well, and 2023 is expected to be another year where a number of key drugs come onto the market.

MGC Pharmaceuticals Ltd (ASX: MXC)

MXC has been rallying on the back of approval for ArtemiC, as a OTC (over-the-counter) drug in the US. The drug will be sold at US Pharmacy Management Benefit networks, from April 2023. The stock is up over 40%, since the announcement. ArtemiC already has 2 million units of order and has benefits that mostly relate to COVID-19. The benefits include the ability to prevent deterioration, achieve faster clinical improvements, and can reduce symptoms associated with COVID.

COVID has mostly disappeared, but is still here to stay as an ongoing disease, not too dissimilar to the flu. This means that COVID will continue to affect a certain amount of patients. The approval as an OTC drug means the drug will likely see global distribution. This leaves plenty of space for the drug to grow, and subsequently, be lucrative for MXC.

Neuren Pharmaceuticals Limited (ASX: NEU)

NEU stock was up 84.2% in the month of March. The stock has rallied on the back of approval of Trofinete for Rett Syndrome, which is expected to bring in significant revenue. The Company also has multiple Alzheimer's drugs that are showing positive results, and for Schizophrenia as well. The Company currently has NUPLAZID for Parkinson's, which is expected to provide \$500 million in annual sales. Clinical development continues across its various pipeline drugs, and significant progress is expected end of 2023.

Management has outlined that Rett Syndrom has the potential for US\$73 million in revenue and up to \$350 million in sales milestones plus royalties. The next milestone payment is US\$40 million, payable following the first commercial sale of trofinetide in the US, which is expected at the end of April 2023. Current estimates put the total number of those who are potential candidates for the Rett Syndrome drug range between 6,000 and 9,000 patients. Meanwhile, the Company potentially has another 55,000 patients in the US, with a potential of 200,000-250,000 patients globally.

NEU's pipeline drugs, and commercialised products, all are showing strong momentum, and the stock price continues to reflect that, as investors continue to assess the potential that NEU's product portfolio has.

ImpediMed Limited (ASX: IPD)

IPD's share price was up over 100% after a major validation from the NCCN (National Comprehensive Cancer Network). NCCN guidelines now state that bioimpedence spectroscopy is an objective measure to identify early signs of lymphoedema. IPD is set to benefit as the Company has the only FDA-cleared BIS technology for assessment of lymphedema, and the Company's SOZO, digital health platform, is broadly accepted for effective screening.

The new guidelines with be highly influential on physicians and clinicians and with the current market size around \$35 million which is expected to grow by 7%-8% p.a until 2029, IPD could see strong revenue's from the sector.

Botanix Pharmaceuticals Ltd (ASX: BOT)

BOT's shares rallied after submitting its anticholinergic/ antimuscarinic drug Sofpironium Bromide, which has just completed a mid-cycle review with the FDA. The drug is the first and only chemical entity, primary axillary hyperdhisos, associated with excessive sweating. The drug primarily works by blocking the sweat signals, by a binding mechanism. The market potential for the drug is expected to be around US\$2.8 billion by 2030.

The drug has already been approved in Japan, with their development partner, Kaken Pharmaceutical, receiving approval to sell it under the brand, ECCLOCk.

The Company also has a number of pipeline drugs including, a Rosacea drug, which has shown positive results in the 1b/2 stage of clinical trials, a drug for acne, which is at the end of phase-2, and atopic dermatitis and an antimicrobial drug entering phase-2 of trials.

The CEO commented that "In the US alone, there are approximately 7.3 million subjects who suffer from severe primary axillary hyperhidrosis which is the patient population in which the successful Phase 3 studies were conducted. Of those subjects, approximately 3.7 million subjects are actively seeking treatment. Even assuming a modest penetration of this population at the current price of competitive treatments (i.e., approximately US\$7,200p.a), this provides a significant market opportunity for Sofpironium Bromide."

Nova EYE Medical Limited (ASX: EYE)

EYE shares have been rallying on the back of clearance of its iTrack Advance device, which has been cleared for sale to surgeons in the US to treat glaucoma. EYE's shares were up as the news of its canaloplasty device came out, which appeals to a broad range of eye care specialists and surgeons.

"We've taken the original iTrack device and incorporated it into an ergonomic handpiece that allows surgeons to easily advance and retract the microcatheter through the canal," Dr Khaimi said. Dr. Khaimi is "confident that surgeons will adopt this device into their treatment algorithm, either as an adjunct to cataract surgery or as a standalone procedure."

Arovella Therapeutics Limited (ASX: ALA)

ALA, which is primarily concerned with therapies related to oncology and the central nervous system, has seen its shares rally 91% in this calendar year to 31 March 2023. The Company has multiple cancer-based therapies including immunotherapy drugs in the pipeline, which are based around killer T-Cells and Natural Killer cell therapies, and finally CAR (chimeric antigen receptor therapy).

The Company's share price has been rallying with half year results coming in better than expected and pipeline drugs are witnessing strong feedback during trials. The Company expanded the DKKI, a monoclonal antibody recently through a license agreement, to be used in conjunction with iNKT therapy. Immunotherapy products

are going to be quite lucrative moving forward, as physicians look for alternatives to traditional cancer therapies, making Arovella's prospects exciting.

Respiri Limited (ASX: RSH)

RSH is an e-Health company, which deals with respiratory health management. The stock has been rallying through March, as the e-Health SaaS company posted improved results with a loss of 0.03 cents. The company is primarily targeting the wheezing market, which remains relatively moderate in size and outlook, but the products remains largely uncontested, which is why the stock is receiving a lot of attention.

Immutep Limited (ASX: IMM)

After rallying up as much as 18.8% during March, IMM's share price finished the month up 8.3%. The Company continues to have strong results for its LAG-3-based drugs. Known as 'EFTI', the drug has shown to have significant clinical effectiveness, including more than doubling response rates over the likes of Keytruda, and currently has an effect on over 9 different types of cancer, where clinical results have been positive in stage-3, and for 2 types of cancer, the drug has reached late-stage results.

Anti-PD1 drugs hit US\$22 billion in sales globally in 2022, and continue to rise at a rapid pace. The inclusion of EFTI, in combination with treatment, should see significantly improved response rates, and therefore, the drug is likely to become a strong part of global cancer therapy. Furthermore, Anti-PDL1 therapy, which is part of the pipeline, should also see the strong response, as the Company looks to move to commercialisation. The potential total market opportunity for this drug is US\$7.6 billion.

The total market for both PD-1 and PD-L1 therapies is expected to hit a total of US\$85 billion in 2028, but could be even higher if the current costs of treatment fall significantly. This leaves plenty of opportunity for the likes of IMM to gain revenue from the sales of its products.

The Company is currently spending around AUD\$5 million - \$7 million in cash per year for its R&D activities and currently has around \$68 million in cash, leaving it plenty of cushion to bring its product to commercial use.

Radiopharm Theranostics Limited (ASX: RAD)

RAD has been rallying ever since the radiopharmaceutical company received approval for the its phase-1 trials, for its imaging drug, that will target pancreatic cancer. The Company has further rallied on the news that it will seek approval to list on the Nasdaq stock exchange.

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