Movers & Shakers - Pharma & Biotech

8 March 2024

Welcome to the first edition of Pharma & Biotech Movers & Shakers for 2024. Pharma and Biotech stocks started the year off with a bang with some big movers in the first few months of the year. Below we take a look at four stocks that have been amongst the best performers in the first two months of the new year.

Nyrada Inc. (ASX: NYR)

Nyrada was the best performing stock in the first two months of 2024, with the share price up 340.9% from 31 December 2023 to 29 February 2024. This was largely driven by the announcement on 28 February, in which the Company reported that NYR-BI03, the Company's lead brain injury program, had demonstrated a significant neuroprotective signal providing evidence of efficacy in the preclinical study. Nyrada's brain injury program is seeking to develop therapies to reduce the long-term disability associated with stroke or traumatic brain injury (TBI) by limiting the progressive cell death that occurs as secondary brain injury.

NYR-BI03 is a first-in-class therapy with a novel mechanism of action which limits secondary brain injury that occurs following a stroke or TBI. NYR-BI03 has been developed to selectively block Canonical Transient Receptor Potential (TRPC) ion channels which are over-activated during brain trauma, causing calcium overload leading to brain cell death. At present, there are no FDA-approved drugs for the treatment of secondary brain injury.

The results from the preclinical study showed that a statistically significant (p.value 0.021) neuroprotection was achieved in those animals that received NYR-BI03 treatment. On average, NYR-BI03 therapy rescued 42% of the brain injury in the prenumbra region. All animals survived the treatment with no drug-related adverse effects reported.

The results from the preclinical study enables NYR-BI03 to progress to Good Laboratory Practice (GLP) studies, which are required to progress to in-human clinical trials. Subject to the successful completion of the GLP studies, the Company will seek to commence a Phase 1 human trial for NYR-BI03 in the 2H'CY2024.

On the back of the results from the preclinical study, the Company raised $1.755 million via a placement. The capital raised will be used for the GLP study and the Phase 1 trial. New shares were issued at $0.075 per CDI, representing a 16.7% discount to the share price prior to the raising. The capital raising adds to the $4.65 million cash on hand the Company had at 31 December 2023.

With over 13 million strokes per year globally and approximately 50 to 60 million new TBI cases per year and no effective treatment to prevent excitotoxicity (the process that leads to secondary brain death), there is a significant unmet clinical need.

Singular Health Group Ltd (ASX: SHG)

Singular Health Group's share price increased 268.4% in the first two months of 2024 on the back of a number of purchase orders.

On 11 January 2024, the Company announced it had received its first order for its 3Dicom software in the US. The order was for 5,000 annual licenses from TechWorks 4 Good on behalf of US Veterans. The order comes after the appointment of Charlie Golf One Solutions LLC (CG1) as a Master Distributor in the US, providing CG1 exclusivity over 5 nominated states in the US, initially.

The 3Dicom for Veterans initiative seeks to assist veterans with the transition from active service to civilian life. At present, personnel are provided with their medical records during service with CDs and doctors within the service able to retrieve medical records and images using the internal MSH-Genesis PACS system. However, upon discharge veterans are often unable to retrieve and share medical records and images except through requesting their medical records via CDs. The 3Dicom platform enables veterans to upload and share their medical records and images from their 3Dicom patient account for improved accessibility, portability and continuity of care.

The revenue generated from the order exceeds the total direct-to-consumer sales of the 3Dicom software in CY2023 of AUD$50,000 by more than 40%. The licenses purchased are being sponsored by stakeholders in the Miami-Dade veteran community and has received support from West Kindall Baptist Hospital and leading veterans services organisations. The Company sees the order as a small-scale pilot program, that if well received can be replicated across the US.

In February, the Company announced it had entered into a two year contract with Roseman University of Health Sciences with a binding purchase order for 50 3Dicom R&D licenses and 5,000 3Dicom patient licenses for a total value of AUD$150,000. The licenses will be used by college students and patients treated at Roseman University's medical school.

On the back of the purchase orders, the Company have commenced works to deploy a number of non-diagnostic artificial intelligence (AI) models into 3Dicom R&D to enable the rapid segmentation of CT and MRI models into a collection of individual anatomical structures that can be selected, added, removed, replaced and analysed. The addition of the AI models will expand on the existing 3Dicom rendering capability to enable users to selectively view and manipulate individual body parts or anatomical systems. By using real patient scans to enhance their understanding of anatomy and diseases, medical students will be better able to prepare for real-world medical cases.

The Company also boosted its balance sheet in February, raising $4.05 million through a placement to institutional, sophisticated and wholesale investors. 36.8 million new shares were issued at $0.11 per share. The capital raised will be used to accelerate the commercialisation of its software in the US on the back of recent sales and to fund some of the AI development.

Pharmaust Limited (ASX: PAA)

Pharmaust's shares were up 191.7% in the first two months of 2024 with developments in the Company's clinical program receiving a positive response from the market.

Pharmaust is focused on repurposing monepantel (MPL) for the treatment of human neurodegenerative diseases and cancer in dogs. MPL is a potent and safe inhibitor of the mTOR pathway. This pathway plays a central role in cell growth and proliferation

of cancer cells and degenerating neurons. The mTOR pathway regulates the cellular "cleaning process", where toxic protein is broken down into macromolecules to be reused. This process is disrupted in most neurodegenerative diseases, including motor neurone disease/amyotrophic lateral sclerosis (MND/ALS).

The Company has reached a number of milestones so far this year. In February the Company completed a Pre-IND meeting with the FDA with the FDA providing feedback and a pathway to potentially receive accelerated and full approval for the treatment of MND/ALS. The FDA confirmed that Pharmaust may receive accelerated and/or full approval from the Phase 2/3 clinical study, subject to demonstrating substantial evidence of effectiveness in the treatment of MND/ALS and an adequate database supporting safety. The FDA also advised there were no minimum requirements for the number of patients and study sites located in the US paving the way for a global Phase 2/3 clinical study. The Company will seek to use sites and patients in Europe and Australia to accelerate recruitment and allow for the Company to also apply for approval from European and Australian regulatory bodies.

The Company released the top line results from its Phase 1 clinical trial for the treatment of MND/ALS. Twelve participants were enrolled in the multicentre, open-label study. The treatment was found to be safe and tolerable with no does limiting toxicities experienced. A total of 56 treatment-emergent adverse events (AEs) were reported with only 3 AEs, all graded mild, considered possibly related to the treatment. Upon completing the study, all participants continued receiving MPL via a special access scheme and opted to enrol in a 12-month open-label extension study.

For all 12 patients (cohort 1 and 2), the estimated rate of decline was 39%, which equates to an additional life expectancy of 13.5 to 56.5 months. The study showed that the rate of disease progression may be slowed by 58% for the cohort of participants receiving the highest dose. This compares to the approved treatment for MND/ALS, Relyvrio, which provides 2 to 9 months additional life expectancy. Further to this, the analysis of biomarkers provided supplemental supporting evidence that MPL slows disease progression with a large reduction in cerebrospinal fluid neurofilament light chain (NfL), which is a measure of neuronal damage.

Pharmaust is seeking to commence a Phase 2/3 clinical trial in 3Q'CY2024. The Phase 2/3 clinical study will be a multicentre, randomised, placebo-controlled, adaptive clinical study evaluating the safety and efficacy of MPL in patients with MND/ALS over 48 weeks. The primary aim will be to assess the efficacy of MPL, as compared to placebo, on the progression of MND/ALS. This will be evaluated as a change from baseline disease severity measured by the ALS Functional Rating Scale-Revised (ALSFRS-R) total score and survival. An interim analysis will be performed at week 24, which would provide the potential to receive accelerated approval from the FDA.

There are a number of approved treatments for MND/ALS, however these drugs provide limited relief and limited slowing of disease progression. With an average life expectancy of just over 2 years from diagnosis and an expected increase in the incidence of MND/ALS of 70% by 2040, the potential to treat MND/ALS and slow progression in a meaningful way would represent a significant market opportunity.

Clarity Pharmaceuticals Ltd (ASX: CU6)

Clarity Pharmaceuticals share price has been on a positive run since late 2023. The share price increased 52.6% from 31 December 2023 to 29 February 2024 and is up 229.5% over the 12-months to 29 February 2024.

Clarity Pharmaceuticals is a clinical stage radiopharmaceutical company developing next generation products to address the growing need for better diagnostics and treatments in oncology through its Targeted Copper Theranostic (TNT) platform.

The Company has a strong balance sheet, with over $37.9 million in cash as at 31 December 2023. The addition of the RDTI of ~$10 million is expected to provide a cash runway into late 2024.

The Company has a number of ongoing clinical trials for its three core products, SAR-bisPSMA, SAR-Bombesin and SARTATE, each of which contain a different targeting agent and bind to different receptors that are present on different cancer cells.

In December 2023, the Company dosed the first patient in the Phase III CLARIFY trial. The trial is a non-randomised, open label trial that will include 383 participants. The aim of the trial is assess the diagnostic performance of ^{64}Cu-SAR-bisPSMA PET to detect prostate cancer within the pelvic lymph nodes. The CLARIFY study is investigating if delayed imaging allows for improved disease detection. The longer half-life of ^{64}Cu may not only allow the detection of additional cancerous lesions on delayed imaging, but also provide timely supply of product covering a broad geographic area and flexibility for the scheduling of patients.

According to the Company, currently approved diagnostic products have low sensitivity, meaning some lesions may remain undetected. Clarity's SAR-bisPSMA product was developed in response to this issue. The dual PSMA targeting agent and delayed imaging feature have the potential to improve product uptake and retention in prostate cancer lesions.

In February, the Company announced the initial results of the Phase 1/2 COBRA trial, which showed that the Company's SAR-bisPSMA is safe and effective in detecting tumours in prostate cancer patients with biocehmical recurrence. In trial participants where the standard of care imaging was unable to detect any lesions, up to ~60% had lesions identified by same-day ^{64}CU-SAR-bisPSMA imaging and up to 80% on next-day imaging, with high specificity.

The possibility of performing next-day imaging is a feature not available to currently approved PSMA-targeted PET products and unique to ^{64}Cu-based SAR diagnostics due to the optimal half-life of ^{64}Cu and the ability of the SAR Technology to prevent leakage of copper isotopes from the radiopharmaceutical in-vivo. The COBRA trial confirmed the benefits of delayed imaging in this patient group as more lesions and more patients with a positive scan were identified on next-day imaging. These results have seen the Company commence plans for a Phase III trial.

WHO IS IIR?

Independent Investment Research, "IIR", is an independent investment research house based in Australia and the United States. IIR specialises in the analysis of high quality commissioned research for Brokers, Family Offices and Fund Managers. IIR distributes its research in Asia, United States and the Americas. IIR does not participate in any corporate or capital raising activity and therefore it does not have any inherent bias that may result from research that is linked to any corporate/ capital raising activity.

IIR was established in 2004 under Aegis Equities Research Group of companies to provide investment research to a select group of retail and wholesale clients. Since March 2010, IIR (the Aegis Equities business was sold to Morningstar) has operated independently from Aegis by former Aegis senior executives/shareholders to provide clients with unparalleled research that covers listed and unlisted managed investments, listed companies, structured products, and IPOs.

IIR takes great pride in the quality and independence of our analysis, underpinned by high caliber staff and a transparent, proven and rigorous research methodology.

INDEPENDENCE OF RESEARCH ANALYSTS

Research analysts are not directly supervised by personnel from other areas of the Firm whose interests or functions may conflict with those of the research analysts. The evaluation and appraisal of research analysts for purposes of career advancement, remuneration and promotion is structured so that non-research personnel do not exert inappropriate influence over analysts.

Supervision and reporting lines: Analysts who publish research reports are supervised by, and report to, Research Management. Research analysts do not report to, and are not supervised by, any sales personnel nor do they have dealings with Sales personnel

Evaluation and remuneration: The remuneration of research analysts is determined on the basis of a number of factors, including quality, accuracy and value of research, productivity, experience, individual reputation, and evaluations by investor clients.

INDEPENDENCE – ACTIVITIES OF ANALYSTS

IIR restricts research analysts from performing roles that could prejudice, or appear to prejudice, the independence of their research.

Pitches: Research analysts are not permitted to participate in sales pitches for corporate mandates on behalf of a Broker and are not permitted to prepare or review materials for those pitches. Pitch materials by investor clients may not contain the promise of research coverage by IIR.

No promotion of issuers' transactions: Research analysts may not be involved in promotional or marketing activities of an issuer of a relevant investment that would reasonably be construed as representing the issuer. For this reason, analysts are not permitted to attend "road show" presentations by issuers that are corporate clients of the Firm relating to offerings of securities or any other investment banking transaction from that our clients may undertake from time to time. Analysts may, however, observe road shows remotely, without asking questions, by video link or telephone in order to help ensure that they have access to the same information as their investor clients.

Widely-attended conferences: Analysts are permitted to attend and speak at widely-attended conferences at which our firm has been invited to present our views. These widely-attended conferences may include investor presentations by corporate clients of the Firm.

Other permitted activities: Analysts may be consulted by Firm sales personnel on matters such as market and industry trends, conditions and developments and the structuring, pricing and expected market reception of securities offerings or other market operations. Analysts may also carry out preliminary due diligence and vetting of issuers that may be prospective research clients of ours.

INDUCEMENTS AND INAPPROPRIATE INFLUENCES

IIR prohibits research analysts from soliciting or receiving any inducement in respect of their publication of research and restricts certain communications between research analysts and personnel from other business areas within the Firm including management, which might be perceived to result in inappropriate influence on analysts' views.

Remuneration and other benefits: IIR procedures prohibit analysts from accepting any remuneration or other benefit from an issuer or any other party in respect of the publication of research and from offering or accepting any inducement (including the selective disclosure by an issuer of material information not generally available) for the publication of favourable research. These restrictions do not preclude the acceptance of reasonable hospitality in accordance with the Firm's general policies on entertainment, gifts and corporate hospitality.

DISCLAIMER

This publication has been prepared by Independent Investment Research (Aust) Pty Limited trading as Independent Investment Research ("IIR") (ABN 11 152 172 079), an corporate authorised representative of Australian Financial Services Licensee (AFSL no. 410381. IIR has been commissioned to prepare this independent research report (the "Report") and will receive fees for its preparation. Each company specified in the Report (the "Participants") has provided IIR with information about its current activities. While the information contained in this publication has been prepared with all reasonable care from sources that IIR believes are reliable, no responsibility or liability is accepted by IIR for any errors, omissions or misstatements however caused. In the event that updated or additional information is issued by the "Participants", subsequent to this publication, IIR is under no obligation to provide further research unless commissioned to do so. Any opinions, forecasts or recommendations reflects the judgment and assumptions of IIR as at the date of publication and may change without notice. IIR and each Participant in the Report, their officers, agents and employees exclude all liability whatsoever, in negligence or otherwise, for any loss or damage relating to this document to the full extent permitted by law. This publication is not and should not be construed as, an offer to sell or the solicitation of an offer to purchase or subscribe for any investment. Any opinion contained in the Report is unsolicited general information only. Neither IIR nor the Participants are aware that any recipient intends to rely on this Report or of the manner in which a recipient intends to use it. In preparing our information, it is not possible to take into consideration the investment objectives, financial situation or particular needs of any individual recipient. Investors should obtain individual financial advice from their investment advisor to determine whether opinions or recommendations (if any) contained in this publication are appropriate to their investment objectives, financial situation or particular needs before acting on such opinions or recommendations. This report is intended for the residents of Australia. It is not intended for any person(s) who is resident of any other country. This document does not constitute an offer of services in jurisdictions where IIR or its affiliates do not have the necessary licenses. IIR and/or the Participant, their officers, employees or its related bodies corporate may, from time to time hold positions in any securities included in this Report and may buy or sell such securities or engage in other transactions involving such securities. IIR and the Participant, their directors and associates declare that from time to time they may hold interests in and/or earn brokerage, fees or other benefits from the securities mentioned in this publication.

IIR, its officers, employees and its related bodies corporate have not and will not receive, whether directly or indirectly, any commission, fee, benefit or advantage, whether pecuniary or otherwise in connection with making any statements and/or recommendation (if any), contained in this Report. IIR discloses that from time to time it or its officers, employees and related bodies corporate may have an interest in the securities, directly or indirectly, which are the subject of these statements and/or recommendations (if any) and may buy or sell securities in the companies mentioned in this publication; may affect transactions which may not be consistent with the statements and/or recommendations (if any) in this publication; may have directorships in the companies mentioned in this publication; and/or may perform paid services for the companies that are the subject of such statements and/or recommendations (if any).

However, under no circumstances has IIR been influenced, either directly or indirectly, in making any statements and/or recommendations (if any) contained in this Report. The information contained in this publication must be read in conjunction with the Legal Notice that can be located at http://www.independentresearch.com.au/Public/Disclaimer.aspx. Readers of this report should have regard to our Financial Services Guide (FSG). which can be accessed at https://independentresearch.com.au/wp-content/uploads/2022/09/IIR-Financial-Services-Guide-_September-2022.pdf.