INDEPENDENT INVESTMENT RESEARCH

Movers & Shakers - Pharma & Biotech

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April continued to be a strong month for Australian pharma and biotech companies with a number of successful trials, and contracts, with potential for global expansion. Furthermore, strong results, and regulatory approvals for many companies, that are on the cusp of revenue gains, made for an interesting month in the sector.

4DMedical Limited (ASX: 4DX)

4DX is a lung imaging technology company that provides both imaging services, and SaaS services model for its XV lung medical ventilation services. The Company has been witnessing strong results with 1H'FY23 revenue surging 37%. The Company's share price surged on 5th of April, after the Company announced it had signed its first SaaS contract with University of Miami. The XV technology will be used for indications across a number of different diseases including COPD. The disease (COPD) provides significant opportunity, with the global market for the disease estimated to be around $22 billion, and expected to increase to $52 billion by 2030, according to Allied Market Research. Meanwhile, the respiratory imaging market size was $14 billion in 2022, and is expected to grow around 7%p.a. by 2030.

This means the SaaS technology could grow quickly on the back of recent contracts, and the Company could see significant revenue gains as we move through 2023, and into 2024. The technology remains a unique one, and with competition sparse, 4DX is well placed to take advantage of what is largely a wide open market. The expectation of this potential is clearly leading the stock to rally.

Cyclopharm Limited (ASX: CYC)

CYC is an innovative nuclear medicine company whose shares have been rallying through the year, as the FDA commences its 6-month review process for Technegas. Approval from the FDA will create an immediate addressable market of USD$180 million p.a. in the diagnosis of Pulmonary Embolism (PE). This excludes the potentially larger market for Technegas application for indications beyond PE, including the diagnosis and management of chronic obstructive pulmonary disease, lung cancer, asthma and long COVID. Technegas is currently available in over 64 countries, however the US represents the single largest market for Technegas.

The Company recorded revenues of $23 million in FY23, up 31% compared to the previous year. Europe and Canada represents the largest source of sales. US approval would provide the next stage for the Company's growth. Technegas has the potential to generate substantial revenue over the years.

CYC's product is clearly competitive. Post approval, which is looking likely, the Company should see significant uptake of its product, in turn leading to the share price continuing to rally.

The Company plans to provide imaging products beyond PE, for diseases such as COPD, which is also a multi-billion market. Management has indicated that it will continue to invest in a strong product cycle on the back of the initial release.

Kazia Therapeutics Limited (ASX: KZA)

KZA, an oncology-focused company, has seen its share price rally on the back of positive news flow. The Company recently received confirmation of listing qualification from Nasdaq. The Company had previously had compliance issues with the stock trading below $1 for 30 consecutive business days.

Beyond the Nasdaq news, the Company has been seeing positive news come out for its Paxalisib drug, which is in an adaptive Phase 2/3 of study. The potential for the glioblastoma drug remains highly positive, and should the Company get past phase-3, the market for glioblastoma remains wide open. Furthermore, the market is expected to grow 8%-9%p.a. until 2030, which means that if the drug were to get to market, the revenue potential is significant.

Another drug candidate is EVT801, which has similar properties to Avastin a well-known cancer inhibitor drug. The drug works by inhibiting VEGFR3, and would be used as an adjunct therapy to current cancer therapies. The potential for the drug in providing a wide range of immunoncology therapy, makes the drug, which is currently in phase 1 clcinal trials, potentially highly lucrative. It remains to be seen where how the drug trials will progress from here.

Telix Pharmaceuticals Limited (ASX: TLX)

TLX reached global sales of $100 million during the March quarter, driven by Illucix, a prostate cancer imaging agent, which is TLX's primary product. Sales were primarily driven by the United States, where the prostate cancer diagnostics market, which is valued at around $3 billion, is expected to grow to around $8 billion by 2028. On the back of FDA approval, Canadian health authorities also approved the product,which could lead to further global expansion.

"This heralds a new era of patient and physician access to gallium-based PSMA-PET imaging and marks an important new stage for Telix as we bring our first commercial product to market in the United States," - Dr. Christian Behrenbruch, Managing Director and CEO at Telix. "Improved imaging can provide physicians with the insights to determine the most appropriate treatment pathway and give patients in the U.S. access to a specific and sensitive imaging tool for the detection of prostate cancer throughout the body."

Anteris Technologies Ltd (ASX: AVR)

AVR is a cardiovascular focused company that primarily deals in heart valve technology, with its DurAVR first-in-class product. The Company's shares were on the move in April on the back of a strong of news flow. AVR's aortic valve device has the potential to deliver unique life-changing treatment for stenosis patients worldwide.

In late 2022, AVR received clearance from the FDA for a feasibility study for DurAVR to evaluate the safety and feasibility of the DurAVR THV system in the treatment of subjects with symptomatic severe native aortic stenosis. The FDA designated the heart valve as a Category B device, which permits the device to be sold during the study. The study will commence in early-2023 and pave the way for a clinical trial in 2024.

The Company raised $35 million from an equity fundraising initiative issuing 1.458 million shares at $24 each. The proceeds will be used for clinical development of the Company's 3D single piece aortic valve.

Furthermore, the Company received a utility patent from the US Patent and Trademark office for its heart valve technology. Finally, the Company struck a deal with v2medtech to create a novel heart valve repair, which requires minimal invasiveness.

Arovella Therapeutics Limited (ASX: ALA)

ALA shares were up 70.5% in April on the back of developments with the Company's iNKT cell therapy platform. ALA is one of the few companies globally developing an iNKT cell therapy platform and is the only company developing a CAR targeting DKK1-peptide.

Pre-clinical data on the Company's lead candidate, ALA-101 (CAR19-iNKT cells), indicated that ALA-101 has the potential to be a novel off-the-shelf therapy to treat CD-19 expressing leukemias and lymphomas. ALA-101 is dual targeting, with the cells targeting CD19 and CD1d. CD19 is an antigen expressed on B cells in leukemias and lymphomas and is a known target for CAR-T cell therapies, while CD1d is expressed on several tumour types including lymphoma and myeloma. In a mouse tumour model, ALA-101 showed an enhanced tumour killing response with the CAR19-iNKT cells resulting in a significant regression of tumour cells after three days while all other treatments observed tumour cell persistence. After 90 days, only mice treated with CAR19-T cells or CAR19-iNKT cells remained alive with 1.5x more mice treated with CAR19-iNKT cells remaining alive after 90 days. The results from the animal models were promising and provide the platform for ALA to progress to clinical trials.

ImpediMed Limited (ASX: IPD)

IPD's share price continued it's positive momentum in April after the National Comprehensive Cancer Network (NCCN) guidelines were updated and now recommend that survivors at risk for lymphoedema should be regularly screened for lymphoedema by symptom assessment, clinical exam, and, if available, bioimpedance spectroscopy. 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. SOZO has a range of different uses, including, a lymphoedema index, HF-Dex heart failure index, and numerous health-related measures for individual basal metabolic rate, fat-free mass, skeletal muscle mass, etc. The Company posted strong quarterly results, 25% growth in its core SaaS business, and an increase of 33% on its average monthly license fee. Management has indicated that the potential market for lymphoedema stands at around $2 billion in the US alone, and $10 billion+ globally. The Company saw its contract value increase by 34% YoY, on a constant currency basis, and 44%, in AUD. The Company now has a total contract value of $3.2 million and a revenue pipeline of $19.5 million.

Cardiex Limited (ASX: CDX)

CDX shares rose on the back of FDA approval for its CONNEQT Pulse vascular biometric monitor. The device includes the market-leading SphygmoCor. The device is expected to have significant clinical and consumer applications, allowing physicians to gain comprehensive insight into cardiovascular disease. The stand-alone nature of the device makes it far easier than the Company's previous device, and that should play a key role as it looks to expand. Heart disease diagnostics is a multi-billion dollar market globally, and the product could see significant revenue flow, once the product is rolled-out.

The CEO commented – "At the time of launch, there is no other vital signs monitor that provides the level of features, personalisation, or vascular health insights that will be available on the Pulse. This technology has the potential to truly revolutionise the way hypertension and vascular disease are diagnosed and managed in the future".

IDT Australia Limited (ASX: IDT)

In late March, IDT unveiled that its license has been upgraded to manufacture injectable medicine allowing the Company to make advanced therapies for clinical trials where there currently is a short supply. The updated licence unlocks a further $6 million in potential sales.

The CEO stated- "We have the opportunity to become the go to partner for clinical trials and expect to attract international pharmaceutical companies and researchers to undertake trials on Australian soil, which will contribute enormously to the growth of the Australian biotech industry."

IDT shares were up 32.8% in the month of April.

Pharmaxis Ltd (ASX: PXS)

PXS shares rallied as news came in that the Company will be adding a combination treatment arm to its Phase 2 trial of PX-5505 in myelofibrosis. The trials will be widened to include myelofibrosis patients already receiving a JAK inhibitor as a standard of care. The Company's latest presentation states that the patients in the current trial showed encouraging signs and tolerance for its drug, which is an alternative for those unsuitable for JAK inhibitors.

The PXS CEO stated - "The agreement with the FDA to expand the patient population in the ongoing phase 2 study to include those patients currently on a JAK inhibitor is an important step forward in realising the benefits of lysyl oxidase inhibition for all myelofibrosis patients and in maximising the commercial opportunity for PXS-5505. We are already in discussion with the existing trial site investigators who have welcomed the opportunity to extend the patient population for the study and anticipate significantly accelerated recruitment."

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