Biotech Daily

Monday January 24, 2022

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: MESOBLAST UP 1%; PATRYS DOWN 22%**

*** TELIX RAISES $175m; PLAN FOR $25m MORE**

*** AROVELLA RAISES $4.6m; PLAN FOR $1.5m MORE**

*** NUHEARA PLAN RAISES $1.1m; TOTAL $5.7m**

*** CYCLOPHARM EXPECTS REVENUE UP 22% TO $18m**

*** TELIX RECEIPTS UP 6% TO $4.1m**

*** USCOM H1 RECEIPTS FALL 51% TO $1.3m**

*** CLINUVEL: GERMAN INSURERS CONTINUE SCENESSE SUPPORT**

*** PATRYS RECEIVES $1.2m FEDERAL R&D TAX INCENTIVE**

*** 4D LUNG TRANSPLANTATION VALIDATION TRIAL**

*** ANTERIS: DURAVR TRIAL INTERIM RESULTS 'NO ADVERSE EVENTS'**

*** VISIONEERING ENROLS 1st CONTACT LENS TRIAL PATIENT**

*** LIVING CELL SIGNS $1.17m AGREEMENT FOR PIG TISSUE WITH NZENO**

*** ARGENICA COMPLETES ARG-007 TOXICOLOGY STUDY**

*** PATRYS: PAT-DX1 PURIFICATION DELAYS TRIAL 6 MONTHS**

*** RESAPP: DOCTORS ON DEMAND LAUNCHES RESAPPDX**

*** UK MHRA REGISTERS ADHERIUM FOR HAILIE MANUFACTURE**

*** RADIOPHARM $696k SCRIP FOR 3 'NANOBODIES' IP**

*** IMMURON TO ASX: 'VALIDATION, HOLIDAY EMAIL DELAYED NEWS'**

*** AUSTRALIAN ETHICAL TAKES 11.3% OF MACH7**

*** EMYRIA 1.1m DR KAREN SMITH SHARES, TATTARANG SHARES EGM**

MARKET REPORT

The Australian stock market fell 0.51 percent on Monday January 24, 2022, with the ASX200 down 36.3 points to 7,139.5 points. Just one of the Biotech Daily Top 40 stocks was up, 35 fell and four traded unchanged. All three Big Caps fell.

Mesoblast was the only BDI-40 company to climb, up one cent or 0.85 percent to $1.19, with 3.7 million shares traded.

Patrys led the falls, down 0.8 cents or 21.6 percent to 2.9 cents, with 78.2 million shares traded. Prescient and Telix lost more than 11 percent; Micro-X fell 10 percent; Imugene and Genetic Signatures were down nine percent or more; Resonance retreated 8.8 percent; Actinogen and Universal Biosensors fell more than seven percent; Amplia and Uscom lost more than six percent; Alcidion, Antisense, Impedimed, Kazia and Neuren fell more than five percent; Avita, Immutep, Pharmaxis and Starpharma fell four percent or more; Dimerix, Medical Developments, Next Science, Paradigm, Polynovo and Proteomics were down more than three percent; Opthea and Orthocell shed more than two percent; Cyclopharm, Emvision, Nanosonics, Pro Medicus and Volpara were down one percent or more; with Clinuvel, Cochlear, Compumedics, CSL and Resmed down by less than one percent.

TELIX PHARMACEUTICALS

Telix says it has raised $175 million through a share placement at $7.70 a share, and hopes to raise a further $25 million in a share plan at the same price.
Telix said the offer price was a 4.8 percent discount to the closing price of shares on January 19, 2022 and it intended to use the funds for its prostate cancer therapy program, expand its targeted therapies pipeline, and launch its Illuccix prostate cancer imaging kit.
The company said the share plan record date was January 21, it would open on January 31 and close on February 11, 2022.
Telix said Dr Christian Behrenbruch and Dr Andreas Kluge would each sell 2,000,000 shares, remaining the largest shareholders, with 22,675,000 shares (7.3%) each.
Telix said that Jefferies (Australia) Pty Ltd, Taylor Collison and Wilsons Corporate Finance were joint lead managers, with Becketts Lawyers as Australian legal adviser.
Telix fell 90 cents or 11.1 percent to $7.19 with 3.9 million shares traded.

AROVELLA THERAPEUTICS (FORMERLY SUDA PHARMACEUTICALS)

Arovella says it has commitments from investors for a $4.57 million placement at 3.8 cents a share and hopes a share plan will raise a further $1.5 million.
Arovella said that Merchant Funds had subscribed for $3 million in the placement along with “very strong support from institutional and sophisticated investors”.
The company said the 3.8 cents price was a 2.5 percent discount to the last traded price.
Arovella said that the funds would be used to progress development of its invariant natural killer T-cell therapy platform and DKK1-peptide targeting monoclonal antibody recently licenced from the Houston, Texas-based MD Anderson Cancer Center.
The company said Baker Young led the placement and had underwritten the share plan to $1.5 million with a sub-underwriting commitment from Merchant Funds for up to $750,000.
Arovella said the record date for the share plan was January 21, it would open on January 24 and close on March 9, 2022.
Arovella was up 0.2 cents or 5.1 percent to 4.1 cents with 5.3 million shares traded.

NUHEARA

Nuheara says it raised $1,067,200 of a hoped-for $3 million through a share purchase plan at 1.6 cents a share.
In December, Nuheara said it had commitments for a $4.6 million institutional placement and hoped to raise $3 million in a share plan (BD: January 16, 2022).
Today, the company said that the share plan took the total funds raised in the capital raising to $5.7 million.
Nuheara fell 0.1 cents or 5.9 percent to 1.6 cents with 7.9 million shares traded.

CYCLOPHARM

Cyclopharm says it expects a record sales increase for the year to December 31, 2021 up 19 percent to 22 percent to $17.5 million to $18.0 million.
Cyclopharm said that the unaudited accounts showed sales were driven “primarily by increased third party distribution agreements and achieved despite reductions in medical diagnostic procedures associated with the ongoing global Covid-19 pandemic”.
The company said that revenue from sales of Technegas generators and patient administration set (PAS) consumables for its lung imaging systems were “robust, slightly exceeding 2020 revenues, with unit sales of each also exceeding those of 2020”.
Cyclopharm said that Technegas service revenue “declined marginally over the period, with generator servicing continuing to be impacted globally by travel and access restrictions associated with the Covid-19 pandemic”.
The company said it had about $28 million in cash at December 31, 2021.
Cyclopharm fell three cents or 1.7 percent to $1.77.

TELIX PHARMACEUTICALS

Telix says that receipts from customers for the 12 months to December 31, 2021 was up 5.9 percent to $4,106,000 compared to the previous corresponding period.
In its Appendix 4C quarterly report, Telix said it had a cash burn for the three months to December 31 of $20,972,000, with cash and equivalents of $22,037,000 at December 31.
Separately, Telix said it had raised $175 million in a placement at $7.70 per share and hoped to raise a further $25 million in a share plan (see above).

USCOM

Uscom says that receipts from customers for the three months to December 31, 2021 was up 79 percent to $1.31 million compared to the three months to September 30, 2021.
In its Appendix 4C quarterly report, Uscom said that receipts from customers for the six months to December 31, 2021 fell 50.9 percent to $1,345,000.
The company said it had a cash burn for the three months to December 31 of $38,000, with cash and cash equivalents of $5,537,000 at December 31, 2021.
Uscom said that sales for the six months had been “impacted by the global Omicron Covid pandemic limiting access to hospitals and their purchasing systems”.
“Normal sales are anticipated to resume as the pandemic resolves and normal hospital business recovers,” Uscom said.
Uscom said that sales for the three months to March 31 2022 were “showing improvement but results will depend on the rate of pandemic recovery and the absence of a successive Covid variant or new widespread infectious pathogens”.
Uscom fell 0.7 cents or 6.7 percent to 9.8 cents.

CLINUVEL PHARMACEUTICALS

Clinuvel says it has a renewed agreement with German health funds for treatment and reimbursement of Scenesse for patients with erythropoietic protoporphyria.
Clinuvel said that the terms and conditions of the agreement with the German National Association of Statutory Health Insurance Funds were confidential.
Clinuvel fell 11 cents or 0.5 percent to $23.50 with 223,232 shares traded.

PATRYS

Patrys says it has received $1,188,581 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.
Patrys said the rebate related to expenditure for the year to June 30, 2021.
Patrys fell 0.8 cents or 21.6 percent to 2.9 cents with 78.2 million shares traded.

4D MEDICAL

4D Medical says it will conduct a 40-lung transplantation patient trial with Melbourne's Alfred Health to validate its XV imaging systems.
In a media release not published on the ASX platform, 4D said that 'Functional lung imaging in the assessment of severe lung disease for lung transplantation' or FIT study would examine patients with conditions including interstitial lung disease, severe chronic obstructive pulmonary disease (COPD), including emphysema and chronic bronchitis, pulmonary hypertension and cystic fibrosis.
The company said that its x-ray-based XV technology had scanned six of the patients "enabling insights gained through four-dimensional imaging to inform decision making by physicians and patients".
4D said the study was led by Monash University's Prof Greg Snell the Alfred Hospital's lung transplant service medical head.
4D managing-director Dr Andreas Fouras said that rejection and infection were "major risks in lung transplants" and 4D's non-invasive imaging had "the potential to enhance patient safety and surgical success".
The company said that some patients in the study would participate in two sub-studies where a second XV technology-enabled scan would be used to determine the value of interventions such as bronchodilators to dilate the bronchi and bronchioles, decreasing resistance in the respiratory airway and increasing airflow to the lungs.
4D fell four cents or 3.4 percent to $1.14.

ANTERIS TECHNOLOGIES

Anteris says 30-day follow up results of five patients in its 10-patient, first-in-human study of Duravr trans-catheter heart valve met or exceeded their study objectives.
Anteris said all five patients underwent the trans-catheter heart valve replacement procedure with no reported adverse events, with heart imaging reporting no clotting, and no heart rhythm disturbances due to the procedure.
The company also said that patients averaged a 20 percent increase from baseline in patient exercise tolerance, as measured by a six-minute walk test.
Anteris said this was a 170 percent greater improvement than observed in studies of other trans-catheter aortic valve replacement valves, indicating "a marked improvement in patients' functional status and exercise tolerance".
Anteris was up 10 cents or 0.6 percent to $17.10 with 96,728 shares traded.

VISIONEERING TECHNOLOGIES

Visioneering says it has enrolled its first of 144 near-sighted, healthy children for a trial of its Naturalvue Multifocal 1-day contact lenses for myopia progression control.
Visioneering said participants would be randomly assigned Naturalvue Sphere single vision contact lenses, as the control lens, or Naturalvue Multifocal contact lenses, as the test lens, with primary outcomes changes in refractive error progression and eye length over time.
The company said that it expected interim data by mid-2023, with longer-term results available mid-2024 and 2025.
Visioneering chief medical officer Dr Ashley Tuan said that with two billion myopic people in the world, and five billion expected by 2050, “now is a prime time for [the company] to be at the forefront of innovation, development, and clinical validation in this industry”.
“The results from [the trial] will allow us to have head-to-head comparison in terms of treatment effectiveness against other products that went through similarly designed multi-centered studies,” Dr Tuan said.
Visioneering chair Dr David Mazzo said the company hoped that the results would “convince greater numbers of practitioners and parents worldwide to use Naturalvue MF as a key part of myopia management".
Visioneering was up 1.5 cents or 1.6 percent to 94.5 cents.

LIVING CELL TECHNOLOGIES

Living Cell says will pay the Auckland-based NZeno up to $NZ1.25 million ($1.17 million) for pig tissue for a third trial of its NTCell for Parkinson’s disease.
In October, Living Cell said that Auckland’s NZeno would breed and maintain pigs to provide brain tissue for its third trial of NTCell in Parkinson’s disease (BD: Oct 26, 2021).
Today, Living Cell said it would pay $NZ250,000 a year for maintenance of the herd, as well as milestone payments of $NZ500,000 payable on regulatory approval and $NZ500,000 on trial completion and approval for commercialization.
Living Cell executive chair Prof Bernie Tuch said that securing access to NZeno’s herd was “a critical milestone as Living Cell progresses the next clinical trial of NTCell in Parkinson’s disease”.
The company said that following the trial, a 2.5 percent royalty up to $NZ2.5 million would be payable on gross revenue from all NTCell sales.
Living Cell said its planned clinical trial in Australia was “likely to be the first xeno-transplantation trial carried out in Australia”, pending approval from the Australian Therapeutic Goods Administration.
Living Cell was unchanged at 0.5 cents with 5.2 million shares traded.

ARGENICA THERAPEUTICS

Argenica says it has completed rat and non-human primate toxicology studies of ARG-007, informing a phase I trial dosing range for tissue death after stroke.
Argenica said it completed preliminary in-vitro geno-toxicity studies and it had begun pharmaco-kinetics and toxicity good laboratory practice studies, with safety studies to follow.
The company said it expected the results of the good laboratory practice studies by April 2022, with the first ethics and data package submissions at the same time.
Argenica fell nine cents or 10.5 percent to 77 cents.

PATRYS

Patrys says that purification of the fermentation process for PAT-DX1 resulted in less drug product than expected, delaying the first human study by six months to mid-2023.

Patrys said that that fermentation process yield for PAT-DX1 was “consistent with the … pilot production run” but purification resulted in lower drug product recoveries than expected, affecting good laboratory practice (GLP) toxicology studies, and in turn delaying the first human study by six months to mid-2023.

Patrys managing-director Dr James Campbell told Biotech Daily that the engineering run was a scale-up to take production of pharmaceutical ingredient from the existing 10 litres to 500 litres.

The company said that GLP toxicology studies must use drug product generated by the same manufacturing process that will be used for the planned phase I clinical trial, and it expected to reschedule the rodent and non-human primate toxicology studies to later this year.

Patrys said it was working with its contract development manufacturing organization (CDMO) to implement improvements for the large-scale purification process, with a further engineering run for PAT-DX1 to begin by July 2022.

The company said that non-GLP toxicology studies in non-human primates using available drug product would begin in the coming months.

Dr Campbell said the company was “clearly frustrated that the purification process did not perform as well as expected”.

“We have worked closely with our CDMO to identify and resolve the purification issues and are confident that the changes being implemented will improve the yield from this step”.

“This set-back to the timing of our PAT-DX1 program is material, but is offset by the significant advances being made with the PAT-DX3 manufacturing program and a range of business development activities,” Dr Campbell said.

RESAPP HEALTH

Resapp says Doctors on Demand has launched its Resappdx on the on-line tele-health platform.

In 2021, Resapp said it had signed a one-year agreement with Doctors on Demand for the use of Resappdx and Sleepcheck in tele-health services (BD: Jul 5, 2021)

Today, Doctors on Demand chief executive officer Kirsty Garrett said “Resappdx will help us to revolutionize the telehealth experience of our patients and clinicians by providing instant, diagnostic insights that previously would have required an in-clinic physical examination of the patient.”

“Resappdx will help our clinicians to appropriately diagnose more patients as part of their video tele-health consultation and importantly identify those patients who do need to be referred for urgent clinical review,” Ms Garrett said.

Resapp managing-director Dr Tony Keating said the partnership with Doctors on Demand would “significantly grow our real-world evidence for Resappdx in a tele-health setting, providing critical health economic data to support future reimbursement submissions in Australia and elsewhere”.

Resapp fell 0.1 cents or 1.7 percent to 5.8 cents.

ADHERIUM

Adherium says the UK Medicines and Healthcare Products Regulatory Agency has registered it as a manufacturer of its Hailie inhaler dose sensors.
Adherium said that while its Hailie product had Conformité Européenne (CE) mark, the MHRA registration provided access to the UK beyond its exit from the European Union.
Adherium chief executive officer Rick Legleiter said the UK was “an important target market for Adherium’s products, with over five million people currently receiving treatment for asthma and about 900,000 diagnosed with chronic obstructive pulmonary disease”.
Adherium fell 0.1 cents or 7.1 percent to 1.3 cents with 6.5 million shares traded.

RADIOPHARM THERANOSTICS

Radiopharm says it has paid Shanghai’s Nanomab Technologies $US500,000 ($A696,000) in shares to acquire three of its radio-pharmaceutical nano-particle patents
Radiopharm said the patents covered three nanoparticles targeting HER-2, a protein associated with breast cancer, TROP-2, a protein associated with triple negative breast cancer, and PTK7, a protein associated with multiple solid tumors.
Radiopharm said it had been using similar nano-particles, which were genetically engineered antibodies able to be labelled with radioactive isotopes to identify and treat tumors, under licence in its pre-clinical and phase I trials.
Radiopharm fell 1.5 cents or 4.1 percent to 35 cents with 1.1 million shares traded.

IMMURON

Immuron has told the ASX that a granted European patent only benefits the company once validated and an email notification was “buried” in Summer holiday messages.
Immuron said it was notified of the European patent grant on January 5, 2022, but announced the news on January 13, 2022.
The company said the patent and its validation was expected to be material.
“Whilst the patent itself was granted on January 5, 2022, the benefit … only arises once the patent is validated in the various European member states,” Immuron said.
“We were notified of the UK validation on January 18, 2022, the Spanish validation on January 14, 2022, and the other countries are in the process of being validated now,” Immuron said.
“Having said that, in this instance the email had been buried amongst a volume of correspondence in an account that was only being checked periodically over the year end-beginning break,” the company said.
Immuron said “the email was located several days after it had been sent”.
“To address this delay the company has taken steps to add email recipients to the notification process and we will in future have a draft announcement near ready to release,” the company said.
Immuron fell half a cent or 3.85 percent to 12.5 cents with one million shares traded.

MACH7 TECHNOLOGIES

Australian Ethical says it has increased its substantial shareholding in Mach7 from 24,003,622 shares (10.15%) to 26,871,450 shares (11.27%).
Australian Ethical said it bought the shares between September 9, 2021 and January 20, 2022, with the largest acquisition 500,000 shares for $381,028 or 76.21 cents a share.
Mach7 fell one cent or 1.4 percent to 71 cents.

EMYRIA

Emyria says its extraordinary general meeting will vote to issue 1.1 million shares to executive director Dr Karen Smith and ratify the Tattarang placement.

The company said Dr Smith was issued 550,000 shares on her appointment on December 6, 2021, with the second two tranches of 550,000 shares each, vesting 12 and 24 months after her reappointment as a director.

The company also said it would seek shareholder approval for the issue of 20,000,000 shares at 25 cents each and 10,000,000 options exercisable at 40 cents each to Dr Andrew 'Twiggy' Forrest's Tattarang, issued on November 24, 2021 using the company's placement capacity.

Emyria fell 2.5 cents or 5.9 percent to 40 cents.