Biotech Daily

Monday February 21, 2022

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: PROTEOMICS UP 7%; AMPLIA DOWN 12%**

*** MESOBLAST: '1st STEM CELL COLITIS COHORT SAFETY, BENEFIT'**

*** STARPHARMA H1 REVENUE UP 200% TO $1.9m, LOSS DOWN 19% TO $8m**

*** PHARMAUST H1 REVENUE UP 52% TO $1.7m, LOSS UP 48% TO $1.2m**

*** AROVELLA 'OVERSUBSCRIBED' PLAN RAISES $2m; TOTAL $6.6m**

*** ADHERIUM HAILIE CPT CODES RATES**

*** IMRICOR: MÜNSTER UNI HOSPITAL STARTS ICMR ABLATION SYSTEM**

*** VECTUS READY FOR 5th VB0004 DOSE COHORT**

*** RECCE: '500mg R327 SAFE, WELL TOLERATED'**

*** PHARMAUST APPOINTS ERGOMED FOR MONEPANTEL COVID-19 TRIAL**

*** GENETIC TECHNOLOGIES 'NATA, CLIA OKAY GENETYPE MULTI-TEST'**

*** CHIMERIC REQUESTIONS CAPITAL RAISING TRADING HALT**

*** COPIA TAKES 5.5% OF PROBIOTEC**

*** PERENNIAL TAKES 9% OF MEDADVISOR**

MARKET REPORT

The Australian stock market was up 0.16 percent on Monday February 21, 2022, with the ASX200 up 11.9 points to 7,233.6 points. Nine of the Biotech Daily Top 40 stocks were up, 25 fell and six traded unchanged. All three Big Caps fell.

Proteomics was the best, up nine cents or 7.2 percent to $1.34, with 183,711 shares traded. Nova Eye, Pharmaxis and Resonance climbed more than three percent; Neuren and Oncosil rose more than two percent; Mesoblast and Orthocell were up more than one percent; with Nanosonics up by 0.2 percent.

Amplia led the falls, down two cents or 11.8 percent to 15 cents, with 48,597 shares traded. Polynovo lost 7.2 percent; Imugene was down 6.7 percent; Avita, Compumedics, Cyclopharm, Prescient and Starpharma retreated more than five percent; Actinogen, Alcidion and Next Science fell more than four percent; Antisense, Emvision, Paradigm, Telix and Universal Biosensors were down more than three percent; Clinuvel, Cynata, Genetic Signatures, Immutep, Pro Medicus, Resmed and Uscom shed more than two percent; Medical Developments lost 1.1 percent, with Cochlear, CSL, Kazia and Volpara down by less than one percent.

MESOBLAST

Mesoblast says the first cohort of six in a trial up-to 48 patients of its mesenchymal stem cells for Crohn's colitis shows the treatment is safe and beneficial.

In 2020, Mesoblast said it had begun an up-to 48-patient, randomized, controlled trial of remestemcel-L for medically refractory Crohn's disease and ulcerative colitis, at Ohio's Cleveland Clinic with its mesenchymal stem cells "delivered by an endoscope directly to the areas of inflammation and tissue injury" (BD: Oct 22, 2020).

Today, the company said that "a single local delivery of remestemcel-L by colonoscopy resulted in rapid mucosal healing and disease remission in these refractory patients at high risk of progression to surgery".

The company said the data was presented at the Congress of European Crohn's and Colitis Organisation, February 16-19, 2022, by the trial's lead investigator Dr Amy Lightner and published in the Journal of Crohn's and Colitis.

The research paper, titled 'A Phase IB/IIA study of remestemcel-L, an allogeneic bone marrow derived mesenchymal stem cell product, for the treatment of medically refractory Crohn's colitis: A preliminary analysis.' has an abstract is available at: https://academic.oup.com/ecco-jcc/article/16/Supplement_1/i412/6513044.

The research paper said that the first cohort had four treatment patients and two control patients, and the seven reported adverse events, were not related to the investigational product.

The abstract said that in the treatment group the simple endoscopy score for Crohn's disease (SES-CD) dropped from 17 at baseline to 5 by three months, the Crohn's disease activity index (CDAI) from, 228 to, 200, and the fecal calprotectin from, 231 to, 67.

The paper said that in the control cohort, the SES-CD increased from, 15.5 to, 25, the CDAI increased from, 146 to, 158, and the fecal calprotectin increased from, 330 to, 505.

The abstract concluded that mesenchymal stem cells were "a safe alternative therapeutic for the treatment of medically refractory Crohn's colitis".

"Early data suggests improved clinical and endoscopic scores by as early as two weeks following [mesenchymal stem cell] delivery," the abstract concluded.

"Early data suggests improved clinical and endoscopic scores as early as two weeks following remestemcel-L delivery," Dr Lightner said.

Mesoblast said that the patients would receive a single dose of remestemcel-L at a dose of 150 million cells to 300 million cells or placebo at the time of colonoscopy.

Mesoblast chief medical officer Dr Eric Rose said the trial was "the first to evaluate local delivery of remestemcel-L directly into the inflamed colon, using objective endoscopic measures of mucosal healing, in patients with colitis who are at high risk of surgical resection of their colon".

Mesoblast was up two cents or 1.8 percent to $1.14 with 1.7 million shares traded.

STARPHARMA

Starpharma says revenue for the six months to December 31, 2021 was up 199.8 percent to $1,913,000 with net loss after tax down 19.0 percent to $8,449,000.

Starpharma said revenue came from sales of its Viraleze, anti-viral nasal spray in Vietnam, as well as its Vivagel for bacterial vaginosis, its Vivagel condom coatings, royalties, and research revenue from commercial partners.

The company said diluted loss per share fell 22.7 percent to 2.08 cents, with net tangible asset backing per ordinary share down 17.6 percent to 14 cents, and cash of $51,254,000 at December 31, 2021 compared to $70,274,000 at December 31, 2020.

Starpharma fell 5.5 cents or 5.3 percent to 98.5 cents.

PHARMAUST

Pharmaust says revenue for the six months to December 31, 2021 was up 52.1 percent to $1,680,173, with net loss after tax up 47.5 percent to $1,227,476.
Pharmaust said its revenue primarily came from its subsidiary Epichem's medicinal chemistry contracts and other activities.
The company said diluted loss per share was up 50.0 percent from 0.26 cents in the previous year to 0.39 cents for the six months to December 31, 2021, net tangible asset backing per share fell 13.0 percent to 1.67 cents, with cash and cash equivalents of $2,632,895 at December 31, 2021, compared to $3,594,871 at December 31, 2020.
Pharmaust fell 0.1 cents or one percent to 9.9 cents.

AROVELLA THERAPEUTICS (FORMERLY SUDA PHARMACEUTICALS)

Arovella says its share plan to raise $1.5 million at 3.8 cents a share is oversubscribed, it will be increased to $2 million and close early with the total raised $6.57 million.
In January, Arovella said it had commitments for a $4.57 million placement at 3.8 cents a share and hoped a share plan will raise a further $1.5 million (BD: Jan 24, 2022).
Today, the company said that with the plan expected to close on March 9, 2022, it had subscriptions for $2.5 million and would close the plan early, raising the maximum amount to $2 million and scaling back the over-subscriptions.
Arovella said the funds would be used to progress development of its invariant natural killer T-cell therapy platform and DKK1-peptide targeting monoclonal antibody.
Arovella fell 0.7 cents or 13.5 percent to 4.5 cents with 26.25 million shares traded.

ADHERIUM

Adherium says it has received reimbursement rates for its Hailie sensor for remote physiologic monitoring (RPM) and remote therapeutic monitoring (RTM).
Adherium said that under the current procedural terminology (CPT) code system the provider would be reimbursed about $US19 for the set-up of the remote monitoring systems, $US55.72 ($A77.34) for the supply of the Hailie device, $US50.18 for the first 20 minutes of monitoring or treatment management services and a further $US40.84 for each additional 20 minutes of monitoring or treatment, should that be required.
Adherium chief executive officer Rick Legleiter told Biotech Daily that Adherium was not the provider, the amounts were not necessarily cumulative and the set-up price was a once-only per patient cost.
The company said that the reimbursement rates for both RPM and RTM, published by the Centres for Medicare & Medicaid Services allowed for a "clear compensation pathway for physicians to remotely monitor respiratory patients prescribed Asthma and chronic obstructive pulmonary disease medications".
Adherium said that it was a "significant development for [its] business model when a reimbursement structure exists to utilize its Hailie sensors and services".
The company said the current Hailie sensors would be used for RTM monitoring respiratory therapy adherence and next generation sensors would be used for RPM with physiological parameters and automatically transmitted data to the healthcare provider.
Mr Legleiter said it was "the first time a set of CPT codes for remote therapeutic monitoring has been included in the physician fee schedule and it is an indication that some of the transformations in digital health policy initiated in response to Covid-19 are beginning to have some permanence in the US".
Adherium was untraded at 1.2 cents.

IMRICOR MEDICAL SYSTEMS

Imricor says that Germany's Münster University Hospital has performed its first interventional cardiac magnetic resonance (ICMR) imaging ablation procedure.
Imricor said the start of procedures at Münster University Hospital "makes it the fifth Imricor site actively performing procedures".
Imricor executive chair Steve Wedan said that "as restrictions ease, we are focused on initiating procedures across all our contracted sites, and this is our first step".
Mr Wedan said that the company had one team "finalizing the installation of our system at the Helios Hospital Berlin-Buch" while he was with another team at the Cardiovascular Institute of South Paris, where four procedures were performed during the week "illustrating the ramp-up of procedure volume that is possible".
Imricor fell 6.25 cents or 7.4 percent to 78 cents.

RECCE PHARMACEUTICALS

Recce says its third cohort of 10-healthy males in the phase I trial of intravenous R327 synthetic antibiotic at 500mg showed safety and tolerability.
Last month, Recce said that the second cohort of seven healthy males in the trial at 150mg showed safety and tolerability (BD: Jan 18, 2022).
Today, the company said that R327 at 500mg had no clinically significant changes in vital signs or adverse events associated with R327.
Recce chief executive officer James Graham said that Recce expected to start dosing cohort four of eight cohorts from 50mg to 16,000mg "in near weeks".
The company said the trial was expected to complete dosing by July 2022.
Recce was up 2.5 cents or 2.3 percent to $1.11.

VECTUS BIOSYSTEMS

Vectus says the trial safety review committee has approved the highest dose of VB0004 and a multiple ascending dose cohort.
Vectus said that the fourth of the five planned cohorts at 100mg in the single ascending dose of its first-in-human trial had been reviewed by the committee, which found "no adverse events … at any of the four doses of VB0004 studied to-date and the latest dose of 100mg has added materially to the therapeutic safety margin for VB0004".
The company said the trial was titled 'A phase I/Ib, first-time-in-human, single centre, double-blind, randomized, placebo-controlled, dose escalating study of the safety, tolerability and pharmacokinetics of single and repeat doses of VB0004 administered orally to healthy volunteers; and to patients with mild to moderate hypertension with low cardiovascular risk'.
Vectus said the prior doses were 2mg, 10mg and 30mg.
The company said it would proceed to the last cohort of 300mg VB0004, along with a food effect study and the first multiple ascending dose, of 10mg VB0004 a day for 14 days.
"This approval represents a significant milestone in VB0004's trajectory," Vectus said.
The company said that interim pharmaco-kinetic analysis showed that the maximum plasma concentration of VB0004 increased with the increased dose, time-to-maximal-concentration did not change, but the plasma half-life increased to 17 hours to 17.5 hours.
Vectus said that the preliminary data provided "further evidence that VB0004 will be amenable to once daily dosing, a desirable feature in medications for chronic conditions such as hypertension, heart failure, kidney failure and pulmonary fibrosis".
Vectus was up nine cents or 6.9 percent to $1.40.

PHARMAUST

Pharmaust says that it has appointed Ergomed Clinical Research to conduct an English trial of monepantel for Covid-19 disease.
Pharmaust said that the Guildford, Surrey-based Ergomed would test the effects of monepantel in individuals infected with severe-acute-respiratory-syndrome coronavirus-2 (Sars-CoV-2), the virus that causes Covid-19.
The company said that Ergomed had identified seven hospitals in five countries that had shown interest in testing the effects of monepantel on Covid-19 patients.
Pharmaust said that the initial endpoints being considered included the recommended dose for a phase II study, assessment of any adverse events, pharmaco-kinetics, time to sustained resolution or improvement of Covid-19 symptoms, time to progression of Covid-19 symptoms and reductions in Sars-Cov-2 virus in the blood stream.
Pharmaust chief executive officer, Dr Richard Mollard said he was expecting the completion of monepantel manufacture this week and its subsequent shipment for tableting.
“Accelerated tablet stability data are expected to be available in May 2022 followed by treatment of Covid-19 patients,” Dr Mollard said.
“Furthermore, with greater certainty now over the tablet stability we can provide clinicians and ethics with more precise start dates and will be ready to finalize trial preparations once the Ergomed feasibility exercise is complete,” Dr Mollard said.

GENETIC TECHNOLOGIES

Genetic Technologies says its Genetype Multi-test has Australian accreditation and US Clinical Laboratory Improvement Amendments approvals.
Genetic Technologies said that the Australian National Association of Testing Authorities had accredited the test and the US Centers for Medicare & Medicaid Services had provided the CLIA certification.
The company said the test provided a risk assessment for breast, ovarian, colorectal and prostate cancers, as well as coronary artery disease and type 2 diabetes.
Genetic Technologies said that the approvals would allow for the commercial launch of the Genetype multi-test for cancers in Australia and the US, with the “official first phase availability” of its Multi-test to health care professionals this week.
Genetic Technologies was up 0.1 cents or 20 percent to 0.6 cents with 42.4 million shares traded.

CHIMERIC THERAPEUTICS

Chimeric has requested a trading halt “pending an announcement in relation to a capital raising”.
Trading will resume on February 23, 2022 or on an earlier announcement.
Chimeric last traded at 20 cents.

PROBIOTEC

Melbourne’s Copia Investment Partners says it has become a substantial shareholder in Probiotec with 4,455,319 shares or 5.48 percent.
Copia Investment said that between December 31, 2021 and February 18, 2022 it bought and sold shares at prices ranging from $2.16 to $2.39 a share.
Probiotec fell six cents or 2.6 percent to $2.21.

MEDADVISOR

Sydney's Perennial Value Management says it has increased its substantial holdings in Medadvisor from 28,518,170 shares (7.55%) to 34,817,863 (9.21%).

Perennial said that between December 22, 2021 and February 17, 2022 it bought the shares on-market, with the single largest purchase 1,661,658 shares for $537,064 or 32.3 cents a share.

Medadvisor was up one cent or three percent to 34 cents.