Biotech Daily

Tuesday May 4, 2021

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH FLAT: IMPEDIMED UP 8%; AMPLIA DOWN 12%**

*** AMPLIA PLACEMENT RAISES $3.8m**

*** CLARITY: US FDA APPROVES PHASE I/IIa PROSTATE TRIAL**

*** RECCE: 'R327 KILLS 99.9% OF SIX PATHOGENS, IN-VITRO'**

*** IMPEDIMED: 'SOZO MEASURES HEART READMISSION RISK'**

*** USCOM DEVELOPS USCOM-O2, BASIC**

*** BOTANIX PLANS BTX1801 DIALYSIS TRIAL**

*** PALLA, M&A LEGAL ISSUES SETTLED, PRODUCTION BEGINS, LAUNCH**

*** MGC RECEIVES $996k ARTEMIC RESCUE ORDER**

*** TOTAL BRAIN, HAMPTONS LIFE $6m AGREEMENT**

*** RESAPP APPOINTS ILARA RESAPPDX KENYA DISTRIBUTOR**

*** MEDADVISOR REQUESTS 'FUNDING FACILITY' TRADING HALT**

*** MEDIBIO: US PATENT FOR MENTAL STATE ASSESSMENT**

*** MEMPHASYS PROF JOHN AITKEN WINS ANDROLOGIST GONG**

*** NUHEARA APPOINTS JOHN LUNA BUSINESS DEVELOPMENT MANAGER**

*** RON HOLLANDS REPLACES IQ3 4-MONTH CO SEC AYSHA HOLLINGDALE**

MARKET REPORT

The Australian stock market was up 0.56 percent on Tuesday May 4, 2021, with the ASX200 up 39.1 points to 7,067.9 points. Sixteen of the Biotech Daily Top 40 stocks were up, 16 fell and eight traded unchanged.

Impedimed was the best, up one cent or 8.3 percent to 13 cents, with 2.8 million shares traded. Next Science and Osprey climbed more than five percent; Oncosil was up 4.3 percent; Nova, Starpharma and Telix were up more than three percent; Immutep, and LBT rose more than two percent; Proteomics and Resmed were up one percent or more; with Clinuvel, CSL, Genetic Signatures, Medical Developments, Mesoblast, Neuren and Pro Medicus up by less than one percent.

Amplia led the falls, down 3.5 cents or 12.3 percent to 25 cents, with 493,342 shares traded. Actinogen lost 7.9 percent; Optiscan fell 4.4 percent; Imugene, Nanosonics, Opthea, Polynovo and Resonance shed two percent or more; Avita, Compumedics, Cyclopharm, Pharmaxis and Volpara were down one percent or more; with Cochlear, Kazia, Paradigm and Universal Biosensors down by less than one percent.

AMPLIA THERAPEUTICS

Amplia says it has raised $3.8 million at 23 cents a share in a private placement to institutional and sophisticated investors.
Amplia said the issue price was a 10.0 percent discount to the 15-day volume weighted price of shares traded to April 29, 2021.
The company said the placement was “strongly supported” by its largest investors Platinum Investment Management and Blueflag Holdings, with Acorn Capital joining the register.
Amplia said the funds would be used to enable activities for its phase II trials in pancreatic cancer and pulmonary fibrosis and provide working capital.
The company said Taylor Collison was the lead manager for the placement.
Amplia fell 3.5 cents or 12.3 percent to 25 cents.

CLARITY PHARMACEUTICALS

Clarity says the US Food and Drug Administration has cleared an investigational new drug application for a 44-patient, phase I/IIa prostate cancer trial, later this year.
Clarity said the multi-centre, single arm, dose escalation study was expected to identify and treat prostate-specific membrane antigen (PSMA)-expressing, metastatic, castrate-resistant, prostate cancer.
The company said the trial would use positron emission tomography imaging with 64-copper-Sartate (64Cu-Sar-bisPSMA) for selection of patients suitable for therapy cycles with 67Cu-Sar-bis-PSMA.
Clarity said that copper-64 which was the diagnostic product and copper-67 was used in the therapeutic product.
Clarity executive chairman Dr Alan Taylor said that the US Food and Drug Administration’s “response suggests not only the importance of developing novel treatments for men with late-stage prostate cancer, whose prognosis is currently very poor, but also validates [the company’s] copper pairing paradigm and the centralized manufacturing concept, which differentiates it from the competitor products and enables product supply to the levels suitable for use in large patient indications”.
Clarity is a public unlisted company.

RECCE PHARMACEUTICALS

Recce says that its R327 is “99.9 percent effective” against six antibiotic resistant pathogens, in-vitro.
Recce said the six antibiotic resistant pathogens were Enterococcus faecium, Staphylococcus aureus, Klebsiella pneumoniae, Acinetobacter baumannii, Pseudomonas aeruginosa, and Enterobacter, known collectively as the ‘Eskape’ pathogens.
The company said the study showed the bactericidal activity of R327 to be “a three-log or 99.9 percent reduction in the number of colony forming units over 24 hours against all six strains at various concentrations and times”.
Recce chief executive officer James Graham said the company was “encouraged by the data from this study and will continue to explore the potential of [R327] to treat hospital-acquired infections”.
“Anti-microbial resistance is one of the most urgent threats to global public health with the suite of Eskape pathogens posing a significant threat due to their virulence and rapid development of drug-resistance,” Mr Graham said.
Recce was up 6.5 cents or 5.75 percent to $1.195.

IMPEDIMED:

Impedimed says that an 89-patient study shows that heart failure patients with a Sozo HF-Dex level above 51 percent have a 4.25 times greater risk of hospital readmission.

In April, Impedimed said that a 133-patient study showed that Sozo bioimpedance spectroscopy was an indicator for heart failure risk and outlined risk parameters for clinical settings, with HF-Dex values between 41.5 percent and 46.3 percent “normal”; 46.4 percent to 50.9 percent “elevated”; and 51.0 percent and 56.5 percent “fluid overload”, with 51 percent a marker for heart failure hospital readmission (BD: Apr 8, 2021).

Today, the company said that of the 10 patients readmitted for heart failure, 70 percent had a discharge HF-Dex level above 51 percent which “corresponds to an odds ratio of 4.25” ($p = 0.0472$).

Impedimed said that seven of 35 (20.0%) patients with HF-Dex levels above 51 percent on discharge were readmitted compared to three of 54 (5.6%) patients with HF-Dex levels below 51 percent.

The company said the research was presented in a paper, titled ‘Clinical Utility of Fluid Volume Assessment in Heart Failure Patients Using Bioimpedance Spectroscopy’ published in the Journal of the American College of Cardiology Abstract Supplement and available at: https://www.abstractsonline.com/pp8/#!/9228/presentation/22547.

Impedimed said the article concluded the information “may be a clinically relevant aid … in clinical risk stratification and fluid volume monitoring of heart failure patients”.

The company said that hospital readmissions cost the US healthcare system about $31 billion a year, hospitals had to cover the cost of readmissions in the first 30 days of discharge and US Medicare levied fines on hospitals for high readmission rates.

The study’s lead author, Annie Burns, said that “after a heart failure-related hospital stay, patients may experience improvement in symptoms even though fluid overload persists”.

Ms Burns said the analysis showed that Sozo had “the potential to identify patients with fluid overload, who are at higher risk of readmission at the time of hospital discharge”.

Impedimed was up one cent or 8.3 percent to 13 cents with 2.8 million shares traded.

USCOM

Uscom says it has developed two cardiovascular monitors, Uscom O2 and Uscom Basic, for sale in China.

Uscom said its Uscom O2 was a high-end version of its Uscom 1A ultra-sonic cardiac output monitor and included direct measurement of blood oxygen saturation which generated beat-to-beat measures of oxygen delivery - a “complex and critical measure of cardiovascular performance”.

The company said its Uscom Basic was a de-featured device which would be marketed against lower functioning technologies in price sensitive tenders.

Uscom said it sold more than 500 units of Uscom 1A in China and its Beijing subsidiary, Uscom China was generating about 70 percent of its global sales.

The company said it required China’s National Medical Products Administration approval for the sale of its devices and expected the process to take about 12 months.

Uscom executive chair Prof Rob Phillips said that “more devices equal more revenue, and additional devices for sale in China, our major market, is the logical strategic next step to promote strong on-going revenue growth”.

“These new devices will expand the market reach of our successful Uscom 1A by creating a three-tiered range of haemodynamic monitoring technologies, each with specialized features for different levels of clinical complexity and price,” Prof Phillips said.

Uscom was unchanged at 15.5 cents.

BOTANIX PHARMACEUTICALS

Botanix says it hopes to begin a phase IIb study of its synthetic cannabidiol BTX1801 for Staphylococcus aureus, or golden staph, in dialysis patients, this year.

Botanix said that it expected to optimize the study design based on a three-month treatment period, with three times weekly nasal treatment of the nose.

In February, the company said that a 66-patient, phase IIa trial showed that BTX1801 gel or ointment could eradicate Staphylococcus aureus bacteria from the nose of healthy participants (BD: Feb 3, 2021).

Today, Botanix said that its synthetic cannabidiol rapidly killed Staphylococcus aureus and methicillin-resistant Staphylococcus aureus (MRSA) “without generating antimicrobial resistance” and it had identified as its target indication the nasal decolonization of Staphylococcus aureus in patients undergoing blood dialysis “to reduce the incidence of life-threatening bloodstream infections”.

The company said that patients with chronic kidney failure had dialysis three to five times a week and were “at a high risk of bloodstream infections, due to their treatment requiring frequent use of catheters … [with] 20 to 40 percent of patients eventually dying from an infection”.

Botanix said that there were limited treatments to prevent bloodstream infections and a range of complicating factors including degradation of the catheter and patient toxicities.

The company said that mupirocin was able to reduce Staphylococcus aureus infections by as much as 70 percent in dialysis patients but it was “never approved and is not expected to be a suitable long-term solution for haemodialysis patients, given the level of resistance to mupirocin … and the fact that mupirocin is now generic, so there is no economic motivation to develop it for this indication”.

Botanix executive chair Vince Ippolito said the company’s “assessment indicates that haemodialysis patients with central venous catheters are at considerable risk of bloodstream infections, with no currently approved treatments”.

“BTX1801’s novel mechanism of action has been shown to rapidly kill [Staphylococcus] aureus and MRSA without generating resistance and the recent positive phase IIa study data demonstrated the clinical utility of BTX 1801 as a nasal decolonisation agent,” Mr Ippolito.

Botanix was up 0.1 cents or 1.2 percent to 8.3 cents with 3.3 million shares traded.

PALLA PHARMA (FORMERLY TASMANIAN POPPY INDUSTRIES)

Palla says that having “settled all outstanding legal issues” with its largest ingredient customer, M&A Pharmachem, it had begun a long-term production partnership.

Palla said that it announced the settling of the legal issues with its largest active pharmaceutical ingredient customer, namely poppy-derived products, was “announced at the release of the 2020 full year results in February”

In February, the company said revenue for the year to December 31, 2020 fell 59.9 percent to $21,905,325 with net loss up 355 percent to $34,756,056 (BD: Feb 26, 2021).

On page 18 of the 47-page full year results document, Palla said the outstanding litigation had been settled, but provided no further details.

Today, the company said the production partnership with the Bolton, England-based M&A Pharmachem involved marketing authorization licences, contract manufacturing, supply agreements and access to M&A’s facility in the UK

Palla said it had launched its Co-Codamol 30mg codeine phosphate-500mg paracetamol caplet combination in the UK.

Palla fell two cents or 4.4 percent to 43 cents.

MGC PHARMACEUTICALS

MGC says it has received its second order from Swiss Pharmacan AG for EUR640,000 ($A995,688.2) of its Artemic Rescue food supplement.
Last month, MGC said it had received an order from Swiss Pharmacan AG for $425,000 of its Artemic Rescue food supplement for Covid-19 (BD: Apr 7, 2021).
The company previously said the artemisinin, curcumin, Boswellia serrata and vitamin C-based Artemic was safe and could prevent the deterioration of Covid-19 patients and achieve faster clinical improvement, based on a 50-patient trial (BD: Dec 15, 2020).
Today, MGC said it was working with Swiss Pharmacan AG to seek approvals for Artemic Rescue to be used as a supplement to support Covid-19 patients and alleviate their symptoms.
MGC was up 0.3 cents or 5.1 percent to 6.2 cents with seven million shares traded.

TOTAL BRAIN

Total Brain says it has a $6 million non-binding agreement with Hamptons Life to develop and commercialize a direct-to-customer version of its mental health platform.
Total Brain said the $6 million fee would be paid upfront for a perpetual, global exclusivity licence, product integration and development services provided for about three years.
The company said the Sydney-based Hamptons Life would pay an annual maintenance fee of $350,000 and Total Brain would have the option to acquire up to 50 percent of the direct-to-customer business from Hamptons Life within five years.
Total Brain said the agreement required minimum annual commercial outcomes to maintain exclusivity.
The company said the agreement would focus on the co-development of a product integrating physical fitness, mental health and nutrition.
Total Brain managing-director Louis Gagnon said “if we can convert these opportunities and successfully develop this partnership to combine mental health-exercise-nutrition resources to build the best ‘lifestyle medicine’ applications in the world, we will not only accelerate our strategy but we will significantly increase our number of end users (database) and our short and long-term value to shareholders.”
Total Brain was up 4.5 cents or 16.7 percent to 31.5 cents with 1.3 million shares traded.

RESAPP HEALTH

Resapp says it has appointed Ilara Health as a non-exclusive distributor to sell its Resappdx smart phone respiratory diagnostic application in Kenya.
Resapp said the distribution agreement, which included promotion and marketing followed a “successful pilot” program by the Nairobi-based Ilara at five partner sites in Kenya.
The company said the Kenya-based Illara Health provided primary care facilities with “next-generation point of care diagnostic tools” and had worked with more than 250 clinics and medical centres in Kenya.
Resapp was up 0.1 cents or two percent to 5.2 cents with 4.6 million shares traded.

MEDADVISOR

Medadvisor has requested a trading halt “pending the release of an announcement regarding a funding facility”.
Trading will resume on May 6, 2021 or on an earlier announcement.
Medadvisor last traded at 28 cents.

MEDIBIO

Medibio says the US Patent and Trademark Office has awarded a patent for its computer-implemented heart rate-based method of assessing mental state.
Medibio said the patent, titled 'Method and System for Assessing Mental State', would protect the method of analysis until June 15, 2036.
The company said the system received a sequence of heartbeat data samples obtained overnight through three distinct periods, pre-sleep, sleep, and post-sleep.
The company said it was conducting trials to validate its MEB-001 medical software to "identify for depressive burden in patients suffering from sleep disturbance".
Medibio was unchanged at 0.7 cents with 4.9 million shares traded.

MEMPHASYS

Memphasys says the American Society of Andrology has awarded its scientific advisory committee head, Prof John Aitken, the Distinguished Andrologist award.
Memphasys was up 0.3 cents or 5.1 percent to 6.2 cents.

NUHEARA

Nuheara says it has appointed John R Luna as its business development manager, effective immediately.
Nuheara said Mr Luna specialized in business development, sales and commercialization of medical devices and hearing healthcare products.
The company said Mr Luna was previously and executive with Ihear Medical, Eargo and Insound Medical.
According to his Linkedin page, Mr Luna holds a Bachelor of Arts from the University of California Santa Barbara.
Nuheara fell 0.2 cents or 4.3 percent to 4.5 cents with 4.5 million shares traded.

IQ3 CORP

IQ3 says it has appointed Ron Hollands to replace company secretary Aysha Hollingdale, effective from May 3, 2021.
In January, IQ3 said it had appointed Aysha Hollingdale to replace Gerado Incollingo as company secretary effective from January 12, 2021 (BD: Jan 17, 2021).
IQ3 was untraded at 15 cents.