Biotech Daily

Thursday May 9, 2024

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: NEXT SCIENCE UP 11%**
- UNIVERSAL BIOSENSORS DOWN 13%

*** 4D MEDICAL US CT LVAS REIMBURSEMENT**

*** CONTROL BIONICS $190k US SALES PERMIT**

*** QUEENSLAND UNI DEVELOPS SEPSIS DRUG, IN MICE**

*** RECCE: 'R327 NEBULIZER REDUCES LUNG BACTERIA, IN MICE'**

*** NEUREN: DAYBUE 58% 9-MONTH CONTINUATION RATE**

*** IMRICOR: VISION-MR LAUSANNE UNI TRIAL APPROVED**

*** ENA: US PATENT FOR INNA-051 INTRA-NASAL ANTI-VIRAL**

*** HERAMED: 3rd 'ALTERNATIVE FINANCING' SUSPENSION EXTENSION**

*** PHARMAUST LOSES DR ROGER ASTON, ROB BISHOP, DR TOM DUTHY**

*** CRYOSITE APPOINTS SCOTT THOMAS DIRECTOR**

*** CONTROL BIONICS APPOINTS SHANNON BOOTHROYD CFO**

*** MARIA CLEMENTE REPLACES ALGORAE CO SEC LEAH PIERIS**

*** BIO-MELBOURNE CONNECTING WOMEN LUNCH 'SOLD-OUT'**

MARKET REPORT

The Australian stock market fell 1.06 percent on Thursday May 9, 2024, with the ASX200 down 82.9 points to 7,721.6 points. Ten of the Biotech Daily Top 40 stocks were up, 19 fell, 10 traded unchanged and one was untraded. All three Big Caps fell.

Next Science was the best, up four cents or 11.4 percent to 39 cents, with 28,246 shares traded. Paradigm improved eight percent; Genetic Signatures was up 4.2 percent; Alcidion, Clarity, Immutep, Micro-X and Opthea rose one percent or more; with Pro Medicus and Telix up by less than one percent.

Universal Biosensors led the falls for the second day in a row, down two cents or 13.3 percent to 13 cents, with 934,495 shares traded. Syntara lost 11.1 percent; Avita fell 8.45 percent; both Atomo and Imugene shed 6.7 percent; Actinogen, Nova Eye and Percheron fell five percent or more; Cyclopharm lost 4.7 percent; Clinuvel, Mesoblast and Neuren fell more than three percent; Cochlear, Curvebeam, Emvision, Resmed and Resonance shed more than two percent; CSL, Medical Developments, Polynovo and Proteomics were down one percent or more; with Nanosonics down by 0.7 percent.

4D MEDICAL

4D Medical says its computed tomography lung ventilation analysis software (CT Lvas) will be reimbursed in the US at $US650.50 ($A999.00) per use, from today.
4D Medical said it was not required to apply for an individual reimbursement code for CT Lvas with the US Centers for Medicare and Medicaid Services after the American Medical Association (AMA) had found two existing codes which covered its use.
The company said the reimbursement provided access to CT-Lvas at more than 4,000 Medicare-certified hospitals in the US.
4D Medical said the software could be performed on existing CT scanners and was available to Medicare beneficiaries suffering from lung disease.
The company said the reimbursement provided “a funding source for providers of the technology beyond full out-of-pocket payment”.
4D Medical said the reimbursement was a “benchmark payment level” and a guide for health insurers in determining their pricing levels “typically at a much higher rate”.
The company said following the approval both its CT Lvas and x-ray velocimetry (XV) Lvas were covered for use in the US by the Centers for Medicare and Medicaid.
4D Medical managing-director Prof Andreas Fouras said “an identified Medicare reimbursement of $US650.50 per scan provides direct access to CT Lvas for the 66 million Americans enrolled in Medicare”.
“The routine use of chest [computed tomography] in the clinical work-up of respiratory patients, combined with the recognized value of our scan, makes the AMA’s decision one of the most significant breakthroughs to date in our history,” Prof Fouras said.
“Furthermore, I believe this decision helps to establish the appropriate pricing of our technology within the [Department of Veterans Affairs],” Prof Fouras said.
“I am excited to note that this news comes less than six months following the US [Food and Drug Administration] clearance of CT Lvas, demonstrating growing strength in our team and our reputation with key organisations such as the AMA and associated medical societies,” Prof Fouras said. “This bodes well for continued success with reimbursement of … products such as IQ-UIP and CT:VQ, both expected to be filed with the FDA in 2024.”
4D Medical was unchanged at 55.5 cents with 2.0 million shares traded.

CONTROL BIONICS

Control Bionics says it has permission to sell up-to $US125,000 ($A190,000) worth of its technology to US government buyers and agencies, over five years.
Control Bionics said it had received a US General Services Administration Multiple Award Schedule contract which gave it “increased credibility and visibility” to market and sell its products to federal, state and local government agencies.
The company said it had begun “a promotions campaign to access new sales through this contracted relationship” and that it had three extensions for a possible total contract duration of 20 years.
Control Bionics said the potential total contract value was $US500,000, including the extensions, with opportunities for re-pricing; and once the initial $US125,000 had been invoiced it was possible to extend the total funding available.
The company said it had sold its products to US Government-funded customers for “many years” and this contract allowed it “to market directly to a variety of Federal departments, such as the Veterans Administration”.
Control Bionics said it expected its sales to be “predominately focused on our flagship Trilogy” product which used its Neuronode wearable sensor technology.
Control Bionics fell 0.1 cents or two percent to 4.9 cents.

UNIVERSITY OF QUEENSLAND

The University of Queensland says it has developed a drug that can prevent sepsis-related organ failure and death by restoring blood vessels, in mice.

The University of Queensland said with the Queensland Children's Hospital, researchers conducted a study of sepsis in mice and showed that EphA4-Fc could reduce blood vessels leaking, which contributed to organ failure in the disease.

The University said that the study, titled 'Inhibiting Eph/ephrin signaling reduces vascular leak and endothelial cell dysfunction in mice with sepsis' was published in the journal Science Translational Medicine, with an abstract available at: https://www.science.org/doi/10.1126/scitranslmed.adg5768.

The study said that EphA4-Fc was a "decoy receptor and pan-ephrin inhibitor [and] resulted in improved survival and reduction in vascular leak, lung injury and endothelial cell dysfunction".

The University of Queensland's Dr Mark Coulthard said "the reason for organ failure in sepsis patients is because the endothelial cells lining blood vessels become leaky, resulting in abnormal fluid shifts which ultimately shut down the blood supply".

"We have identified markers for vascular damage in children admitted to hospital with fever and suspected infection and the protein-signaling pathways associated with this in the cells," Dr Coulthard said.

"The drug we have developed targets these interactions, to restore the function of vascular endothelial cells," Dr Coulthard said.

Dr Coulthard said further research was needed including animal studies and a clinical trial, but results from pre-clinical testing using human blood samples were "promising".

"We tested our drug on blood samples from 91 children admitted to hospital with fever and suspected infection, and noted changes in the biomarkers similar to those in our mouse studies," Dr Coulthard said.

"This suggests the drug could be effective in humans as well," Dr Coulthard said.

The University said the research was funded by the Australian National Health and Medical Research Council, The University of Queensland and the Children's Hospital Foundation.

RECCE PHARMACEUTICALS

Recce says a study shows its R327 anti-infective administered using a nebulizer is effective at treating Mycobacterium abscessus lung infections, in mice.

Recce said the study showed in both lungs R327 "significantly decreased Mycobacterium abscessus bacterial colonization ($p < 0.01$), and the mice maintained a stable body weight through the study period, indicating the treatment's safety and tolerability".

The company said mycobacterium abscessus infections were "a major cause of mortality and morbidity in cystic fibrosis patients … [and that] current treatment guidelines recommend a prolonged and intense combination therapy consisting of several antibiotic agents with significant adverse effects".

Recce said the study was conducted at its anti-infective research unit in Melbourne's Murdoch Children's Research Institute.

Recce chief executive officer James Graham said the "results represent a significant milestone in the development of nebulized treatments for lung infections".

"The ability of R327 to significantly decrease bacterial infections in the lungs without adverse effects on the host is a testament to its potential as a safe and effective treatment option," Mr Graham said.

Recce fell 1.5 cents or 2.3 percent to 65 cents.

NEUREN PHARMACEUTICALS

Neuren says its trofinetide marketed in the US by Acadia as Daybue, for Rett syndrome has a nine-month continuation rate of 58 percent.
Earlier this year, Neuren rebutted claims by New York's Culper Research about Daybue's discontinuation rate, quoting Acadia saying 76 percent of patients remained on therapy after six months based on confirmed discontinuations, or 68 percent based on confirmed patient discontinuations and patients 60-days past refill (BD: Feb 16, 2024).
Today, the company said there were 862 patients currently on therapy.
Neuren fell 79 cents or 3.9 percent to $19.31 with 1.4 million shares traded.

IMRICOR MEDICAL SYSTEMS

Imricor says it has final Swiss regulatory authority to begin its Vision-MR cardiac ablation catheter for atrial flutter trial at Switzerland's Lausanne University Hospital.
Earlier this year, Imricor said it had approval for an up-to 91-patient study of its cardiac ablation catheter and irrigation pump products at the Baltimore, Maryland's Johns Hopkins Hospital (BD: Jan 21, 2024).
At that time, the company said the trial would study the safety and efficacy of atrial flutter ablation procedures using its Vision-MR (magnetic resonance) cardiac ablation catheter and HAT500RF generator and irrigation pump, with analysis after 76 patients had a seven-day follow-up.
Later, Imricor said it had trial approval from Lausanne University Hospital, but required final approval from the Swiss regulatory authority Swissmedic (BD: Mar 8, 2024).
Today, the company said installation planning had begun and cases were expected to begin by July 2024 and that the study was expected to support US Food and Drug Administration approval of its products.
Imricor executive chair Steven Wedan said the approval was "another major milestone in our execution of [the] … clinical trial and in the opening of the US market for Imricor".
"This marks the third site fully approved to commence the trial, and we are nearing the phase where patients are enrolled and treated," Mr Wedan said.
"We are right on track with our plans and schedules," Mr Wedan said.
Imricor fell 2.5 cents or 5.2 percent to 45.5 cents.

ENA RESPIRATORY

ENA says the US Patent and Trademark Office has allowed a patent relating to its INNA-051 intranasal, anti-viral for respiratory diseases.
ENA said that the patent, titled 'Novel molecules' would protect "the composition of matter for INNA-051 and various back-up molecules, formulations and method-of-use" until at least 2042.
The company said it had 30 granted patents related to INNA-051 in the US, Europe, the UK, Japan and China, with "an additional 39 pending applications in various jurisdictions".
ENA chief executive officer Dr Christophe Demaison said the company's intellectual property "portfolio provides robust and long-lasting protection with potential exclusivity for INNA-051 out to at least 2042 and likely for five years post that date".
"This gives us great confidence in the future global commercial value of our innate immune modulators as we continue to drive forwards in clinical development," Dr Demaison said.
ENA is a private company.

HERAMED

Heramed has requested a third extension to its suspension in relation to “proposed financing and board changes”.
Last month, Heramed requested a suspension following a trading halt regarding board changes, business restructure and the rights issue shortfall; and later, extended its suspension twice (BD: Apr 3, Apr 5, Apr 8, Apr 29, 2024).
Heramed said it expected trading to resume on May 13, 2024, or on an earlier announcement.
Heramed last traded at 1.7 cents.

PHARMAUST

Pharmaust says chair Dr Roger Aston and directors Robert Bishop and Dr Thomas Duthy have resigned from the company, effective immediately.
Pharmaust said it had promoted director Sam Wright to interim chair, with interim chief executive officer John Clark appointed managing-director.
The company said Marcus Hughes was” one of the largest shareholders in Pharmaust and had been appointed a non-executive director.
Pharmaust said that Mr Hughes had more than 20 years of experience with listed companies and had worked for Lend Lease, Fortescue Metals and Rio Tinto.
Pharmaust did not state a reason for the resignations and said that it was finalizing Mr Clark’s services agreement.
Mr Wright said the company had “made new additions to the board of directors with the drive, requisite experience and skill set that will allow for the continued development and success of Pharmaust and monepantel at this pivotal stage of the company”.
Dr Aston said on behalf of the departing directors that they were “thankful for the opportunity to serve Pharmaust”.
Pharmaust fell four cents or 18.2 percent to 18 cents with 10.4 million shares traded.

CRYOSITE

Cryosite says it has appointed Scott Thomas as a director.
Cryosite said Mr Thomas had “experience in the financial services profession both in Australia and the UK” having held senior roles at Australia and New Zealand Banking Group and Vanguard Investments.
The company said Mr Thomas held a Bachelor of Commerce from the University of Melbourne and a Master of Applied Finance from Sydney’s Macquarie University.
Cryosite was unchanged at 85 cents.

CONTROL BIONICS

Control Bionics says it has appointed Shannon Boothroyd as its chief financial officer, replacing part-time chief financial officer Dominik Kucera, effective from May 13, 2024.
Control Bionics said Ms Boothroyd had more than 20 years of finance and accounting experience including in the US and that her “US experience will be invaluable … given the extent of the company’s US operations”.
According to her Linkedin profile, Ms Boothroyd held a Bachelor of Business Administration from Ypsilanti, Michigan’s Eastern Michigan University and a Master of Science from Troy, Michigan’s Walsh College.

ALGORAE PHARMACEUTICALS (FORMERLY LIVING CELL TECHNOLOGIES)

Algorae says Maria Clemente has been appointed its company secretary, effective immediately following Leah Pieris resigning from Automic Group.
Algorae said that Maria Clemente worked for Automic group.
Algorae was up 0.1 cents or 9.1 percent to 1.2 cents.

BIO-MELBOURNE NETWORK

The Bio-Melbourne Network says tickets to its Connecting Women Lunch, to be held on May 17, 2024, have sold out.
In 2022 and 2023, the Bio-Melbourne Network said those Connecting Women Lunches were sold out (BD: May 10, 2022, May 17, 2023)
The Bio-Melbourne Network said the event would “provide a powerful platform for networking, diversity, fostering new connections, and exploring opportunities for growth and collaboration”.
The Network said Humanise Health founder Krystal Barter would be the guest speaker at the event, sponsored by CSL, Avatar Brokers, 4D Medical, the City of Melbourne, Philips Ormonde Fitzpatrick, Radium Capital, Brandon Capital, La Trobe University, Cell Therapies, Mexec, Crux Biolabs, Telix and Zoetis Australia.
For more information, go to: https://biomelbourne.org/event/connecting-women-lunch-3/.