Biotech Daily

Tuesday November 5, 2024

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: AVITA UP 10%; SYNTARA DOWN 7%**

*** UNI NSW DEVELOPS WHOOPING COUGH STRAIN TEST**

*** VALE QBIOTICS CHAIR DR SUSAN FODEN**

*** MEMPHASYS RAISES $1.9m**

*** BCAL AUSTRALIAN BREASTEST COMMERCIAL LAUNCH DELAYED**

*** PYC APPROVED FOR MULTIPLE 75mg VP-001 RP11 DOSES**

*** RECCE DOSES 20 R327 SKIN INFECTION PATIENTS**

*** IMUGENE VAXINIA BILE TRACT PATIENT 2-YEAR COMPLETE RESPONSE**

*** RESPIRI: 'US REIMBURSEMENT INCREASES SERVICES, FEES'**

*** IMUGENE WINS 3-YEAR US VAXINIA PATENT EXTENSION**

*** NOXOPHARM ISSUES $500k 'UNNAMED' SHAREHOLDER NOTE**

*** PENGANA TAKES 12% OF ONCOSIL**

*** NOXOPHARM DILUTED TO 16% OF NYRADA**

*** ALTNIA, HELIUM, DR IAN DIXON BELOW 5% OF NYRADA**

MARKET REPORT

The Australian stock market fell 0.4 percent on Tuesday November 5, 2024, with the ASX200 down 32.8 points to 8,131.8 points. Thirteen of the Biotech Daily Top 40 stocks were up, 18 fell, eight traded unchanged and one was untraded. All four Big Caps fell.

Avita was the best, up 31 cents or 10.1 percent to $3.38, with 570,935 shares traded. Curvebeam climbed 9.1 percent; Imugene improved 6.8 percent; Clarity and Starpharma rose two percent or more; Alcidion and Telix were up one percent or more; with Clinuvel, Cyclopharm, Mesoblast, Nanosonics, Orthocell and SDI up by less than one percent.

Syntara led the falls, down 0.3 cents or 6.7 percent to 4.2 cents, with 1.1 million shares traded. Atomo, Compumedics, Medadvisor and Resonance fell four percent or more; Medical Developments and Nova Eye lost more than three percent; 4D Medical, Cynata and Proteomics shed more than two percent; Aroa, Dimerix, EBR, Impedimed, Micro-X, Opthea and Polynovo were down one percent or more; with Cochlear, CSL, Neuren, Pro Medicus and Resmed down by less than one percent.

UNIVERSITY OF NEW SOUTH WALES

The University of New South Wales says it has developed a “genomic test that can identify the specific strains of whooping cough”, or bacterium Bordetella pertussis.
The University of New South Wales said the technology was developed by a team led by its Prof Ruiting Lan and the University of Technology Sydney’s Dr Laurence Luu.
The University said the researchers hoped “to use the assay to pinpoint the strain responsible for the current outbreak in Australia”.
The University of New South Wales said that in 2024, all Australia states and territories reported a rise in whooping cough cases compared to previous years, and that information on the strain involved could “play a crucial role in improving both the management of the outbreak and future vaccine development”.
The University said whooping cough was a severe respiratory disease with symptoms that include a persistent cough that can last up to 100 days and that the disease was highly infectious, with one infected person potentially spreading it to up to 18 susceptible individuals without vaccination.
UNSW said its researchers developed a highly sensitive strain test without the need to grow bacteria using DNA sequencing on clinical swabs of whooping cough.
The University said it had developed a multiplex polymerase chain reaction (mPCR) sequencing assay, which could directly sequence the residual whooping cough DNA left after a polymerase chain reaction (PCR) test and needed as few as four copies of the bacteria DNA to work effectively.
UNSW said researchers tested the assay on 178 leftover diagnostic DNA samples from two previous Australian outbreaks, with samples collected in 2010-’12 and 2019.
The University said the research was conducted with Prof Vitali Sintchenko from the New South Wales Health Pathology Institute of Clinical Pathology and Medical Research and Dr Jenny Robson from Sullivan Nicolaides Pathology, Queensland.
The University said the study, titled ‘Deciphering Bordetella pertussis epidemiology through culture-independent multiplex amplicon and metagenomic sequencing’ was published in the Journal of Clinical Microbiology, with an abstract available at: https://journals.asm.org/doi/10.1128/jcm.01178-24.
Lead researcher Dr Luu said the study paved “the way for real-time surveillance of whooping cough strains, overcoming current testing limitations.”
“Our results provide important baseline data to understand how whooping cough has changed in Australia and could be used to help guide us through the current outbreak,” Dr Luu said.
“Our past research suggests that whooping cough is evolving against the vaccine,” Dr Luu said.
“Having said that, the vaccine is still very effective at protecting against serious disease,” Dr Luu said.
“We found that the strains that were associated with the big 2008-’12 epidemic had evolved to no longer produce one of the three components that's targeted by the vaccine,” Dr Luu said.
“Surprisingly, we also identified a number of cases where the infection wasn't caused by whooping cough, but by another closely related bacterium called Bordetella holmesii,” Dr Luu said.
“In the clinical laboratories, the two bacteria share the same diagnostic marker, but what we see is that in 2019 there were actually two species that were causing the infection, and even cases where they were co-infected with two different bacteria,” Dr Luu said.
“By knowing what strains are transmitting in the community, this will allow us to spot and respond to outbreaks faster,” Dr Luu said.

QBIOTICS GROUP

Qbiotics says that “with profound sadness [it] announces the passing of Dr Susan Foden, non-executive chair”.
Qbiotics said it extended its “deepest sympathies and condolences to Dr Foden’s family, friends and colleagues”.
The company said Dr Foden, 71, was appointed as a Qbiotics director on October 14, 2019, and was a member, and for a period the chair, of the remuneration committee.
Qbiotics said Dr Foden was its executive chair through 2023 and 2024, and that her oversight had been “instrumental for preserving the company’s momentum and stability during a leadership transition period”.
Qbiotics managing-director Stephen Doyle said Dr Foden “was an integral part of our company, guiding us with her strong leadership, commitment to excellence and tireless dedication”.
“Her contributions to Qbiotics and to the industry as a whole have been immeasurable, and her loss will be deeply felt by all who had the privilege of knowing and working with her,” Mr Doyle said.
“Our thoughts and condolences are with Dr Foden’s family,” he said.
“She will be sadly missed,” Mr Doyle said.
Qbiotics is a public unlisted company.

MEMPHASYS

Memphasys says it has raised about $1,000,000 in a placement and about $857,000 of a hoped for $1,000,000 in a share purchase plan at 0.6 cents a share.
In September, Memphasys said it had ‘firm commitments’ for a $1.0 million placement and hoped to raise $1.0 million in a share plan (BD: Sep 12, 2024).
At that time, the company said the issue price would be the lesser of 0.8 cents a share or a 20 percent discount to the five-day volume weighted average price of shares, with investors to receive one attaching option for each share purchased, exercisable at 1.1 cents each within two years.
Today, Memphasys said the top-up offer was open until December 13, 2024 and that it could place the remaining securities.
Memphasys fell 0.15 cents or 20 percent to 0.6 cents with 13.5 million shares traded.

BCAL DIAGNOSTICS

Bcal says a National Association of Testing Authorities factory audit has delayed its Sydney Breast Clinic launch of Breastest expected by April 2025.
In April, Bcal founder Jayne Shaw said the company expected to launch Breastest in “late 2024” and told Biotech Daily that as a stepping stone to Australia Therapeutic Goods Administration (TGA) approval, the company was developing its test as a lab-developed assay (BD: Apr 2, 12, 2024).
Today, the company said the National Association of Testing Authorities had requested additional information, adding “several weeks to the approval process”.
Bcal said that Breastest would be available to patients as an adjunct to the standard mammogram, with the hope “of providing improved results and greater surety to clinicians and patients”.
Bcal was unchanged at 10.5 cents with three million shares traded.

PYC THERAPEUTICS

PYC says it has approval to dose three patients with multiple doses of 75 micrograms (µg) of VP-001 for retinitis pigmentosa type 11 (RP11).
Earlier this year, PYC said it would conduct an up-to six-patient, multiple ascending dose study of VP-001 for RP11 in two cohorts of three patients each receiving either 30µg or 75µg (BD: Apr 29, 2024).
Today, the company said it expected to administer patients in the final cohort "their first dose of VP-001 before the end of the month", with patients in the open label extension of the single ascending dose study progressing to repeat dosing at the 75µg dose and there had been no treatment emergent-serious adverse events reported.
PYC said that final cohort data at eight weeks and 12 weeks of follow-up was expected to be available by April 2025 and it would use the data to engage the US Food and Drug Administration on the design of a registrational study.
PYC was unchanged at 19 cents.

RECCE PHARMACEUTICALS

Recce says it has dosed 20 of the 30 patients in its phase II study of R327 topical gel for acute bacterial skin and skin structure infections.
Last month, Recce said it had dosed 15 of 30 patients in the trial (BD: Oct 9, 2024).
Last week, the company said data from 14 patients in the trial showed it was safe and led to a "complete cure or improvement" (BD: Oct 28, 2024).
Today, Recce said with 20 patients dosed, interim data showed R327 gel had a "promising efficacy and safety profile".
The company said the data showed "a strong therapeutic response, with all patients completing treatment with R327 achieving positive outcomes, showing either complete cure or notable improvement", with no serious adverse events reported, and dosing expected to be completed this year.
Recce chief medical advisor Dr Alan Dunton said the interim results were "a remarkable advancement … to address critical unmet medical needs in anti-infective therapies".
Recce was up two cents or 4.5 percent to 46.5 cents.

IMUGENE

Imugene says one patient with bile tract cancer in its phase I trial of Vaxinia for metastatic advanced solid tumors has passed "more than two years in remission".
In 2022, Imugene said it had dosed the first of 100 patients in its phase I trial of CF33-hNIS Vaxinia oncolytic virotherapy for advanced solid tumors (BD: May 18, 2022).
Today, the company said its cohort review committee had cleared the first three patients in its bile tract cancer expansion cohort after safety and no dose limiting toxicities were found, with full enrolment of up-to 10 patients opened.
Last year, Imugene said it had dosed the first phase I Vaxinia and pembrolizumab combination patients; and later, said it had 'early positive signals' from 34 patients treated with either monotherapy or combination therapy and had US Food and Drug Administration fast track status for bile duct cancer (BD: Mar 3, Nov 6, Nov 28, 2023).
Imugene managing-director Leslie Chong said the company was "very pleased to see the two-year milestone reached for the bile tract cancer patient who has maintained a complete response … [and] an outstanding result for the patient given the limited treatment options available".
Imugene was up 0.3 cents or 6.8 percent to 4.7 cents with 37.2 million shares traded.

RESPIRI

Respiri says proposed changes to US reimbursement of remote patient monitoring will increase the amount of services delivered and the fees received for its services.

Respiri said a US Centers for Medicare and Medicaid Services (CMS) change meant the collection and transmission of data from remote patient monitoring devices would be reduced from every 16 days to every two days.

The company said the change could increase the number of Respiri-managed patients using its Wheezo device qualifying for monthly reimbursement from about 50 to 70 percent up-to 90 percent, or an additional $US108,000 ($A164,000) a year for every 1,000 patients on its remote patient monitoring program.

Respiri said the CMS had proposed two changes that reduced “the amount of time clinical staff must engage in interactive communication with a patient caregiver during the month”.

The company said it expected a 100 percent increase in monitoring services delivered by its clinical staff, which at current reimbursement rates might increase its per patient monthly fees from between $US70-to-$US90 to between $US140-to-$US180.

Respiri said revised reimbursement rates were “yet to be finalized and announced by CMS but regardless, [remote patient monitoring] services appear to be part of the reimbursement landscape for the foreseeable future”.

Respiri managing-director Marjan Mikel said the changes appeared “to be an acceptance that negotiating the growing cost burden of healthcare provision will require a different approach and a different mix of services to deliver outcomes more cost effectively and that [remote patient monitoring] is a critical part of this”.

Respiri was up 0.2 cents or 2.5 percent to 8.1 cents.

IMUGENE

Imugene says the US Patent and Trademark Office has approved a three-year patent extension for oncolytic virotherapy CF33, which included its Vaxinia cancer therapy.

In 2019, Imugene said it would acquire Vaxinia and its CF33 oncolytic virus technology for cancer tumors with its patents protected until 2037 (BD: Jul 15, 2019).

Today, the company said the patent, titled ‘Chimeric Poxvirus Composition and Uses Thereof’ would protect its intellectual property until 2040.

Ms Chong said the extension was “a significant milestone”.

NOXOPHARM

Noxopharm says it has issued an additional $500,000 convertible note to an undisclosed, existing, long-term shareholder at 12 percent interest.

Earlier this year, Noxopharm said it would issue $2.6 million in convertible notes converting at 9.92 cents, a 20 percent discount to the five-day volume weighted average price to September 6, 2024, or a lower price if the company has a capital raise, but no lower than 7.0 cents a share, and would expire on January 2, 2026 (BD: Sep 27, 2024).

Today, the company said the notes would provide “ongoing funding for the company and helps it to explore all capital management and other potential opportunities” and would be secured against its Federal Government Research and Development Tax Incentive for the year to June 30, 2025.

The company said the unnamed investor would receive 100,000 options, exercisable at 14.88 cents each by September 10, 2027.

Noxopharm fell 2.5 cents or 19.2 percent to 10.5 cents with 1.2 million shares traded.

ONCOSIL MEDICAL

Pengana Capital Ltd says it has increased its substantial shareholding in Oncosil from 385,714,286 shares (10.19%) to 535,714,286 shares (11.97%).
The Sydney-based Pengana said that on November 1, 2024 it bought 150,000,000 shares in a placement for $1,500,000, or one cent a share.
Last week, Oncosil said it had “commitments” to raise $7.0 million in a placement at 1.0 cent a share, with a $1.0 million share purchase plan to follow (BD: Oct 28, 2024).
Oncosil was unchanged at 0.8 cents with 4.3 million shares traded.

NYRADA, NOXOPHARM

Nyrada says Noxopharm’s 33,373,245 share-holding in the company has been diluted from 18.60 percent to 15.92 percent.
Last week, Nyrada said it raised $3.36 million in a placement at 12 cents per Chess depository interest, with a $1.0 million purchase plan to follow (BD: Oct 28, 2024).
Nyrada was unchanged at 11.5 cents.

NYRADA

Nyrada says Altnia Holdings for Dr Ian Dixon and Helium Management increased and were diluted from 10,114,033 shares (5.64%) to 10,380,699 (4.95%) (see above).