Biotech Daily

Monday June 24, 2024

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: EMVISION UP 8%; NEXT SCIENCE DOWN 14%**

*** IMMUTEP RETAIL RIGHTS RAISE $10.6m; TOTAL $100.2m**

*** EMVISION: FEDERAL $1.25m GRANT, BRAIN SCANNER PRODUCTION LINE**

*** CLINUVEL WINS EU SCENESSE FOR VP ORPHAN DRUG STATUS**

*** CYCLOPHARM TECHNEGAS 3-YEAR US REIMBURSEMENT**

*** PROTEOMICS, EUROBIO TO SELL PROMARKER D IN FRANCE**

*** HERAMED: 'HERACARE ON TELSTRA HEALTH SOON'**

*** RECCE PHASE II R327 BACTERIAL INFECTION TRIAL APPROVED**

*** IMUGENE DOSES 1st I-V ONCARLYTICS COMBINATION PATIENT**

*** CLARITY RECEIVES $9.95m FEDERAL R&D TAX INCENTIVE**

*** RADIOPHARM TAKES 'CAPITAL RAISING' HALT TO SUSPENSION**

*** NUHEARA EGM 18% OPPOSE DIRECTOR SHARES**

*** VANGUARD TAKES 5% OF POLYNOVO**

*** SELECTOR FUNDS TAKES 6.5% OF NANOSONICS**

*** CAPITAL PROPERTY, CARRINGTON TRUST TAKE 7.5% OF BCAL**

*** AUDEARA FOUNDER DR CHRIS JEFFERY BELOW 5%**

*** ARGENT (MGC PHARMA) APPOINTS SHORE CAPITAL UK BROKER**

MARKET REPORT

The Australian stock market fell 0.8 percent on Monday June 24, 2024, with the ASX200 down 62.3 points to 7,733.7 points. Nine of the Biotech Daily Top 40 stocks were up, 22 were down, eight traded unchanged and one was untraded. All three Big Caps fell.

Emvision was the best, up 17 cents or 8.4 percent to $2.19, with 112,955 shares traded. Cyclopharm climbed 6.3 percent; Actinogen was up 3.1 percent; 4D Medical, Clarity and Medadvisor rose more than two percent; Polynovo and Proteomics were up more than one percent; with Pro Medicus up by 0.5 percent.

Next Science led the falls, down 3.5 cents or 14.3 percent to 21 cents, with 750,474 shares traded; followed by Resmed down $4.22 or 13.2 percent to $27.74, with 8.6 million shares traded – apparently on news that an Eli Lilly phase III trial of tirzepatide for moderate-to-severe obstructive sleep apnoea in adults with obesity met all endpoints. Alcidion lost 7.7 percent; Imugene and Percheron fell more than six percent; Curvebeam and Dimerix were down more than five percent; Amplia, Impedimed, Nanosonics and Syntara fell four percent or more; Mesoblast, Micro-X, Prescient and SDI were down more than three percent; Avita, Opthea and Starpharma shed two percent or more; Clinuvel and Medical Developments were down one percent or more; with Cochlear, CSL, Genetic Signatures, Neuren and Telix down by less than one percent.

IMMUTEP

Immutep says its one-for-16 retail rights offer at 38 cents a share has raised $10.6 million, taking the total with the placement and institutional offer to $100.2 million.
Immutep said it had raised $89.6 million at 38 cents a share in a $72 million fully-underwritten placement and $17.6 million one-for-16 institutional rights offer, with a $10.6 million retail offer to follow (BD: Jun 3, Jun 5, 2024).
Today, the company said the fully-underwritten retail component of the entitlement offer had raised $6.7 million from eligible shareholders, with the remaining shortfall taken up by Bell Potter Securities as sole underwriter.
Immutep was unchanged at 42 cents with 3.4 million shares traded.

EMVISION MEDICAL DEVICES

Emvision says it has received the final $1,250,000 of its Federal Government grant for its Emu brain scanner and has opened a commercial production line for the product.
In 2022, Emvision said it had a $5 million Federal Government Modern Manufacturing Initiative grant for its portable brain scanner product (BD: Aug 29, 2022).
At that time, the company said the grant would be split into $3,750,000 for the year to June 30, 2022, and $1,250,000 for the year to June 30, 2023, and support initial production of the first-generation portable brain scanner as well as quality systems, engineering personnel and other expenditure.
Today, Emvision said the device would be manufactured at its Macquarie Park, Sydney premises and it could build, test and release about one brain scanner per week.
The company said that “with modest personnel additions, under its current configuration, the production line is anticipated to have capacity for the build, test and release of up-to three Emu brain scanner devices per week”.
Emvision was up 17 cents or 8.4 percent to $2.19.

CLINUVEL PHARMACEUTICALS

Clinuvel says the European Medicines Agency has granted orphan drug designation to Scenesse, or afamelanotide 16mg, for treating variegate porphyria (VP).
Clinuvel said variegate porphyria was a genetic disorder similar to erythropoietic protoporphyria (EPP) light intolerance.
The company said the orphan drug designation was a “step along the regulatory pathway” to extend the existing approved label for Scenesse to include VP.
Earlier this month, Clinuvel said it had withdrawn a submission to expand marketing authorization for Scenesse to adolescents with EPP in Europe, following the EMA’s request for more data for its application (BD: Jun 3, 2024).
Today, the company said the orphan drug designation approval for Scenesse in VP was based on medical need to treat chronic skin lesions in VP, use of Scenesse in EPP and its phase II study endpoints and results.
Earlier this year, Clinuvel said its six-patient, phase II study of Scenesse, for VP met its primary endpoints, including reducing disease severity (BD: Mar 4, 2024).
Today, the company said the designation would give it regulatory support and commercial incentives including post-authorization market exclusivity of 10 years.
Clinuvel chief scientific officer Dr Dennis Wright said expanding the existing Scenesse label to include other porphyrias was “demand driven, as patients and physicians request our photo-protective treatment.”
Clinuvel fell 16 cents or one percent to $15.23 with 138,819 shares traded.

CYCLOPHARM

Cyclopharm says the US Center for Medicare and Medicaid Services (CMS) has provided pass-through reimbursement status for Technegas for three years.

Earlier this month, Cyclopharm said the CMS had granted pass-through reimbursement for Technegas, from July 1, 2024 (BD: Jun 5, 2024).

Today, the company the reimbursement allowed Technegas to be reimbursed separately from the procedures with which it was used, leading to “higher overall reimbursement and better financial incentives for healthcare providers”.

Cyclopharm said transitional pass-through status was “expected to expedite market penetration by promoting quicker adoption of Technegas into clinical practice”.

Cyclopharm managing-director James McBrayer said the company was “extremely pleased with the additional information provided by CMS”.

“The clinical superiority of Technegas over competing products are well established and with [transitional pass-through], users now have both the clinical motivation and financial incentive to implement Technegas,” Mr McBrayer said.

“In line with clinical guidelines in Europe and Canada, the adoption of Technegas in the US, facilitated by reimbursement, is also expected to advance the introduction of 3-dimensional SPECT [single-photon emission computed tomography] and SPECT/CT [computed tomography] imaging, which are techniques superior to the 2-dimensional imaging predominantly used in the US,” Mr McBrayer said

“This advancement is expected to allow nuclear medicine to compete for market share currently held by CTPA [computed tomography pulmonary angiography], as well as facilitating beyond pulmonary embolism applications,” Mr McBrayer said.

Cyclopharm was up 9.5 cents or 6.3 percent to $1.595.

PROTEOMICS INTERNATIONAL LABORATORIES

Proteomics says the Paris-based Eurobio Scientific will exclusively distribute its Promarker D predictive blood test for diabetic kidney disease in France.

Proteomics said Eurobio was “the leading independent distributor of in-vitro diagnostics in France” and developed, manufactured and distributed diagnostic products and services.

The company said Eurobio had a five-year, sub-distribution deal with Apacor Ltd, with an option to extend for an additional five-year, and that it would receive payment for each Promarkerd kit sold.

In 2021, Proteomics said it had a two-year exclusive distribution agreement with the Wokingham, England-based Apacor for its Promarker D diagnostic in Great Britain; and last year, said it had extended the deal (BD: Nov 23, 2021; Feb 15, 2023).

Proteomics was up one cent or 1.1 percent to 89.5 cents.

HERAMED

Heramed says its Heracare foetal heart monitor will “soon” be available to medical practices using Telstra Health’s Medicaldirector patient management software.

Last year, Heramed said it had joined Telstra Health’s marketplace to educate and market its Heracare remote foetal heart monitor to general practitioners in Australia, with the product expected to be launched with Telstra health “by April 2024” (BD: Nov 21, 2023).

Today, the company said it would initially recruit five-to-10 clinics and aimed to onboard patients through Telstra Health’s general practitioner customer base “by the end of calendar year 2024”.

Heramed was up 0.2 cents or 6.9 percent to 3.1 cents with 1.3 million shares traded.

RECCE PHARMACEUTICALS

Recce says it has Australian human research ethics committee (HREC) approval for a 30-patient, open-label phase II trial of its R327 topical gel for “all bacterial skin infections”.
Recce said the approval allowed it to “bring together the clinical studies of [diabetic foot infection] DFI, wound infections and more, under one key centralized regulatory category”.
Earlier this year, the company said a five-patient, phase I/II trial of R327 for diabetic foot infection met its primary endpoints; and later, said an independent safety committee “unanimously agreed” the trial was fit for expanded access (BD: Jan 21, Feb 26, 2024).
Today, Recce said the trial would study the bio-availability of single and multiple-doses of R327 as a treatment for a “broad range” of acute bacterial skin and skin structure infections, including diabetic foot infections, necrotizing fasciitis and post-operative wound infections, as well as clinical efficacy and toxicity.
Recce said it was working with the Geelong-based Barwon Health for the trial, enabling it to access a “diverse patient population and provide valuable insights on the gel’s performance across various … conditions”.
Recce managing-director James Graham said the approval marked “another significant milestone for Recce and the clinicians striving to discover an effective treatment for [acute bacterial skin and skin structure infections]”.
Recce fell three cents or 5.2 percent to 54.5 cents.

IMUGENE

Imugene says it has dosed the first patient in the intra-venous combination arm of its up-to 45 patient, phase I trial of its Oncarlytics with Blincyto for solid tumors.
Last year, Imugene said it had dosed the first combination patient in the intra-tumoral arm of its up-to 52 patient, phase I trial of its Oncarlytics, a CD19-expressing oncolytic virotherapy, and Blincyto, or blinatumomab (BD: Oct 26, 2023).
At that time, the company said the trial of adult patients with advanced or metastatic solid tumors would evaluate the safety and efficacy of an intra-tumoral injection and an intra-venous infusion of Oncarlytics alone and in combination with blinatumomab.
Today, Imugene said the first intra-venous combination patient had cholangio-carcinoma, or bile tract cancer, and was dosed at the Duarte, California-based City of Hope Hospital.
The company said that subject to the rate of patient enrolment, preliminary early combination data was expected by January 2025.
Imugene said it had three sites in the US, including the City of Hope, the Ohio’s University of Cincinnati and Austin, Texas’ MD Anderson Cancer Center, and had the potential to open a total of 10 sites.
Imugene managing-director Leslie Chong said the company was “pleased to enrol the first [intra-venous] combination patient and further advance our … trial, which combines our CD19 oncolytic virus with the already approved and marketed CD19 bi-specific in patients with advanced solid cancers”.
“While CD19 has been a powerful target for blood cancers, no such targets currently exist for solid cancers,” Ms Chong said.
“We aspire to change that with Oncarlytics, which causes cancers to display CD19 on their cell surface so that an approved CD19 therapeutics can target and kill the cancer,” Ms Chong said.
“If successful, Oncarlytics could open up 90 percent of the market as CD19 products are only approved in blood cancer and provide a new treatment option for patients with solid tumors,” Ms Chong said.
Imugene fell 0.4 cents or 6.8 percent to 5.5 cents with 64.0 million shares traded.

CLARITY PHARMACEUTICALS

Clarity says it has received $9,951,692 from the Australian Taxation Office under the Federal Government's Research and Development Tax Incentive program.
Clarity said the incentive related to research and development expenditure for the year to June 30, 2023 and would provide further funding for the development of its "targeted copper theranostics platform of products for various cancer indications".
Clarity was up 13 cents or 2.8 percent to $4.73 with 1.1 million shares traded.

RADIOPHARM THERANOSTICS

Radiopharm has requested a suspension, following Thursday's trading halt "in relation to a potential capital raising" (BD: June 20, 2024).
Trading will resume on June 25, 2024, or on an earlier announcement.
Radiopharm last traded at 3.4 cents.

NUHEARA

Nuheara says an extraordinary general meeting carried all 14 resolutions, with up-to 18.22 percent opposition to 10 of the resolutions.
Last month, Nuheara said the meeting would vote to issue 5,429,334 performance rights to managing-director Justin Miller (BD: May 22, 2024).
Today, the company said Mr Miller's performance rights were opposed by 23,238,681 votes (18.22%), with 104,328,887 votes (81.78%) in favor; along with similar opposition to the issue of shares and salary sacrifice shares to Mr Miller, chair Cheryl Edwardes and directors Kathryn Giudes and David Buckingham.
Nuheara said the remaining four resolutions, related to the issue of placement shares and options, all passed more easily.
According to its most recent notice, Nuheara had 235,775,757 shares on issue, meaning that the votes against Mr Miller's performance rights amounted to 9.86 percent of the company, sufficient to requisition extraordinary general meetings.
Nuheara was in a suspension and last traded at 8.1 cents.

POLYNOVO

Vanguard Group says it has become a substantial shareholder in Polynovo with 34,514,142 shares, or 5.0004 percent of the company.
The Philadelphia, Pennsylvania-based Vanguard Group said that in more than 650 transactions between February 21 and June 18, 2024 it bought shares at prices ranging from $1.97 to $2.43 and sold shares at prices ranging from $1.95 to $2.26.
Polynovo was up three cents or 1.3 percent to $2.41 with 1.7 million shares traded.

NANOSONICS

Selector Funds Management Ltd says it has increased its substantial shareholding in Nanosonics from 15,187,962 shares (5.01%) to 19,772,677 shares (6.53%).
The Sydney-based Selector Funds said that it acquired 4,584,715 shares in 'various' market purchases but did not disclose the consideration or the dates of the transactions, as required under the Corporations Act 2001.
Nanosonics fell 14 cents or 4.7 percent to $2.86 with 1.5 million shares traded.

BCAL DIAGNOSTICS

Capital Property Corporation Pty Ltd as trustee for Carrington Trust says it increased its holding in Bcal from 16,193,425 shares (6.40%) to 23,693,425 shares (7.54%).
The Canberra-based Capital said that between February 21, 2022 and June 7, 2024, it bought shares, with the single largest purchase 7,500,000 shares in a placement on June 7, 2024 for $750,000, or 10.0 cents a share.
Earlier this month, Bcal said it had “firm commitments” to raise $10.5 million at 10 cents a share in a placement (BD: Jun 3, 2024).
Bcal was up half a cent or 4.8 percent to 11 cents.

AUDEARA

Dr Chistopher Jeffery says he has ceased his substantial holding in Audeara with the sale of 4,000,000 shares for $136,000, or 3.4 cents a share, on June 19, 2024.
In 2021, Audeara said it was founded in 2015 by Brisbane doctors and engineers, Dr James Fielding, Dr Jeffery and Alex Afflick (BD: May 18, 2021).
Today, the Brisbane-based Dr Jeffrey said he sold the shares through C J New Ventures Pty Ltd.
Last week, Audeara chair David Trimboli said with his related parties he increased his holding in the company to 21,591,210 shares (14.87%) following the purchase of 4,000,000 shares on June 19, 2024 for $136,000 (BD: Jun 21, 2024).
According to his previous shareholder notice, Dr Jeffery and C J New Ventures became substantial in Audeara with 9,668,657 shares.
According to its most recent filing, Audeara had 145,224,130 shares on issue, meaning that Dr Jeffery’s remaining 5,668,657 share-holding amounted to 3.9 percent of the company.
Audeara fell 0.4 cents or 9.3 percent to 3.9 cents.

ARGENT BIOPHARMA (FORMERLY MGC PHARMACEUTICALS)

Argent, formerly Medical Grade Cannabis Pharma, says it has appointed the Guernsey, UK-based Shore Capital Stockbrokers as its UK corporate broker, effective immediately.
In 2021, the-then MGC said it opened on the London Stock Exchange following a GBP6.5 million ($A12.4 million) ‘oversubscribed’ placement at 1.475 British pence (2.81 Australian cents), closed at 2.38 pence, and later fell to less than 0.25 of a penny (BD: Feb 4, 2021).
Last year, MGC said 96.6 percent of extraordinary general meeting votes backed a 1,000-to-one consolidation; and this year, said 99.67 percent of its extraordinary general meeting voted to change its name to ‘Argent Biopharma’ (BD: Oct 26, 2023; Mar 19, 2024).
Today, Argent managing-director Roby Zomer said the appointment was “a further step in our comprehensive restructuring process to position Argent Biopharma in pioneering drug discovery within the biopharmaceutical sector, supported by the strengthening of our management team and advisory board”.
Argent was up one cent or 3.3 percent to 31 cents.