Biotech Daily

Thursday October 3, 2024

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: PRESCIENT UP 12.5%; UNIVERSAL BIOSENSORS DOWN 9%**

*** ISLAND 'FIRM COMMITMENTS' FOR $3.5m PLACEMENT**

*** LUMOS WINS BARDA $4.4m FOR FEBRIDX**

*** CYCLOPHARM US VETERANS AFFAIRS TECHNEGAS DEAL**

*** ISLAND DOSES 4 PHASE IIa ISLA-101 DENGUE FEVER VOLUNTEERS**

*** IMMUTEP ENROLS PHASE II EFTI BREAST CANCER TRIAL**

*** BIO-MELBOURNE: AUSTRALIAN MEDTECH MANUFACTURING ALLIANCE**

*** RADIOPHARM REQUESTS FDA PRE-IND BETABART MEETING**

*** IMMURON REQUESTS 'TRIAL DATA' TRADING HALT**

*** BOTANIX 50% DIRECTOR FEES HIKE, 36m BOARD 'RIGHTS' AGM**

*** CANN 4.5m CEO JENNI PILCHER OPTIONS AGM**

*** GENETIC TECHNOLOGIES RECEIVES $1.8m FEDERAL R&D TAX INCENTIVE**

*** ALLEGRA DIRECTOR DR NICHOLAS HARTNELL TAKES 89.8%**

*** DR NICHOLAS HARTNELL REPLACES ALLEGRA CHAIR PETER KAZACOS**

*** BOTANIX 12.5% CHAIR PAY RISE TO $655k; APPOINTS STAFF**

*** BENJAMIN GISZ REPLACES SOMNOMED DIRECTOR HAMISH CORLETT**

MARKET REPORT

The Australian stock market edged up 0.09 percent on Thursday October 3, 2024, with the ASX200 up 7.0 points to 8,205.2 points. Thirteen of the Biotech Daily Top 40 companies were up, 20 fell and seven traded unchanged.

Prescient was the best, up half a cent or 12.5 percent to 4.5 cents, with 2.1 million shares traded. Orthocell rose 11 percent; both Atomo and Cynata climbed 10 percent; Mesoblast was up 8.4 percent; Cyclopharm and Paradigm were up more than seven percent; Avita rose six percent; Percheron climbed five percent; Alcidion was up 3.6 percent; Emvision rose 2.5 percent; Opthea was up 1.85 percent; with CSL and Telix by less than one percent.

Yesterday's one cent of 6.7 percent best, Universal Biosensors, led the falls, down 1.5 cents or 9.4 percent to 14.5 cents, with 39,000 shares traded. Nova Eye lost 5.3 percent; 4D Medical, Imugene and Medadvisor fell four percent or more; Actinogen, Clinuvel, Curvebeam, Immutep, Impedimed, Resonance and Starpharma were down three percent or more; Genetic Signatures, Neuren, Polynovo and Syntara shed more than two percent; Aroa, Cochlear and Nanosonics were down more than one percent; with Clarity, Pro Medicus and Resmed down by less than one percent.

ISLAND PHARMACEUTICALS

Island says it has 'firm commitments' to raise $3.5 million through an institutional placement at seven cents a share, with one attaching option per share.
Island said the options would be exercisable at seven cents each, with half expiring within a year of issue and the rest expiring two years from issue, subject to approval.
The company said the issue price was an 11.39 percent discount to the 15-day volume weighted average price.
Island said the funds would be used to for its ISLA-101 dengue fever study, finish due diligence on its galidesivir program and, if successful, acquire and advance the program.
Last month, Island said it had paid the Durham, North Carolina-based Biocryst Pharmaceuticals $US50,000 ($A75,109) for a 12-month exclusive period in which it could acquire Biocryst's galidesivir anti-viral molecule (BD: Jul 3, Sep 11, 2024).
Today, the company the placement was supported by investors who "approached the company to offer cornerstone support".
Island said investors included Race managing-director Dr Daniel Tillett, the Hong Kong-based Angus Walker, Island co-founder and major investor Dr Bill Garner, shareholder Jason Carroll and non-executive director Chris Ntoumenopoulos.
The company the first tranche of shares worth $1,905,555 would be issued under its existing placement capacity, with the remaining shares and 50,000,000 options subject to shareholder approval, including Mr Ntoumenopoulos' securities.
Island said it managed the placement, with no broking fees paid to external parties.
Island was up 2.5 cents or 31.25 percent to 10.5 cents with 5.4 million shares traded.

LUMOS DIAGNOSTICS HOLDINGS

Lumos says it has $US2,984,571 ($A4,350,000) from the US Biomedical Advanced Research and Development Authority (BARDA) for its Febridx infection diagnostic.
Lumos said the BARDA grant would support a planned clinical laboratory improvement amendments (CLIA)-waiver clinical study and US Food and Drug Administration regulatory filing for its Febridx, point-of-care, finger-prick blood test to differentiate bacterial from viral respiratory infections.
The company said BARDA would support the CLIA waiver study, which would compare test use among untrained users to trained users and provide regulatory expertise and support for the application to obtain a CLIA-waiver from the FDA.
Lumos said the contract value, if all options were exercised, was $US8,258,774.
The company said that the project had been funded in whole, or in part, with US Federal funds from the Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response and BARDA.
Lumos managing-director Doug Ward said that since early clinical practice, doctors had "relied primarily on clinical observation to determine whether patients require antibiotics for acute respiratory conditions".
"Febridx is a powerful diagnostic which can provide a quick and clear clinical evaluation, and in doing so, can reduce over-prescription of antibiotics," Mr Ward said.
"BARDA's expertise and the associated funding will support our objective of expanding the test's utility, from its current use case in moderate/high complexity labs, to US CLIA-waived point-of-care settings, including physician offices, urgent care clinics, or other outpatient clinics," Mr Ward said.
"Should this goal be achieved, Febridx's ability to improve antibiotic stewardship will be vastly expanded," Mr Ward said.
Lumos was up 0.6 cents or 16.2 percent to 4.3 cents with 24.5 million shares traded.

CYCLOPHARM

Cyclopharm says it has an interim agreement to supply 120 US Government Veterans Health Administration hospitals with its Technegas lung imaging device.

Cyclopharm said the deal would provide Veterans Affairs hospitals with nuclear medicine departments immediate access to the pharmaceutical and consumable components of its Technegas computed tomography lung ventilation imaging device.

The company said the first purchase order was complete.

Cyclopharm did not disclose commercial terms; but last year, Cyclopharm managing-director James McBrayer told Biotech Daily the company would receive $US7,000 ($A10,585) for Technegas generator installation, $US7,000 a year in licencing and a per patient payment of $US225 (BD: Dec 5, 2023).

The company said the deal was “the first step to Technegas’ inclusion on the broader US Federal Supply Schedule … [which was] a simplified procurement service for US Federal agencies to obtain products across the entire US Government system, including the Department of Defense, Veterans Administration and Public Health Service hospitals”.

Cyclopharm said installations at Veterans Affairs, Department of Defense and Public Health Service sites were expected to begin “in the first half of 2025”.

Mr McBrayer said the agreement bypassed “the need for Cyclopharm to negotiate separate contracts with each of the 20 regional procurement offices within the [Veterans Affairs] or potentially follow a reseller pathway that would delay the deployment of Technegas, distance us from our customers and impact margins beyond the legislated discounts required for federal contracts”.

“Throughout this process, we have leveraged our commercial experience and success in the 65 other countries where Technegas is the preferred agent of choice,” Mr McBrayer said. “In these markets, complementary and evolving technologies are continually expanding Technegas’ indications for use in respiratory medicine.”

Cyclopharm was up 11.5 cents or 7.5 percent to $1.64.

ISLAND PHARMACEUTICALS

Island says it has dosed all four participants in the phase IIa, preventative component of its 14-patient phase IIa/b trial of ISLA-101 for dengue fever.

Last year, Island said it was awarded $US1.3 million ($A1.89 million) from the US Department of Defense’s Congressionally Directed Medical Research Program for a phase IIa trial of ISLA-101 for dengue fever (BD: Jul 7, 2023).

Today, Island said that following dosing with ISLA-101, the four patients in the prevention arm of the study would be administered an attenuated strain of dengue fever on October 4, 2024, with symptoms to be monitored for 90 days.

The company said the attenuated strain of the virus was developed to allow for the study of dengue infected volunteers in a highly controlled setting, and that the strain caused a mild but clinically relevant dengue infection in the enrolled subjects.

Island said it expected data from the phase IIa study by the end of 2024 and to begin the 10-patient, phase IIb, therapeutic arm “in early 2025”.

Island managing-director Dr David Foster said the company was “weeks away from understanding the potential impact of our drug ISLA-101 on dengue fever”.

“As the first company in the world to investigate an agent as both a prophylactic and therapeutic against dengue in a clinical setting with a challenge virus, we are proud to be conducting this innovative trial to find a preventative and/or treatment for this devastating virus, at a time when infection rates are rapidly growing around the globe,” Dr Foster said.

IMMUTEP

Immutep says it has enrolled all 65 metastatic breast cancer patients in its phase II trial of eftilagimod alpha, or efti, with standard-of-care paclitaxel.

Last year, Immutep said it had dosed six-patients in its up-to 58 patient phase II trial of efti with paclitaxel for breast cancer, with no safety issues (BD: Nov 6, 2023).

At that time, the company said it had dosed the breast cancer patients with a 90mg dose of efti, formerly IMP321, in combination with paclitaxel chemotherapy, in the open-label, safety lead-in part of its phase II/III trial and had reported “no safety or tolerability issues” with no dose limiting toxicities.

Today, Immutep said it had enrolled 65 patients with metastatic hormone receptor positive (HR+), human epidermal growth factor receptor 2 (HER2)-negative/low or triple-negative breast cancer who had exhausted endocrine therapy.

The company said patients were enrolled at 22 sites in Europe and the US and had been randomized to receive either 30mg or 90mg of efti with paclitaxel to determine the optimal biological dose.

Immutep fell one cent or 3.1 percent to 31 cents with 3.5 million shares traded.

BIO-MELBOURNE NETWORK, VICTORIA GOVERNMENT

The Bio-Melbourne Network says it will partner with industry bodies to form the Australian Medtech Manufacturing Alliance, with Victoria Government seed funding.

The Bio-Melbourne Network said the partnership would include Ausbiotech, MTP Connect, the Australian Manufacturing Technology Institute Ltd (AMTIL) and the Industry Capability Network Victoria.

A spokesperson for the network told Biotech Daily that the amount of funding provided by the Victorian Government was confidential.

The Bio-Melbourne Network said the alliance sought to create a “unified industry voice and will advocate on behalf of Victorian [small-to-medium-enterprise] medical technology manufacturers across the key issues impacting the sector”.

The Network said the Alliance would address “procurement issues to increase the proportion of locally-made [medical technologies] in the Australian healthcare system, a goal that can be achieved by drawing on the wide variety of high-quality [medical technology] products already on offer from local manufacturers”.

Bio-Melbourne said it would work with partners to develop programs to help companies “identify and navigate contestable local market opportunities”.

The Network said that there was no help in Australia for local medical technology manufacturers to sell to the Australian health system, compared to international jurisdictions that had clear pathways that supported local manufacturers.

The Bio-Melbourne Network said that “for early-stage Australian [medical technology] manufacturers who are often exporting to other well-established health markets, having a home market customer is an important proof point”.

The Network said the alliance invited Victorian medical technology manufacturers, as well as contract manufacturing and development companies, to participate.

The Bio-Melbourne Network chief executive officer Karen Parr said Australia was “home to world-class [medical technology] innovators and manufacturers”.

“Increasing awareness of these companies and growing local content in health, will support Australian health services to continue to deliver world-leading care and strengthen our country’s sovereign capabilities,” Ms Parr said.

For further information, or to become a supporter, email: info@biomelbourne.org.

RADIOPHARM THERANOSTICS

Radiopharm says it has requested a pre-investigational new drug application meeting with the US Food and Drug Administration for its Betabart cancer therapy.
Radiopharm said the Betabart B7-H3 targeting radio-antibody was the first radio-pharmaceutical agent developed by Radiopharm Ventures, its joint venture with the Houston, Texas-based MD Anderson Cancer Center.
In 2022, the company said it had a joint-venture with the University of Texas MD Anderson Cancer Centre to develop radio-pharmaceutical products for cancer and hoped to develop least four therapeutic products based on the MD Anderson Centre's intellectual property (BD: Sep 14, 2022).
Today, Radiopharm said B7-H3 was an immune checkpoint molecule that was over-expressed in several tumor types, with deregulated B7-H3 expression linked with tumor aggressiveness and poor outcomes.
The company said Betabart was the "first and only targeted radio-pharmaceutical in development against the 4Ig subtype of B7-H3" which was the most common subtype expressed on human tumors.
Radiopharm said pre-clinical studies of Betebart showed tumor shrinkage and prolonged survival in animals, and with its pre-clinical data package and quality production it was preparing an investigational new drug application to the FDA for a phase I/II first-in-human trial of Betabart in multiple tumor types in the US, which it expected to begin in "mid-2025".
Radiopharm managing-director Riccardo Canevari said the company was "extremely pleased with the strong collaboration with MD Anderson and the early results we saw with Betabart are impressive, so we're looking forward to developing this further".
Radiopharm fell 0.1 cents or 3.6 percent to 2.7 cents with 6.7 million shares traded.

IMMURON

Immuron has requested a trading halt to allow it to "analyze and interpret Campetec hyperimmune bovine colostrum trial data prior to making an announcement".
Trading will resume on October 7, 2024, or on an earlier announcement.
Immuron last traded at 10 cents.

BOTANIX PHARMACEUTICALS

Botanix says investors will vote to increase the director fee pool 50 percent to $450,000 and grant 36,000,000 performance rights to its chair and directors.
Botanix said its annual general meeting would vote to increase the amount of fees payable to its non-executive directors from $300,000 a year to $450,000 a year to appoint additional directors, remunerate its directors appropriately, keep fee levels commensurate with market rates and reflect market competitiveness.
The company said shareholders would vote to grant chair Vince Ippolito 24,000,000 incentive performance rights, valued at $966,000, and directors Matthew Callahan, Dr Stewart Washer, Danny Sharp and Dr William Bosch 3,000,000 rights valued at $143,250, each, expiring five years from the issue date.
Botanix said the meeting would vote to adopt the remuneration report, re-elect Dr Bosch, ratify the issue of shares, approve the issue of up-to 100,000,000 securities over three years, renew the proportional takeover provisions and approve termination benefits.
The meeting will be held at Level 9, Mia Yellagonga Tower 2, 5 Spring Street, Perth on November 4, 2024 at 9am (AWST).
Botanix fell two cents or five percent to 38 cents with 8.0 million shares traded.

CANN GROUP

Cann says its annual general meeting will vote to issue 4,500,000 options to chief executive officer Jennifer Pilcher and 1,200,000 options in lieu of fees to directors.
Cann said shareholders would vote to issue Ms Pilcher's options as part of her long-term incentive plan.
The company said the options would vest in three equal tranches, with tranches of options exercisable at six cents, eight cents and 10 cents, respectively, by June 30, 2029, and were in addition to her $375,000 yearly pay plus superannuation.
Cann said the meeting would vote to issue chair Dr Julian Chick 600,000 options in exchange of a salary decrease from $120,000 a year to $100,000, with directors Douglas Rathbone and Robert Barnes to receive 300,000 options, each, for a reduction in fees from $65,000 to $55,000, for the year to September 30, 2025.
The company said investors would vote to adopt the remuneration report, re-elect Mr Rathbone, ratify the issue of 40,000,000 shares, 711,963 convertible notes and 6,735,867 options to Obsidian Global GP, as well as approve 6,735,867 options to Everblu Capital Pty Ltd and approve the additional 10 percent placement capacity.
The meeting will be held at Lander & Rogers, Level 15, 477 Collins Street, Melbourne on November 6, 2024 at 10am (AEDT).
Cann Group fell 0.4 cents or 5.7 percent to 6.6 cents with 1.7 million shares traded.

GENETIC TECHNOLOGIES

Genetic Technologies says it received $1.84 million from the Australian Tax Office under the Federal Government's Research and Development Tax Incentive program.
Genetic Technologies said the rebate related to research and development expenditure for the year to June 30, 2024.
Genetic Technologies was up 0.4 cents or 10.3 percent to 4.3 cents.

ALLEGRA MEDICAL TECHNOLOGIES

Allegra director Dr Nicholas Hartnell says he has increased his substantial shareholding from 106,199,153 shares (88.79%) to 107,411,776 shares (89.80%).
In May, Allegra said Allegra Innovations, a related party of director Dr Hartnell, would pay 0.4 cents a share in a cash bid, valuing it at $478,444 (BD: May 27, 2024).
In August, the company said Allegra Innovations Pty Ltd held 80.6 percent of the company, with shareholders who had accepted the offer to be paid within 10 days of acceptance (BD: Aug 12, 2024).
Today, the Bowral, New South Wales-based Dr Hartnell said that with Robinwood and Allegra Innovations he acquired the shares "as a result of acceptances of takeover offers made by [Allegra Innovations] dated June 20, 2024".
Allegra was in a suspension and last traded at 2.9 cents.

ALLEGRA MEDICAL TECHNOLOGIES

Allegra says director Dr Nicholas Hartnell will replace chair Peter Kazacos, effective immediately, with chief executive officer Jenny Swain appointed a director.
Today, the company said Mr Kazacos had "decided to step down as non-executive chairman" and had been with the company since 20-06.

BOTANIX PHARMACEUTICALS

Botanix says it will increase executive chair Vince Ippolito's annual pay 12.5 percent from $US400,000 ($A582,496) to $US450,000 ($A655,308) and has appointed staff.

Botanix said that since January 2023 Mr Ippolito, along with other directors and staff, had taken a 50 percent pay reduction and no annual bonuses to "conserve the company's cash".

The company said Mr Ippolito would have an increased base salary, with "no credit for the 50 percent salary, or annual bonus forgone" and that his at-risk cash, short-term incentive for the year to June 30, 2025 had increased from 35 percent to 50 percent of his yearly pay.

Botanix said the board had "also resolved to grant Mr Ippolito 24,000,000 incentive performance rights in seven separate tranches, based on the achievement of specified revenue performance and other milestones".

The company said that it had also appointed John Walsh head of sales, Sheetal Sahel head of marketing, Kevin Wojciechowski head of healthcare professionals marketing and sales training and Darin Van Arsdalen director of sales operations.

Botanix said Mr Walsh was most recently regional business director of Dermavant Sciences, which was previously managed by Mr Ippolito and its chief executive officer Howie McKibbon and had held senior sales roles at dermatology companies including Anacor and Pfizer.

The company said Ms Sahel was most recently head of marketing and commercial operations at Novan Inc and head of marketing and commercial strategy at Cassiopea Inc and had held senior marketing roles at Galderma.

Botanix said Mr Wojciechowski had worked at Avalere Health and had been director of marketing and sales training at Journey Medical as well as senior product marketing manager at Medicis and other sales training roles with Stryker, Cephalon and Johnson & Johnson.

The company said Mr Arsdalen had worked at Incyte, Strata Skin Sciences, Encore Dermatology and Graceway Pharmaceuticals.

SOMNOMED

Somnomed says TDM Growth Partners' Benjamin Gisz will replace director Hamish Corlett, effective from October 8, 2024.

Somnomed said Mr Corlett was also a director of TDM Growth Partners, which was its largest shareholder, and had served as a director since May 1, 2018.

The company said Mr Gisz had extensive investing and financial markets experience, including at Investec Group and Credit Suisse, and was currently a director at Pet Circle and had been a director at Pacific Smiles Ltd.

Somnomed said Mr Gisz held a Bachelor of Commerce from the University of Sydney.

Somnomed fell one cent or 2.5 percent to 39 cents.