Biotech Daily

Thursday November 9, 2023

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: IMUGENE UP 36%; KAZIA DOWN 21%**

*** TELIX APPOINTS WIIK NORDIC DISTRIBUTOR**

*** NUHEARA RETAIL RIGHTS RAISE $500k; TOTAL $3m; $7m SHORTFALL**

*** CARDIEX: $7.5m C2 VENTURES LOAN**

*** SYNTARA (PHARMAXIS) DOSES 1st PHASE II PXS-4728 IRBD PATIENT**

*** IMMUTEP ENROLS PHASE IIb EFTI HEAD, NECK CANCER TRIAL**

*** BLUECHIIP SAMPLE-MANAGEMENT ORDER**

*** RACE RC220 'MEETS MANUFACTURING STANDARDS'**

*** PROTEOMICS RECEIVES $1.85m FEDERAL R&D TAX INCENTIVE**

*** PINNACLE BELOW 5% IN COCHLEAR**

*** PREMIER DILUTED FROM 8.7% TO 1.1% OF MGC**

*** BIO-MELBOURNE 1st mRNA LECTURE TOMORROW**

*** INVEX APPOINTS DAVID WHEELER DIRECTOR**

MARKET REPORT

The Australian stock market was up 0.28 percent on Thursday November 9, 2023, with the ASX200 up 19.5 points to 7,014.9 points. Fourteen of the Biotech Daily Top 40 stocks were up, 21 fell, four traded unchanged and one was untraded.

Imugene was the best, up 2.9 cents or 35.8 percent to 11 cents, with 414.8 million shares traded. Proteomics climbed 7.9 percent; Compumedics was up 5.6 percent; Antisense and Cynata were up more than three percent; Nova Eye and Orthocell rose more than two percent; CSL, Emvision, Neuren and Opthea were up more than one percent; with Cochlear, Polynovo, Pro Medicus, SDI and Telix up by less than one percent.

Yesterday's 37.5 percent best, Kazia, led the falls, down 2.3 cents or 20.9 percent to 8.7 cents, with 2.8 million shares traded. Alcidion and Universal Biosensors lost more than six percent; Amplia, Avita, Dimerix, Micro-X and Next Science were down five percent or more; 4D Medical, Actinogen and Volpara fell more than four percent; Impedimed, Genetic Signatures and Resmed were down more than three percent; Paradigm shed 2.5 percent; Clinuvel, Immutep, Mesoblast and Prescient were down more than one percent; with Cyclopharm, Medical Developments and Nanosonics down by less than one percent.

TELIX PHARMACEUTICALS

Telix says it has an exclusive agreement with the Hinnerup, Denmark-based Wiik Pharma ApS to distribute its Illucix prostate cancer imaging agent in the Nordic region.
In an email not released to the ASX, Telix said Wiik was a supplier and distributor of nuclear medicine products and services and would distribute Illucix in Denmark, Finland, Norway and Sweden for three years from the national approval date in each country.
Wiik chief executive officer Yacoub Amin said the deal was “a major step … to improve the diagnosis and treatment” of patients with difficult-to-detect and treat diseases and had “high expectations” for Illuccix and potential diagnostics and therapeutics in the pipeline.
Telix executive Raphaël Ortiz said the company had “a network of leading distribution partners in Europe with a strong footprint to optimize our service to customer sites and ensure we can bring Illuccix to patients across the region, subject to regulatory approval”.
Telix was up two cents or 0.2 percent to $9.57 with 749,778 shares traded.

NUHEARA

Nuheara says its retail offer at 13 cents a share raised about $500,000, taking the total with the institutional offer to $3.0 million and leaving a shortfall of about $7 million.
Last month, Nuheara said it hoped to raise about $10 million in an accelerated, one-for-2.64, non-renounceable, non-underwritten entitlement offer (BD: Oct 10, 2023).
Today, the company said that it had received commitments for about $900,000 of the shortfall, and was seeking firm commitments to place the remaining $6.1 million.
Nuheara said the funds would “strengthen … [its] capability to execute on its accelerated US expansion and expected future opportunities”.
Nuheara fell half a cent or 3.85 percent to 12.5 cents.

CARDIEX

Cardiex says it has a $7.5 million loan from chair and managing-director controlled C2 Ventures at 10 percent or 15 percent per annum, depending on shareholder approval.
Cardiex said executive chair Niall Cairns and managing-director Craig Cooper owned C2 Ventures Pty Ltd which would commit to up-to $1.5 million in a placement and rights offer.
The company said the loan would be in $1.5 million increments, six monthly from a base of $1.5 million to $7.5 million between July 1 and December 31, 2024.
Cardiex said interest will accrue on the principal outstanding at 10 percent per annum during the period beginning on the date of the loan and ending on, if shareholder approval is not obtained to convert loans into equity, the day of the shareholders meeting; and otherwise, the maturity date.
The company said that if shareholder approval was not obtained, the interest rate would be 15 percent per annum during the period commencing on and from the day after the shareholder meeting and ending on the maturity date.
Cardiex said it might elect whether to pay interest in cash and if interest was not paid in cash, it would automatically be capitalized.
The company said that subject to all necessary approvals, some or all of the outstanding moneys may be repaid by issuing securities to C2 Ventures.
Cardiex said the funds would be used for operations, product development, marketing costs of product launches, market development, capital raising costs and paying debts.
The company said it had agreed to hold a shareholder meeting to seek approval “for the conversion to equity of all loans under the loan facility, up-to the maximum facility limit”.
Cardiex was untraded at 13.5 cents.

SYNTARA (FORMERLY PHARMAXIS)

Syntara says it has dosed the first of 40 patients in its randomized, controlled, phase II study of PXS-4728 for isolated rapid eye movement sleep behavior disorder (IRBD).
Last year, the then Pharmaxis said the British charity Parkinson's UK granted it GBP2.9 million ($A4.9 million) for the PXS-4728 study (BD: Sep 1, 2022).
Today, the company said the first patient was dosed at the University of Sydney's Parkinson's Disease Research Clinic in a study based on research that showed the development of IRBD, a condition where "otherwise healthy people start acting out their dreams" was the "strongest predictor for the development of Parkinson's and dementia … [and] more than 70 percent of IRBD patients transitioned to a neurodegenerative disease".
The company said the trial would examine whether targeting inflammation in the brain of people with IRBD might be a neuro-protective strategy to prevent Parkinson's disease.
Syntara said it expected the study to cost about $5.8 million, would start recruitment in the UK this year and continue throughout 2024, with results expected by July 2025.
Syntara chief executive officer Gary Phillips said "this trial initiation importantly marks the first of three phase II studies scheduled to commence before the end of the year".
Last month, the then Pharmaxis said it had sold its mannitol respiratory business to Sydney's Arna Pharma (BD: Oct 19, 2023).
Today, Mr Phillips said: "IRBD patients have very few treatment options available so this study provides hope for an effective treatment with potential to move towards the longer-term goal of stopping neurodegeneration."
"The company's other studies in myelofibrosis and scar prevention after surgery for burn injuries offer similar potential to change patient lives," Mr Phillips said.
Syntara was unchanged at three cents.

IMMUTEP

Immutep says it has enrolled all 171 patients in its phase IIb trial of efti, with pembrolizumab for recurrent or metastatic head and neck squamous cell carcinoma.
Immutep said 138 patients with tumors expressing programmed-cell death-ligand 1 (PD-L1), with a combined positive score (CPS) of more than one, had been enrolled into a randomized first cohort, or cohort A and receive 30mg of eftilagimod alpha, or efti, with 400mg of pembrolizumab, or Keytruda, every six weeks or 400mg of Keytruda alone.
The company said 33 patients with PD-L1 expressing tumors (CPS < 1) were enrolled in cohort B and they were "not expected to respond to Keytruda monotherapy, with a typical overall response rate of up-to five percent, and therefore were not randomized".
Immutep said "due to more patients with negative PD-L1 expression (CPS <1) who were eligible for, and allocated to the cohort B, and the number of patients in screening at the time of achieving the trial's enrolment goal, the trial enrolled 171 patients".
The company said the study's primary endpoint was overall response rate of evaluable patients measured by response evaluation criteria in solid tumors (Recist), with secondary endpoints including overall survival, overall response rate according to 'immune Recist', progression free survival, and duration of response.
Immutep said it would perform primary analysis after all subjects had completed at least three cycles of treatment, which would take 18 weeks, or discontinued the trial, and that all relevant data for the primary endpoint had been collected, cleaned and analyzed.
Immutep said it expected to report data from the trial before July 2024.
Immutep chief scientific officer Dr Frédéric Triebel said the completion of patient enrolment was "an important milestone in the clinical development of efti".
Immutep fell half a cent or 1.7 percent to 29.5 cents with 1.2 million shares traded.

BLUECHIIP

Bluechiip says it has an order for its sample-management solution from an unnamed California-based pharmaceutical company.
Bluechiip said the customer, which could not be named, was the third “global top-20 pharmaceutical company” from whom it had received an order.
The company said the order took the number of laboratories using its technology to 28, run by 17 separate customers, but did not state the commercial terms of the agreement.
Bluechiip managing director Andrew McLellan said the company was confident that companies would continue to look to its “advanced sample management solution as they acknowledge the increasing importance of tracking valuable samples and the temperature history of those samples in their safekeeping”.
Bluechiip was up 0.2 cents or 8.7 percent to 2.5 cents.

RACE ONCOLOGY

Race says its RC220 bisantrene formulation for cancers has met manufacturing quality specifications according to a contract development and manufacturing organization.
Race said receiving a certificate of testing had cleared it for use in its toxicology and safety pharmacology study, and “significantly de-risks the RC220 good manufacturing campaign underway at Ardena”.
Earlier this year, the company said it would pay Ardena Holding NV about $US1 million ($A1.5 million) to provide good manufacturing practice-standard RC220 intravenous bisantrene (BD: Jul 12, Oct 5, 2023).
Today, Race said that the San Diego, California-based Societal CDMO had engineered a batch of more than 1,500 vials of RC220, and that the batch had met the manufacturing quality specifications required for an intravenous drug product.
Race executive director Dr Pete Smith said “bringing a new [intravenous] drug product like RC220 to the clinic is a complex undertaking that requires successful progress through multiple checkpoints”.
“The recent data confirming that RC220 satisfied all manufacturing quality specifications when produced at scale for the first time represents an incredibly important milestone, as it strongly supports our ability to produce … material suitable for human clinical use,” Dr Smith said.
Race fell 8.5 cents or 8.1 percent to 96.5 cents.

PROTEOMICS INTERNATIONAL LABORATORIES

Proteomics says it has received $1,848,832 million from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.
Proteomics said the rebate related to expenditure for the year to June 30, 2023.
Proteomics was up seven cents or 7.9 percent to 96 cents.

COCHLEAR

The Brisbane-based Pinnacle Investment Management Group says it has ceased its substantial holding in Cochlear.
In July, Pinnacle said it became substantial with 3,299,003 shares (5.02%), and today said it bought, sold, and transferred shares between June 7 and November 3, 2023, with the single largest sale 91,000 shares on September 26 for $23,529,870, or $258.57 a share.
Cochlear was up $1.48 or 0.6 percent to $253.90 with 121,921 shares traded.

MGC PHARMACEUTICALS

Premier Fund Managers Ltd says its 8.67 percent substantial holding in MGC was diluted to 1.08 percent, with its 383,885,951 shares consolidated to 383,886 shares.
Yesterday, MGC said it had completed its one-to-1,000 consolidation, following overwhelming investor approval at its general meeting, and had settled its $US7.9 million ($A12.5 million) placement, issuing 31,000,000 post-consolidation shares at 25.5 US cents, or 40 Australian cents, a share (BD: Nov 1, 2023).
Today, the Surrey, UK-based Premier said it was diluted due to the placement increasing the number of post-consolidation shares on issue from 4,430,491 shares to 35,430,491 shares.
MGC was up 4.5 cents or 8.1 percent to 60 cents.

BIO-MELBOURNE NETWORK

The Bio-Melbourne Network says the first of four lectures in its mRNA series will be held in Melbourne tomorrow, November 10, 2023, from 8am-to-11am (AEDT).
The Bio-Melbourne Network said “based on the demand and success of the first lecture series” it was hosting a second series for the Victorian RNA community.
The Network said the lectures, hosted in collaboration with mRNA Victoria, presented “an opportunity for global leading specialists in the RNA field to share their knowledge with the local RNA community”.
The Bio-Melbourne Network said the lectures would be followed by networking which was “an opportunity to foster connections between researchers, industry and government to build a connected and collaborative ecosystem in Victoria”.
The Bio-Melbourne Network said the first lecture, titled ‘The RNA Platform: The Breadth of Possibility Beyond mRNA’ would focus on the RNA platform and its different modalities beyond mRNA.
The Network said speakers included Olivia Newton John Cancer Research Institute chief executive officer Prof Marco Herold, Peter MacCallum Cancer Centre’s head of RNA Biology and Cancer Laboratory Dr Vi Wickramasinghe and Rage Biotech chief executive officer Dr Christopher Wraight.
The Network said RNA was “an emerging global modality that promises treatments for previously ‘undruggable’ diseases”.
“This lecture will provide an insight into the breadth of the RNA platform potential and the flexibility it provides to target a range of disease types,” the Network said.
“While the Covid-19 pandemic proved the efficacy of mRNA vaccines, RNA as a platform technology has broader implications across multiple modalities such as mRNA, anti-sense oligonucleotides, short-interfering RNA, self-amplifying RNA, circular RNA and aptamers,” the Bio-Melbourne Network said.
“It can also be used to encode other functional biological molecules such as monoclonal antibodies and cytokines,” the Network said.
The Network said the event, at International Chamber House, Theatrette, Level 5, 121 Exhibition Street, Melbourne from 7.45am (AEDT) would not be streamed online, registration was free for members and only on-the-day, with more information at: https://biomelbourne.org/event/the-rna-platform-the-breadth-of-possibility-beyond-mrna/.
The Bio-Melbourne Network said the three remaining lectures would be held on February 20, March 14, and May 28, 2024.

INVEX THERAPEUTICS

Invex says it has appointed David Wheeler as a non-executive director, effective from November 8, 2023.

Invex said Mr Wheeler had more than 30 years of experience, including his current roles as director and partner of Pathways Corporate, chair of Protean Energy Ltd, PVW Resources Ltd and Avira Resources Ltd as well as a director of Ragnar Metals Ltd, Tyranna Resources Ltd, MOAB Ltd, Cycliq Group Ltd, Cradle Resources Ltd and OZZ Resources Ltd.

Invex was up half a cent or 2.2 percent to 23.5 cents.