Biotech Daily

Thursday December 12, 2024

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: UNIVERSAL BIOSENSORS UP 14%; CLARITY DOWN 12%**

*** SYNTARA PLACEMENT RAISES $15m**

*** NEUREN: ACADIA COMPLETES $234m DAYBUE VOUCHER SALE**

*** ORTHOCELL RECEIVES 1st SINGAPORE REMPLIR ORDER**

*** IMMUTEP: 'EFTI STRONG OVERALL SURVIVAL IN HEAD, NECK CANCER'**

*** CYNATA DOSES 1st PHASE I CYP-001 KIDNEY TRANSPLANT PATIENT**

*** BCAL SYDNEY LABORATORY NATA ACCREDITED**

*** LTR OPENS SPONTAN TELEHEALTH**

*** MEMPHASYS: 'HERANOVA TO DISTRIBUTE FELIX FOR IVF IN CHINA'**

*** ECHO IQ 21m CHAIR, DIRECTOR RIGHTS, OPTIONS EGM**

*** AUDEARA CHAIR DAVID TRIMBOLI INCREASES, DILUTED TO 12.6%**

*** NAOS TAKES 26.8% OF BTC**

*** CHIMERIC CHAIR PAUL HOPPER INCREASES, DILUTED TO 12.4%**

*** MERCHANT FUNDS TAKES 5.1% OF NEUROTECH**

*** KEN NELSON REPLACES ECHO IQ DIRECTOR SIMON TOLHURST**

MARKET REPORT

The Australian stock market fell 0.28 percent on Thursday December 12, 2024, with the ASX200 down 23.3 points to 8,330.3 points. Ten of the Biotech Daily Top 40 companies were up, 23 fell and seven traded unchanged.

Universal Biosensors was the best, up 1.5 cents or 13.6 percent to 12.5 cents, with 332,595 shares traded. Curvebeam climbed 7.7 percent; Proteomics was up 6.35 percent; Immutep improved 5.6 percent; Emvision and Orthocell were up four percent or more; Cyclopharm was up 3.5 percent; Atomo rose 2.6 percent; with Avita, Pro Medicus and Resonance up by more than one percent.

Clarity led the falls, down 62 cents or 12.0 percent to $4.55, with five million shares traded. Percheron lost 10 percent; Actinogen and Dimerix both shed 6.7 percent; Micro-X and Paradigm were both down 5.6 percent; Cynata and Syntara fell more than four percent; Alcidion, EBR, Nova Eye and Opthea were down more than three percent; 4D Medical, Amplia, Imugene and Prescient shed more than two percent; Clinuvel, Cochlear, Nanosonics and Neuren were down one percent or more; with CSL, Mesoblast, Polynovo, Resmed, SDI and Telix down by less than one percent.

SYNTARA (FORMERLY PHARMAXIS)

Syntara says it has “firm commitments” to raise $15.0 million at six cents a share in a placement to “institutional and high net worth investors”.
Syntara said issue price was a 10.4 percent premium to the 30-day volume weighted average price, and a 10.4 percent discount to the last traded price, and was 114.3 percent higher than the 2.8 cents price of its previous placement.
Earlier this year, the company said it had raised $5.0 million placement at 2.8 cents a share to cover the claimed amounts owing from its sale of mannitol (BD: Jul 30, 2024).
Today, Syntara said the funds would be used for its clinical trials of SNT-5505 for myelofibrosis, as well as for trials of a variant of Parkinson’s disease (idiopathic rapid eye movement sleep behavior disorder or IRBD), scar trials and a myelo-dysplastic syndrome (MDS) clinical trial, as well as for drug development, employee research costs and general working capital.
The company said $2,600,000 of the placement was subject to shareholder approval, with $580,000 invested by KP Rx, a fund managed by an unnamed director of the company.
A Syntara spokesperson told Biotech Daily that director Hashan De Silva had taken over Karst Peak from Adam Leitzes and renamed it KP Rx.
Syntara said Canaccord Genuity and Euroz Hartleys were joint lead managers.
Syntara fell 0.3 cents or 4.5 percent to 6.4 cents with 40.55 million shares traded.

NEUREN PHARMACEUTICALS

Neuren says Acadia has completed the $US150 million ($A234 million) sale of the Daybue priority review voucher and it will receive one-third of the proceeds.
Last year, Neuren said that North America partner Acadia Pharmaceuticals had US Food and Drug Administration approval for Daybue, or trofinetide, for Rett syndrome in adults and children two years of age and older (BD: Mar 13, 2023).
Last month, the company said it expected one-third of the proceeds from Acadia’s $US150 million ($A227 million) sale of the Daybue rare paediatric disease priority review voucher (BD: Nov 6, 2024).
Neuren fell 20 cents or 1.5 percent to $13.24 with 485,881 shares traded.

ORTHOCELL

Orthocell says distributor Device Technologies Asia has received its first orders in Singapore for its Celgro-based Remplir collagen wrap for peripheral nerve repair.
Earlier this year, Orthocell said it had Singapore Health Sciences Authority approval for Remplir use in peripheral nerve repair (BD: Oct 8, 2024).
Last month, the company said Device Technologies Asia would exclusively distribute Remplir in Singapore for an initial five-year term (BD: Nov 27, 2024).
Today, Orthocell did not state the quantity of units sold or value of the sale.
Orthocell managing-director Paul Anderson said the company was “delighted to report first sales to [Device Technologies] Asia earlier than expected”.
“Device Technologies is our chosen distribution partner in Australia, New Zealand and Singapore and have moved quickly to begin selling our leading nerve repair product Remplir in Singapore,” Mr Anderson said.
“We expect additional sales, revenue growth and surgeon adoption of Remplir to accelerate in the new year,” Mr Anderson said.
Orthocell was up four cents or four percent to $1.04 with 1.85 million shares traded.

IMMUTEP

Immutep says 31 cohort B head and neck cancer patients in its phase IIb trial of efti with Keytruda show “strong overall survival, progression-free survival, and durability”.
In June, Immutep said the 171-patient trial showed eftilagimod alpha, or efti, with anti-programmed cell death-1 therapy pembrolizumab (Keytruda) in patients with a combined positive score of more than one (CPS>1), cohort A, led to “overall response rates that exceed Keytruda monotherapy” (BD: Jun 27, 2024).
At that time, Immutep said 58 of 118 evaluable patients in cohort A had a 32.8 percent overall response when treated with the combination compared to a 26.7 percent overall response in the 60 patients treated with Keytruda alone (BD: Jun 27, 2024)
Later, the company said cohort A patients dosed with efti had a complete response rate of 6.9 percent, compared to 3.7 percent for Keytruda alone (BD: Sep 16, 2024).
Today, Immutep said the further data was from patients in cohort B with a combined positive score of less than one (CPS<1), meaning that they “typically do not respond well to anti-PD-1 therapy alone”.
The company said “positively, median overall survival has not yet been reached and the 12-month [overall survival] rate is 67 percent, both well above historical controls” compared to a 12-month overall survival rate of 39 percent for Keytruda alone.
Immutep said cohort B showed progression-free survival of 5.8 months compared to 2.1-month historical progression free survival with Keytruda alone.
The company said interim median duration of response was 9.3 months in cohort B compared to 2.6-month historical data of Keytruda alone.
Immutep said the complete response rate increased from 9.6 percent to 12.9 percent and 16.1 percent, according to response evaluation criteria in solid tumors, compared to no complete responses as shown in historical data of Keytruda monotherapy.
The company said the efti combination therapy continued “to be well-tolerated with no new safety signals” and it would engage with regulatory authorities.
Immutep managing-director Marc Voigt said the data was “an encouraging step in the right direction towards potentially bringing a new approach to this underserved population, representing up to 20 percent of patients with this difficult disease”.
Immutep was up two cents or 5.6 percent to 37.5 cents with 11.7 million shares traded.

CYNATA THERAPEUTICS

Cynata says it has dosed the first patient in its 16-patient, phase I/II trial of CYP-001 mesenchymal stem cells with standard-of-care for kidney transplant.
Earlier this year, Cynata said the Netherlands had approved an up-to 16-patient, phase I trial of its CYP-001 for kidney transplant patients (BD: Aug 21, 2023).
At that time, the company said it would supply CYP-001 for the trial which was funded and managed by Leiden University Medical Centre, and retain full commercial rights.
Today, Cynata said the first six renal transplant patients would receive either one or two infusions of CYP-001 as well as standard treatment, and subject to a safety review a further 10 patients would receive two infusions of CYP-001.
Cynata managing-director Dr Kilian Kelly said the trial would help build the body of data on the use of Cymerus induced pluripotent stem cell-derived mesenchymal stem cells in “a wide range of clinical indications”.
“There are clear parallels between use of CYP-001 in kidney transplant recipients, and use of CYP-001 in graft versus host disease, which led to very promising safety and efficacy outcomes in a completed phase I clinical trial,” Dr Kelly said.
Cynata fell one cent or 4.8 percent to 20 cents.

BCAL DIAGNOSTICS

Bcal says its Sydney clinical services laboratory has formal accreditation from the National Association of Testing Authorities Australia (NATA).

Bcal said the certification was awarded to the laboratory's quality systems and, following validation, it would seek to have its Breastest for breast cancer added to NATA's scope of tests able to performed at the laboratory.

The company said the first phase of Breastest's commercial launch in Australia was in partnership with the Sydney Breast Clinic and the test would "be offered as an adjunct to mammography".

Bcal said that the accreditation was "a major milestone for the company" and it was completing the necessary validation studies for Breastest, which remained on track to be made available to clinicians "in the first quarter of 2025".

Bcal chief executive officer Shane Ryan said the certification "was an international standard for clinical laboratories and certifies that the laboratory quality systems, documentation and protocols meet the international and Australian standards".

Bcal fell 1.2 cents or 10.9 percent to 9.8 cents with 5.8 million shares traded.

LTR PHARMA

LTR says it has launched its online healthcare platform for the regulated prescription of its Spontan erectile dysfunction nasal spray ahead of schedule.

Last month, LTR said with Perth's Restorative Sexual Health Clinic it would open an online men's health platform for therapeutic services and prescriptions by April 2025 (BD: Nov 12, 2024).

Today, the company said the platform provided access to treatments, including but not limited to its Spontan, providing Australian men with convenient access to healthcare professionals and evidence-based treatments.

LTR said the early launch was "driven by strong market demand and operational readiness".

In August, the company said the first erectile dysfunction patients had been dosed with its Spontan nasal spray version of vardenafil, marketed as Levitra, under the Australian Therapeutic Goods Administration's special access scheme, (BD: Aug 5, 2024).

LTR fell 3.5 cents or 3.8 percent to 89.5 cents with 1.7 million shares traded.

MEMPHASYS

Memphasys says it has a letter of intent with Hong Kong's Heranova Lifesciences HK Ltd to distribute its Felix sperm separation system for in-vitro fertilization (IVF) in China.

Memphasys said Heranova provided "diagnostics and treatments for women's health, with a focus on endometriosis and female fertility.

The company said Heranova would conduct an initial clinical assessment by an in-vitro fertilization clinic in China to confirm that Felix was "acceptable for clinical use and pave the way for the execution of an exclusive distribution agreement with the option of licencing and manufacturing the Felix system in the territory".

Memphasys said Heranova would finance clinical trials and applications for regulatory approval in the territory, and that the commercial aspects would include an upfront fee and royalties, payable to Memphasys, but were "yet to be determined".

Memphasys was up 0.1 cents or 20 percent to 0.6 cents with 6.8 million shares traded.

ECHO IQ

Echo IQ says shareholders will vote to issue 13,000,000 performance rights and 8,000,000 options to executive chair Andrew Grover and director Steve Formica.
Last month, Echo IQ said resolutions to issue 6,500,000 performance rights to Mr Grover as well as 4,500,000 rights to Mr Formica and 1,000,000 rights for director Stephen Picton were withdrawn from its annual general meeting (BD: Nov 13, 2024).
In an announcement today titled 'Appointment of leading cardiac focused US-based non-executive director', the company said an extraordinary general meeting would vote to issue the performance rights and options as part of Mr Grover and Mr Formica's long-term incentive.
Echo IQ said the performance rights would vest on milestones relating to US Food and Drug Administration approval and the receipt of reimbursement codes for its Echosolv cardiac screening device as well as share-price and revenue targets.
The company said the options were exercisable at 35 cents each by December 31, 2028.
Echo IQ said it would seek shareholder approval "at an upcoming shareholders' meeting of the issue of the performance rights and options to the directors" but did not disclose the date of the meeting.
Echo IQ was up 0.25 cents or one percent to 25.25 cents.

AUDEARA

Audeara chair David Trimboli says he has increased and been diluted in the company from 21,591,210 shares (14.87%) to 22,134,796 shares (12.64%).
The Perth-based Mr Trimboli said that with Seefeld Investments Pty Ltd he was diluted in a placement and received 543,586 shares in lieu of $17,938 worth of his director's fees on December 11, 2024.
Last week, Audeara said it had commitments to raise $1.35 million at four cents a share, with one attaching option for every three shares issued (BD: Dec 5, 2024).
Audeara was untraded at 4.4 cents.

BTC HEALTH

Naos Asset Management Ltd says it has increased its substantial shareholding in BTC from 83,364,340 shares (25.72%) to 86,897,697 shares (26.81%).
The Sydney-based Naos said that on December 3, 2024 it bought 3,553,357 shares for $193,654, or 5.45 cents a share.
BTC was up 0.8 cents or 13.6 percent to 6.7 cents.

CHIMERIC THERAPEUTICS

Chimeric executive chair Paul Hopper says he has increased and been diluted in the company from 94,994,574 shares (10.5%) to 194,994,574 shares (12.4%).
The Melbourne-based Mr Hopper said that with Deborah Coleman, Moreglade Ptd Ltd and Kilinwata Investments Pty Ltd he bought 100,000,000 shares on December 9, 2024 for 0.8 cents a share in a placement.
Earlier this year, Chimeric said it had raised $5 million at 0.8 cents a share in a placement, with one attaching option for every share purchased, with Mr Hopper to subscribe for up-to $1 million, subject to shareholder approval (BD: Oct 21, 2024).
Chimeric was unchanged at 0.6 cents with 2.9 million shares traded.

NEUROTECH INTERNATIONAL

Merchant Funds Management Pty Ltd says it has become a substantial shareholder in Neurotech with 53,099,919 shares, or 5.10 percent.

The Perth-based Merchant Funds said that it bought shares between September 10 and December 9, 2024, with the single largest purchase 3,333,334 shares on September 19 for $200,000, or six cents a share.

Neurotech was unchanged at 5.6 cents.

ECHO IQ

Echo IQ says it has appointed the Dallas, Texas-based Ken Nelson as a non-executive director, effective from yesterday, following Simon Tolhurst's resignation.

Echo IQ said Mr Nelson had more than 20 years of experience, having worked for cardiac and diagnostics monitoring business Biotelemetry and wearable device company Bardy Diagnostics.

The company said Mr Nelson was a partner at Medtech Advantage Fund, chair of Israel's Cardiacare and a director of Heartbeam, Acarix, Epitel and Happitech.

According to his Linkedin profile, Mr Nelson held a Bachelor of Arts from Nashville, Tennessee's Vanderbilt University.

Echo IQ said Mr Nelson would receive 4,000,000 options exercisable at the 30-day volume weighted average price for the month of December 2024, within five years, in addition to annual director fees.