Biotech Daily

Wednesday June 26, 2024

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH UP: ACTINOGEN UP 32%; ATOMO DOWN 4%**

*** ACTINOGEN: 'DATA SHOWS PTAU181 PROGRESSES ALZHEIMER'S'**

*** TGA FINES 6 'MEDICAL MARIJUANA' COMPANIES $627k**

*** RACE: RC220 BISANTRENE 'SAFE FOR HUMAN TRIALS'**

*** IMRICOR WINS 1st HUNGARIAN ICMR ORDER**

*** CLEO, FDA MEET FOR OVARIAN CANCER TEST**

*** NYRADA, REBION PARTNER FOR TRAUMATIC BRAIN INJURY**

*** REGAL FUNDS TAKES 29% OF OPTHEA**

*** ALLAN GRAY REDUCES TO 9% OF STARPHARMA**

*** ALLEGRA DIRECTOR DR NICHOLAS HARTNELL TAKES 54%**

*** CRYOSITE LOSES DIRECTOR ANDREW KROGER**

*** FORMER CRYOSITE DIRECTOR ANDREW KROGER REDUCES TO 27%**

*** CRYOSITE CHAIR MARK KERR, LINDMARK TAKE 18%**

*** LAURIE THOMAS FAMILY TAKES 8% OF CRYOSITE**

*** TRYPTAMINE ADVISOR DR ROBIN CARHART-HARRIS RENEWS CONTRACT**

MARKET REPORT

The Australian stock market fell 0.71 percent on Wednesday June 26, 2024, with the ASX200 down 55.8 points to 7,783.0 points. Seventeen of the Biotech Daily Top 40 stocks were up, 14 were down and nine traded unchanged.

Actinogen was the best, up one cent or 32.3 percent to 4.1 cents, with 31.8 million shares traded. Cyclopharm climbed 10.8 percent; both Cynata and Impedimed improved 7.7 percent; Polynovo was up 6.6 percent; Amplia and Resonance rose more than five percent; Clarity and Opthea were up more than four percent; Immutep and Neuren increased more than three percent; Dimerix and Nova Eye rose more than two percent; Compumedics and Medical Developments were up more than one percent; with CSL, Nanosonics and Telix up by less than one percent.

Atomo led the falls, down 0.1 cents or 3.85 percent to 2.5 cents, with 769,117 shares traded; followed by 4D Medical down two cents or 3.5 percent to 55.5 cents with 612,625 shares traded. Avita, Clinuvel, Medadvisor, Micro-X, Paradigm, Percheron, Prescient and Pro Medicus shed two percent or more; Cochlear, Emvision, Mesoblast, Resmed and SDI were down one percent or more; with Genetic Signatures down by 0.7 percent.

ACTINOGEN MEDICAL

Actinogen says placebo patient data from its biomarker study of Xanamem for Alzheimer's disease shows elevated pTau181 leads to "much more rapid progression".

In 2022, Actinogen said a 72-patient, phase IIa, Alzheimer's disease biomarker study showed Xanamem had "a therapeutic effect in patients" who had a phosphorylated tau (pTau) biomarker-positive blood profile (BD: Oct 10, 2022)

At that time, the company said the study used blood biomarker samples from its phase IIa placebo-controlled, 186-patient 'Xanadu' study which found Xanamem "did not achieve statistical significance" (BD: May 7, 2019).

Today, the company said the biomarker study results went through a blinded analysis at Sweden's University of Gothenburg and found that of 34 placebo patients, 18 in with elevated pTau181 levels showed "more rapid clinical progression" compared to the 16 patients with lower levels, measured across four endpoints.

Actinogen said the results were measured using Alzheimer's disease composite score, or Adcoms, ($p < 0.001$), a clinical dementia rating scale, or CDR-SB ($p < 0.001$), mini-mental state examination, or MMSE ($p = 0.12$) and 14-item Alzheimer's disease assessment scale -cognitive subscale, or ADAS-Cog14 ($p = 0.19$).

The company said that patients with low pTau levels "generally did not worsen during the 12-week trial", which confirmed that the original Xanadu trial population contained "a high proportion of non-progressive patients, many of whom may have had an alternative diagnosis to Alzheimer's disease".

Actinogen said its phase IIb trial was using elevated plasma pTau181 levels to select patients "in whom a Xanamem treatment effect is more likely to be demonstrable over the 36-week treatment period".

The company said the study, titled 'Plasma pTau181 Predicts Clinical Progression In A Phase II Randomized Controlled Trial of the 11-beta-HSD1 Inhibitor Xanamem for Mild Alzheimer's Disease" was published in the peer-reviewed Journal of Alzheimer's Disease, with the full article available at: https://bit.ly/3XG7NaS.

Actinogen chief executive officer Dr Steven Gourlay told Biotech Daily that the publication showed "the detail of our very valuable dataset from the phase IIa trial in biomarker-positive patients with Alzheimer's disease".

"It supports the design of our on-going … phase IIb trial that uses pTau181 to select patients with more progressive disease," Dr Gourlay said.

"It also confirms the rationale for using a cognitive composite and CDR-SB endpoints as sensitive measures of Xanamem benefit," Dr Gourlay said.

Actinogen was up one cent or 32.3 percent to 4.1 cents with 31.8 million shares traded.

AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION

The Therapeutic Goods Administration says it has fined six business and two individuals a total of $627,252 for the alleged unlawful advertising of medicinal cannabis.

The TGA said it was alleged that each business unlawfully promoted the use and supply of prescription-only medicinal cannabis on their websites and social media platforms, as well as allegedly endorsing the use of medicinal cannabis for treating serious diseases, conditions and disorders.

The TGA said Botanic Wellness Ltd was issued 13 notices for $244,140, both Grandiosa Imports Pty Ltd and Releaf Group Ltd were issued seven notices for $131,460, each, Nectartek Australia Pty Ltd was issue four notices for $75,120, Turkken Pty Ltd and an individual were issue two notices for $22,536, Cymra Life Sciences Ltd was issue one notice for $18,780 and another individual was issued one notice for $3,756.

RACE ONCOLOGY

Race says non-clinical studies in rats and dogs show its RC220 formulation of bisantrene has “an excellent safety profile”, with human clinical trials expected to begin by 2025.
Last year, Race said it had signed contracts worth $2.74 million with the Stilwell, Kansas-based Attentive Science and Adelaide’s Agilex Biolabs to conduct safety and toxicology studies of its RC220 formulation of bisantrene for peripheral infusion (BD: Oct 5, 2023).
Today, the company said the studies aimed to show in “two animal species that RC220 is safe and amenable to administration via peripheral IV infusion in humans and establish an acceptable starting dose for phase I clinical studies”.
Race said three doses of RC220 formulation of bisantrene were administered through peripheral veins and showed “similar systemic effects to those seen when using the historical bisantrene formulation administered via a central line”.
The company said the studies were completed on time and on budget and that “no unexpected or unacceptable toxicities were observed”.
Race said that at four weeks post-treatment “all observed toxicities were reversible”.
The company said that there were “no RC220 formulation-specific adverse macroscopic or histological findings at the sites of infusion”, meaning that, unlike the historical bisantrene formulation, peripheral IV administration of RC220 bisantrene was “devoid of adverse infusion site or vein reactions”.
Race said the data supported the use of RC220 bisantrene in human clinical trials
The company said the data would support regulatory and ethics submissions for its phase Ia/Ib trial of RC220 bisantrene in Australia, Hong Kong & South Korea, an investigator-led phase I/II acute myelogenous leukemia trial and a US Food and Drug Administration investigational new drug application in 2025.
Race chief executive officer Dr Daniel Tillett said the results were “another major milestone in bringing our new drug product to cancer patients”.
Race was up 10.5 cents or 6.1 percent to $1.815.

IMRICOR MEDICAL SYSTEMS

Imricor says it has an order for its interventional cardiac magnetic resonance (ICMR) imaging systems from Budapest, Hungary’s Semmelweis University Hospital.
Imricor said the order was its first in Hungary and followed a public tender approval process “due to the size of the capital purchase”.
The company did not disclose the commercial terms of the agreement.
Imricor said the purchase included its advantage-magnetic resonance electro-physiology recorder and stimulator, along with several third-party capital devices it sells including the Osypka HAT-500 RF ablation generator, Nordicneurola’s in-room monitors, and an Optoaccoustics communication headset system.
The company said that the purchase included “enough Imricor consumable products for the first 15 procedures”.
Imricor said installation of the ICMR laboratory equipment was “planned for July, with on-site training to follow” and first cases expected to commence by 2025.
Imricor chair and managing director Steve Wedan said the company’s “European sales leader Piero Zoppi promised steady activation of sites this year, and he and his team are delivering exactly that”.
“The tender process is sometimes required at new sites, but we know that only Imricor can bid on an ‘ICMR electrophysiology system’ because we are the only company in the world that makes one,” Mr Wedan said.
Imricor was up 2.5 cents or 5.3 percent to 50 cents.

CLEO DIAGNOSTICS

Cleo says it has “constructive and positive feedback” from the US Food and Drug Administration on the approval process for its ovarian cancer detection blood test.
Cleo said it had an initial pre-submission meeting with the FDA which was “designed to permit Cleo to receive early guidance from FDA review teams prior to an eventual application submission”.
The company said the meeting outcome provided “confidence that Cleo’s clinical rial designs and strategic direction are appropriately aligned with FDA requirements”.
Cleo said it was pursuing expedited FDA approval for its first ovarian cancer test, called “the pre-surgical triage test” through a 510(k) submission.
The company said the approach was “the quickest pathway to achieve regulatory approval for devices that achieve ‘substantial equivalence’ to an existing predicate”.
Cleo said its clinical trial design had been approved in both the US and Australia, with trial sites in the process of being contracted and patient recruitment “to commence shortly”.
Earlier this year, the company said that it had appointed New York’s contract research organization Lindus Health to help conduct a 10-month, 500-patient clinical trial of its ovarian cancer test clinical trial to support an FDA 510(k) application (BD: Apr 11, 2024).
Cleo fell half a cent or 1.6 percent to 30 cents.

NYRADA INC

Nyrada says it has a partnership with Boston’s Rebiscan Inc, or Rebion, to research traumatic brain injury and for non-dilutive funding opportunities.
Nyrada said Rebion had a “neural performance scanning technology to identify and monitor functional impairments in the brain, stemming from disease or injury” and that the partnership would advance therapies for traumatic brain injury sufferers.
The company said the collaboration included “joint research, conference presentations, and applications for non-dilutive funding grants”.
Nyrada said the “mid-term goal” of the partnership was to conduct a study on the efficacy of its brain injury therapy with Rebion’s brain injury detection and monitoring capabilities.
The company said the study could potentially be part of its “phase II trial of NYR-BI033 currently scheduled for 2025”.
Nyrada said there were “no immediate financial implications for Nyrada from entering this partnership” but any material costs or benefits arising from collaborative activities, including discoveries or grants, would be communicated to the market.
Nyrada was up 0.2 cents or 3.7 percent to 5.6 cents.

OPTHEA

Regal Funds Management says it has increased its substantial holding in Opthea from the equivalent of 152,169,776 shares (22.96%) to 312,995,827 shares (28.68%).
Sydney’s Regal Funds said it traded Australian shares and American depository shares (ADSs), between November 17, 2023 and June 21, 2024, with the single largest purchase 156,833,767 shares on June 21, 2024 for $62,733,507, or 40 cents a share.
Earlier this month, Opthea said its placement and one-for-1.22, partially underwritten institutional rights offer at 40.0 cents a share had raised about $171.5 million, with a retail offer for $55.9 million to follow (BD: Jun 12, 14, 2024).
Today, Regal Funds said it currently held 289,736,603 Australian shares (26.55%) and 2,907,403 ADSs (2.13%), with each ADS equivalent to eight Australian shares.
Opthea was up 1.5 cents or 4.35 percent to 36 cents with 2.8 million shares traded.

STARPHARMA HOLDINGS

Allan Gray Australia Pty Ltd says it has reduced its substantial shareholding in Starpharma from 43,591,315 shares (10.58%) to 38,239,700 shares (9.28%).
The Sydney-based Allan Gray said that between May 15 and June 21, 2024 it sold 5,351,615 shares for $530,227, or an average of 9.9 cents a share.
Starpharma was unchanged at 8.9 cents with 3.2 million shares traded.

ALLEGRA MEDICAL TECHNOLOGIES

Allegra director Dr Nicholas Hartnell says he has increased his substantial shareholding from 54,888,805 shares (45.89%) to 64,774,943 shares (54.15%).
In May, Allegra said Dr Hartnell would pay 0.4 cents a share in a cash bid, valuing it at $478,444; and last week, filed his bidder's statement (BD: May 27, Jun 20, 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.

CRYOSITE

Cryosite says 12-year director Andrew Kroger has resigned from the company, effective from today.
In 2011, Cryosite said it had appointed Mr Kroger as a non-executive director, replacing chair Theo Onisforou (BD: Nov 22, 2011).
At that time, the company said Mr Kroger had a long-term interest in Cryosite as one of the original investors when it listed on the ASX in 2002.
Today, Cryosite said Mr Kroger had "indicated that he will remain a substantial shareholder of the company".
Cryosite chair Mark Kerr said Mr Kroger's "commitment, involvement and support of the company over the last 20 years have been nothing short of outstanding".
"Mr Kroger retires from the board, with Cryosite in its strongest trading position since listing and substantial room for further growth," Mr Kerr said.
Cryosite was up 8.5 cents or 7.4 percent to $1.235.

CRYOSITE

Former Cryosite director Andrew Kroger says he has reduced his substantial shareholding in the company from 20,043,702 shares (41.07%) to 13,043,702 shares (26.72%).
The London-based Mr Kroger said that with Melbourne's Austen Bay Pty Ltd and Daltonvale Pty Ltd he sold 7,000,000 shares off-market on June 21, 2024 for $7,350,000, or $1.05 a share.

CRYOSITE

Cryosite chair Mark Kerr says he has increased his substantial shareholding in Cryosite from 7,154,494 shares (14.66%) to 9,000,000 shares (18.44%).
The Melbourne-based Mr Kerr said that with :INDA Marie Kerr and the Lindmark Investments staff superannuation fund he bought 2,000,000 shares off-market on June 21, 2024 for $2,100,000, or $1.05 a share, and sold 154,494 shares off-market for $162,219, or $1.05 a share.

CRYOSITE

Laurie Thomas says that the Laurie Thomas Family Nominees Pty Ltd has become a substantial shareholder in Cryosite with 4,000,000 shares, or 8.195 percent.
Melbourne's Laurie Thomas said that on May 7, 2024 1,000,000 shares were acquired for $850,000, or 85 cents a share and on June 21, 2024 3,000,000 shares were bought for $3,150,000, or $1.05 a share.

TRYPTAMINE THERAPEUTICS (FORMERLY EXOPHARM)

Tryptamine says its scientific advisory board (SAB) chair Dr Robin Carhart-Harris has agreed to continue in the role for an additional three-year term.
Tryptamine said Dr Carhart-Harris was a psycho-pharmacologist at the University of California, San Francisco and founder of the Centre for Psychedelic Research at Imperial College London.
The company said Dr Carhart-Harris held a Bachelor of Science from Bournemouth University, a Master of Arts from Brunel University and a Doctor of Philosophy from the University of Bristol.
Tryptamine did not disclose the date or duration of Dr Carhart-Harris' original employment contract.
The company said Dr Carhart-Harris would "continue to serve in an advisory capacity, including oversight of the review process for internal developments across the company's pipeline".
Tryptamine said Dr Carhart-Harris would "also provide strategic consulting and occasional independent advice with respect to internal protocols and development initiatives".
Tryptamine fell 0.1 cents or 4.8 percent to two cents with 1.8 million shares traded.