



Biotech Daily

Wednesday December 20, 2023

Daily news on ASX-listed biotechnology companies

- * **ASX UP, BIOTECH EVEN: SYNTARA UP 8%; UNIVERSAL BIOSENSORS DOWN 9%**
- * **LTR TELLS ASX AWARE QUERY 'PATENT REPORT NOT MATERIAL'**
- * **EPSILON ADMINISTRATORS CANCEL 2 BOARD SPILL EGMs**
- * **NEUREN ENROLS PHASE II NNZ-2591 ANGELMAN TRIAL**
- * **PROTEOMICS, OMICS 5-YEAR PROMARKERD CHILE DEAL**
- * **IMRICOR SIGNS EAST AGENCY 5-YEAR QATAR DEAL**
- * **ACTINOGEN OPENS 1st PHASE IIb XANAMEM ALZHEIMER'S TRIAL SITE**
- * **OPTHEA RECEIVES \$8.8m FEDERAL R&D TAX INCENTIVE**
- * **PHARMAUST RECEIVES \$553k FEDERAL R&D TAX INCENTIVE**
- * **VELOCIMETRY, ANDREAS, HELEN FOURAS DILUTED TO 17% OF 4D**
- * **VIKING DILUTED TO 11.3% OF LBT**
- * **DR DAVID CADE TO REPLACE TELIX CMO DR COLIN HAYWARD**
- * **UNIQUEST APPOINTS ANDREW MORGAN DIRECTOR**
- * **ATOMO LOSES DIRECTOR DR CURT LABELLE**
- * **JUSTIN CALLAHAN REPLACES FISHER & PAYKEL PAUL SHEARER IN SALES**
- * **BIO-MELBOURNE 5th MEDTECH SEMINAR: CARDIO-VASCULAR HEALTH**

MARKET REPORT

The Australian stock market was up 0.65 percent on Wednesday December 20, 2023, with the ASX200 up 48.8 points to 7,537.9 points. Fifteen Biotech Daily Top 40 stocks were up, 16 fell, eight traded unchanged and one was untraded. All three Big Caps rose.

Syntara was the best, up 0.2 cents or 8.3 percent to 2.6 cents, with 435,298 shares traded. Proteomics climbed 7.5 percent; Imugene improved five percent; Nova Eye was up 4.35 percent; Avita, Compumedics and Medical Developments were up more than three percent; 4D Medical, Amplia, Clinuvel, Emvision and Opthea rose two percent or more; CSL, Mesoblast, Paradigm, and Resmed were up one percent or more; with Cochlear, and Telix up by less than one percent.

Universal Biosensors led the falls, down two cents or 9.1 percent to 20 cents, with 50,015 shares traded. Next Science lost 7.35 percent; Curvebeam fell 5.6 percent; Neuren and SDI were down four percent or more; Prescient was down three percent; Alcidion, Clarity, Dimerix, Orthocell and Starpharma shed two percent or more; Antisense, Nanosonics and Polynovo were down more than one percent; with Cyclopharm and Pro Medicus down by less than one percent.

LTR PHARMA

LTR has told an ASX aware query that a preliminary report regarding its intellectual property was not material.

Last week, LTR listed on the ASX to commercialize its Spontan intra-nasal spray for erectile dysfunction (BD: Dec 11, 2023).

On December 15, the ASX noted that a 'Preliminary Report' said "in respect of 38 claims in the patent application ... [that] lack an inventive step ... as being obvious" compared to two existing patents and other claims were "so unclear that no meaningful opinion could be formed [because they] are dependent claims and are not drafted in accordance with the second and third sentence of Rule 6.4(a)" of the Patent Co-operation Treaty.

Last night after the market closed, LTR Pharma told the ASX that the preliminary report was an expression of opinion under the Patent Co-operation Treaty, generally not binding or final and just "a typical part of the patent process".

LTR said "for the time being, the relevant applications continue to be prosecuted and there is no change as to the status of the patent applications as a result of the issuance of the preliminary report".

The company said it did "not consider that a reasonable person would expect [the] information ... to have a material effect on the price or value of its securities".

The ASX asked LTR when it became aware of the report and the company said it had been told on December 13, 2023, by Strategic Drug Solutions Inc, a company whose intellectual property it had licenced and used to create the compound SDS-089, or Spontan.

LTR has previously said that Spontan is a nasal spray version of vardenafil marketed by Bayer as the Levitra oral tablet (BD: Dec 11, 2023)

Today, the company said that Strategic Drug Solutions Inc was "currently responsible for the management and prosecution of the patent applications".

LTR said the preliminary report was not reported by Strategic Drug Solutions at the time it was issued, noting that it did not expect to receive reports on any matters relating to patent applications when there was "no effective change as to the status".

LTR fell one cent or 3.1 percent to 31 cents.

EPSILON HEALTHCARE (IN VOLUNTARY ADMINISTRATION)

Epsilon administrator SV Partners' Ian Purchas says that two extraordinary general meetings to remove and appoint directors have been cancelled.

On Monday, SV Partners' Ian Purchas said he and Hugh Armenis had been appointed voluntary administrators of Epsilon following a resolution by the company's directors, to assess its "business operations and financial affairs" (BD: Dec 18, 2023).

Today, the administrators cancelled the December 22, 2023 extraordinary general meeting to elect Peter Giannopoulos, Lou Cattelan and Gary Radcliff as directors and remove chair Xiao (Josh) Cui and Stuart Cameron, as directors.

The administrators said they had cancelled the second meeting scheduled for January 19, 2024, to remove founder and deputy chair Alan Beasley as a director.

Last month, Mr Beasley requisitioned the first meeting to replace directors Mr Cameron and Mr Cui; and earlier this month, another meeting was requisitioned to remove Mr Beasley (BD: Nov 21, Dec 15, 2023).

Today, the administrators said they could remove and appoint directors under section 442A of the Corporations Act 2001, and had cancelled the meetings to avoid the unnecessary costs and disruptions associated with holding the meetings.

Epsilon was in a suspension at 2.4 cents.

NEUREN PHARMACEUTICALS

Neuren says it has completed enrolment for its 20-patient, phase II trial of NNZ-2591 for Angelman syndrome, with top-line results expected by October 2024.

Neuren said the trial would be conducted on children aged three to 17 years at three hospitals in Australia, with patients receiving an oral liquid dose of NNZ-2591 twice daily, for 13 weeks of treatment.

The company said there were currently no approved medicines for Angelman syndrome, which caused severe development delay and learning disabilities around the ages of six to 12 months, and typically involved balance issues and motor impairment, as well as debilitating seizures.

Neuren said the trial, like its phase II trials in children with Phelan-McDermid Syndrome, Pitt Hopkins Syndrome and Prader-Willi syndrome, had been granted orphan drug designation by the US Food and Drug Administration, and was being developed under an investigational new drug application.

Neuren chief executive officer Jon Pilcher said “we are grateful to the Angelman community in Australia including both [Foundation for Angelman Syndrome Therapeutics] Australia and the [Angelman Syndrome Association Australia], together with the trial site teams, who have enabled this important milestone to be achieved”.

“We now look forward to the remaining patients completing the trial and to releasing the first results of treatment with NNZ-2591 in children with Angelman syndrome,” Mr Pilcher said.

Neuren fell \$1.03 or 4.3 percent to \$22.93 with 1.2 million shares traded.

PROTEOMICS INTERNATIONAL LABORATORIES

Proteomics says it has signed a five-year deal with Omics Global Solutions to sell its Promarkerd diabetic kidney disease test in Chile.

Proteomics said the licence was initially for Chile exclusively, in which one in eight adults had diabetes and the San Juan, Puerto Rico-based Omics would try to expand to other countries in Central and South America.

The company said the agreement included royalties based on sales of the test, which Omics would manufacture.

Proteomics managing-director Dr Richard Lipscombe said Omics was “the first licence partner for Promarkerd, sold as Innovatio-ND2, launching the test in Puerto Rico and the Dominican Republic ahead of entry to the United States market”.

Proteomics did not disclose the commercial terms of the agreement.

Proteomics was up six cents or 7.5 percent to 86 cents.

IMRICOR MEDICAL SYSTEMS

Imricor says it has a five-year deal with the Doha, Qatar-based East Agency WWL to sell its cardiac ablation products, but did not state the commercial terms.

Imricor said the deal gave East Agency exclusive rights to market and sell its interventional cardiac magnetic resonance imaging cardiac ablation products in Qatar.

The company said Qatar was the second Middle Eastern country its products were sold in following Saudi Arabia.

Imricor chair Steve Wedan said the agreement was “just the latest step in growing our global footprint, and we intend to continue expanding in the Middle East with additional countries over time”.

Imricor was unchanged at 55 cents.

ACTINOGEN MEDICAL

Actinogen says it opened the first site for its 220-patient, phase IIb trial of Xanamem for Alzheimer's disease, with results from the first 100 patients expected by July 2025.

In May, Actinogen said it had amended the then 330-patient trial and expected a delay of up-to 12 months; and later, said it had decreased dose arms and patient numbers in the trial to reduce the cost and time to initial results (BD: May 24, Sep 26, 2023).

Today, the company said the double-blind, placebo-controlled trial would compare 10mg Xanamem daily against placebo for 36 weeks.

Actinogen said the trial's primary endpoint was "a cognitive test battery comprising seven different digital assessments".

The company said secondary endpoints were "the Clinical Dementia Rating, ... a combined cognitive and functional measure, and the Amsterdam Activity of Daily Living scale, which is purely a purely functional measure".

Actinogen chief executive officer Dr Steven Gourlay said positive data from three separate placebo-controlled trials suggested "Xanamem may provide clinically significant benefits and reduce disease progression".

"The purpose of the new trial is to robustly confirm this benefit in a larger group of patients and thereby enable the expansion of the program toward regulatory approval and global access for patients," Dr Gourlay said.

Actinogen was unchanged at 2.3 cents.

OPTHEA

Opthea says it has received \$8.8 million from the Australian Taxation Office under the Federal Government's Research and Development Tax Incentive program.

Opthea said the rebate related to expenditure in Australia and overseas on its OPT-302 for wet age-related macular degeneration for the year to June 30, 2023.

Opthea was up one cent or 2.25 percent to 45.5 cents.

PHARMAUST

Pharmaust says it has received \$553,435 from the Australian Taxation Office under the Federal Government's Research and Development Tax Incentive program.

Pharmaust said the rebate related to research and development expenditure for the year to June 30, 2023.

Pharmaust was up half a cent or 4.35 percent to 12 cents.

4D MEDICAL

Velocimetry Consulting, Prof Andreas and Helen Fouras say their 65,701,465 shareholding in 4D Medical has been diluted from 19.22 percent to 16.81 percent.

4D Medical founder Prof Fouras said that in the previous notice he, his spouse Helen and Velocimetry Consulting held 66,350,161 shares, but 648,696 shares were no longer deemed to be a relevant interest "under historical employee arrangements involving non-mandatory escrow arrangements".

In three notices, Velocimetry Consulting, Prof and Ms Fouras said that they had been diluted in the \$35 million placement at 79 cents a share to acquire the Imbio imaging company (BD: Dec 11, 2023).

4D Medical was up 1.5 cents or 2.1 percent to 72.5 cents with 1.4 million shares traded.

LBT INNOVATIONS

Brisbane's Viking BCM Pty Ltd says its 141,776,792 shares in LBT have been diluted from 12.27 percent to 11.26 percent, due to the issue of shares on December 19, 2023. In October, LBT said it hoped to raise \$4.5 million in a one-for-four rights offer at 0.5 cents a share; and later, said it had raised the full amount (BD: Oct 13, Dec 8, 2023). LBT fell 0.2 cents or 16.7 percent to one cent.

TELIX PHARMACEUTICALS

Telix says Dr David Cade will replace Dr Colin Hayward as group chief medical officer, effective from January 1, 2024.

Telix said Dr Cade was currently its Asia-Pacific chief executive officer and had been chief business officer and head of investor relations, and previously was the chief medical officer at Cochlear and Sirtex Medical.

The company said Dr Cade held a Bachelor of Medicine and Bachelor of Surgery from Melbourne's Monash University and a Master of Business Administration from the University of Melbourne's Business School and Barcelona's Ramon Llull University's Esade Business and Law School.

Telix said Dr Hayward was stepping down to pursue other interests.

Telix was up three cents or 0.3 percent to \$9.82 cents with 740,738 shares traded.

UNIQUEST, THE UNIVERSITY OF QUEENSLAND

The University of Queensland's commercialization company Uniquet says it has appointed Andrew Morgan as a director, effective today.

Uniquet said Mr Morgan was the founder of corporate advisor Catapult Partners and had worked for Lazard, HSBC Investment Bank and Grant Samuel.

According to his LinkedIn page, Mr Morgan held a Bachelor of Laws and a Bachelor of Commerce from the University of Queensland.

ATOMO DIAGNOSTICS

Atomo says Dr Curt LaBelle, who was appointed as a non-executive director on October 21, 2016 has resigned, effective immediately.

Atomo chair John Keith said that "on behalf of the board, I warmly thank Curt for his valuable contribution to Atomo".

Atomo was unchanged at 2.2 cents.

FISHER & PAYKEL HEALTHCARE CORPORATION

Fisher & Paykel says Justin Callahan will replace the head of sales and marketing Paul Shearer following his retirement, effective from April 1, 2024.

Fisher & Paykel said Mr Callahan was its current president of North America and Europe and Mr Shearer would continue in a part-time advisory position for two years.

The company said general manager of respiratory humidification Mr Niccol was promoted to the role chief operating officer, with Malena Ortiz and Desh Edirisuriya appointed as managers of Mexico and New Zealand operations, respectively, and Raelene Leonard appointed as general counsel and company secretary.

Fisher & Paykel said the changes were all effective from April 1, 2024.

Fisher & Paykel fell 32 cents or 1.4 percent to \$21.99 with 325,830 shares traded.

BIO-MELBOURNE

The Bio-Melbourne Network says it will host a fifth Australian medtech seminar titled 'Innovations in Cardiovascular Health: Bridging Technology and Care'.

In March, the Bio-Melbourne Network said that with the Australian Medical Technologies Manufacturing Centre it would host four seminars supporting the Victorian medical technology manufacturing sector (BD: Mar 14, 2023).

Today, the Network said it had extended the medical technologies series for 2024 and the fifth seminar included speakers from Monash University, Monash Heart and Hydrix Medical who would discuss "accelerating cardio-vascular medical technology innovation, manufacturing advancements and how innovators are changing the landscape of healthcare".

The Network said the event would be at the conference room, Level 2, Victorian Heart Hospital, 631 Blackburn Road, Clayton on February 13, 2024 from 4:30pm to 7:15pm (AEDT).

For details and registration, go to: <https://bit.ly/3NA1I9S>.