



Biotech Daily

Monday November 11, 2024

Daily news on ASX-listed biotechnology companies

- * **ASX DOWN, BIOTECH UP: NOVA EYE UP 10%; RESONANCE DOWN 12%**
- * **HERAMED 'FIRM COMMITMENTS' FOR \$1m PLACEMENT**
- * **TRUSCREEN: 'CERVICAL CANCER DEVICE COMPARABLE TO LBC'**
- * **RECCE: INDONESIA OKAYS PHASE III R327 DFI TRIAL**
- * **CLARITY SIGNS 2nd CU-67 SAR-BIS-PSMA PRODUCTION DEAL**
- * **IMUGENE DOSES 1st ONCARLYTICS INTRA-TUMORAL COMBINATION PATIENT**
- * **MILAN HOSPITAL IMPLANTS ONCOSIL PANCREATIC CANCER DEVICE**
- * **NEURIZON 'POSITIVE OPINION' FOR EU NUZ-001 ALS ORPHAN STATUS**
- * **ANTEOTECH REQUESTS 'CAPITAL RAISING' TRADING HALT**
- * **TRYPTAMINE AGM 54% DEFEAT PETER MOLLOY OPTIONS, ELECTION**
- * **PINNACLE TAKES 5.0% OF COCHLEAR**
- * **PLATINUM TAKES 14.3% OF AMPLIA**
- * **JM FINANCIAL, NO PLAN B TAKE 15.1% OF IMEX**
- * **NEUROTECH APPOINTS DR ANTHONY FILIPPIS M-D, ON \$468k PA**
- * **ISLAND LOSES CHAIR DR MACLEMAN, DIRECTOR ANNA DR LAVELLE**
- * **RHYTHM APPOINTS GAVIN FOX-SMITH DIRECTOR**
- * **ORTHOCELL APPOINTS US HEADS OF SALES, MEDICAL AFFAIRS**

MARKET REPORT

The Australian stock market fell 0.35 percent on Monday November 11, 2024, with the ASX200 down 28.9 points to 8,266.2 points. Twenty of the Biotech Daily Top 40 companies were up, 14 fell and six were unchanged.

Nova Eye was the best, up 1.5 cents or 10.3 percent to 16 cents, with 414,472 shares traded. Percheron climbed 7.5 percent; Aroa, Immutep and Starpharma improved more than six percent; Genetic Signatures was up 5.9 percent; Actinogen, Imugene and Mesoblast were up more than four percent; Alcidion, Clarity and EBR were up more than three percent; Cochlear and Orthocell rose more than two percent; Amplia, Proteomics, Resmed, SDI and Telix were up one percent or more; with Avita, CSL, Nanosonics and Opthea up less than one percent.

Resonance led the falls, down 0.55 cents or 12.0 percent to 4.05 cents, with 2.4 million shares traded. Atomo fell 4.55 percent; 4D Medical, Compumedics, Dimerix, Impedimed and Universal Biosensors lost more than three percent; Cyclopharm and Micro-X shed more than two percent; with Clinuvel, Emvision, Medical Developments, Neuren, Polynovo and Pro Medicus down by one percent or more.

HERAMED

Heramed says it has “firm commitments” to raise \$1.02 million at 1.7 cents a share in a private placement to three unnamed “leading institutional investors”.

Last month, Heramed said it raised \$3.1 million at 1.7 cents a share, a 19 percent discount to the 15-day volume weighted average price, in a placement (BD: Oct 23, 2024). Heramed said the funds would be used to “strengthen the company’s financial position and provide an ability to drive both the Heracare commercialization strategy, while building a sustainable pipeline of non-dilutive funding through grants and research partnerships”. The company said Westar Capital Ltd managed the placement and would receive a six percent capital raising fee.

Heramed was up 0.1 cents or 4.8 percent to 2.2 cents with five million shares traded.

TRUSCREEN

Truscreen says a study of 1,908 women shows its cervical cancer test had 65.08 percent sensitivity and 64.76 percent specificity, “comparable to liquid-based cytology (LBC)”.

Truscreen said the study was conducted by researchers at Shanghai’s Fudan University in women who had received LBC, human papillomavirus testing and colposcopy testing. The company said the tests were studied for their detection of high-grade squamous intraepithelial lesion, adenocarcinoma in situ, or more severe lesions in patients with different transformation zone types.

Truscreen said the study found that its device’s sensitivity and specificity was comparable to cytology which had 57.14 percent sensitivity and 64.47 percent specificity ($p > 0.05$).

The company said in patients with type three transformation zone its non-invasive optical-electrical device outperformed cytology with sensitivity of 72.29 percent compared to 65.06 percent and specificity of 67.39 percent compared to 64.29 percent, respectively.

The study, titled ‘Evaluation of a real-time optoelectronic method for the detection of cervical intraepithelial neoplasia and cervical cancer in patients with different transformation zone types’ was published in the journal Springer Nature, with the full article available at: <https://www.nature.com/articles/s41598-024-78773-w>.

The study said Truscreen had a positive predictive value of 11.55 percent and a negative predictive value of 96.33 percent, “similar to liquid-based cytology”.

Truscreen fell 0.1 cents or 5.3 percent to 1.8 cents.

RECCE PHARMACEUTICALS

Recce says it has ethics approval to start its up-to 300-patient, phase III, double-blinded, placebo-controlled trial of R327 topical gel for diabetic foot infections (DFI) in Indonesia. Recce said the trial would study R327 for the treatment of diabetic foot infections, with the first patients expected to be enrolled by “mid-December”.

The company said the trial would run for about 12 months, with first results anticipated in “late 2025 and expected regulatory approval and commercial launch in ... 2026”.

Recce said the trial would cost about \$US2.0 million (\$A3.0 million) and was covered by the Australian Federal Government’s Research and Development Tax Incentive program. The company said the trial would be conducted at PT Siloam International Hospitals, the largest private hospital network in Indonesia.

Recce managing-director James Graham said the approval was a “landmark milestone in Recce’s clinical program development”.

“We look forward to evaluating R327 in our first phase III trial,” Mr Graham said.

Recce was up 1.5 cents or 3.2 percent to 48.5 cents.

CLARITY PHARMACEUTICALS

Clarity says the Charlotte, North Carolina-based Nucleus Radiopharma Inc will manufacture its copper-67 Sar-Bis-prostate specific membrane antigen (PSMA). Clarity said Nucleus Radiopharma was a contract development and manufacturing organization “dedicated to the development and manufacturing of targeted radio-therapies” supported by Mayo Clinic, Astrazeneca and General Electric Healthcare. The company said the agreement with Nucleus complemented “the existing agreement with Northstar Medical Radioisotopes for the production of copper-67 Sar-Bis-PSMA, allowing Clarity to continue building supply chain capacity ahead of a phase III trial and commercialization with this product” (BD: May 25, 2021; Apr 4, 2024).

Clarity said Nucleus would manufacture the radio-therapy for prostate cancer at its facility in Rochester, Minnesota and distribute to all 50 US states.

The company did not disclose the commercial terms of the agreement.

Clarity said Nucleus expected to open additional factories in Arizona and Pennsylvania which were “in line with the timelines for development of ... Clarity’s copper-67 Sar-Bis-PSMA product, ensuring broad drug supply throughout the US”.

Clarity executive chair Dr Alan Taylor said the company continued to strengthen its “manufacturing network, ensuring prostate cancer patients in need of novel radio-pharmaceutical treatments can get access to what we believe is a best-in-class product, on time and on demand”.

“We have seen excellent data from the ... trial and in case studies as part of the US Food and Drug Administration expanded access program with copper-67 Sar-Bis-PSMA and look forward to progressing the development of this important therapy to address the large unmet need in prostate cancer care,” Dr Taylor said.

Clarity was up 28 cents or 3.9 percent to \$7.48 with 1.1 million shares traded.

IMUGENE

Imugene says it has dosed the first of up-to 40-patients in the intra-tumoral injection, combination arm of its phase I trial of Oncarlytics, or CF33-CD19, for solid cancer tumors. Last year, Imugene said it had dosed the first combination patient in the intra-tumoral arm of its up-to 52 patient, phase I trial of its Oncarlytics, a CD19-expressing oncolytic virotherapy, and Bincyto, or blinatumomab (BD: Oct 26, 2023).

At that time, the company said the trial of adult patients with advanced or metastatic solid tumors would evaluate the safety and efficacy of an intra-tumoral injection and an intravenous infusion of Oncarlytics alone and in combination with blinatumomab.

Today, the company said the trial was “designed to convert hard-to-treat ‘targetless’ tumors to CD19-expressing solid tumors that can be targeted”.

Imugene said the first intra-tumoral, combination arm participant was a colorectal cancer patient and was dosed at Chicago’s Northwestern University.

The company said the trial was being conducted at seven US sites, with the potential for 10 sites to recruit up-to 40 patients with advanced solid cancers.

Imugene managing-director Leslie Chong said the company was “pleased to have dosed the first patient in the intra-tumoral arm of our ... trial”.

“With CD19 being a well-established target in blood cancers, we are optimistic about the effectiveness it could show in solid tumors,” Ms Chong said.

“Oncarlytics has the potential to induce expression of CD19 on the surface of solid tumors and allowing existing CD19 therapies to recognize and attack the cancer,” Ms Chong said. Imugene was up 0.2 cents or 4.35 percent to 4.8 cents with 30 million shares traded.

[ONCOSIL MEDICAL](#)

Oncosil says Milan, Italy's Istituto Nazionale dei Tumori successfully implanted its pancreatic cancer therapy device in a patient on November 8, 2024.

Oncosil said the phosphorous-32 brachytherapy procedure was "a significant milestone in the treatment of locally advanced pancreatic cancer".

The company said the Istituto Nazionale dei Tumori was "recognized as one of Europe's premier cancer centers, known for its clinical excellence, pioneering research, and commitment to advancing cancer therapies".

Oncosil was up 0.05 cents or 7.1 percent to 0.75 cents with 7.2 million shares traded.

[NEURIZON THERAPEUTICS \(FORMERLY PHARMAUST\)](#)

Neurizon says it has a "notice of positive opinion" from the European Medicines Agency for its orphan medicinal product application for NUZ-001 for amyotrophic lateral sclerosis.

In September, the then Pharmaust said it had requested orphan medicinal product status by the European Medicines Agency for the then monepantel, now NUZ-001, for the motor neuron disease known as amyotrophic lateral sclerosis (ALS) (BD: Sep 17, 2024).

Today, the company said it expected to receive the official decision "in December".

Neurizon said orphan medicinal product designation would provide "reduced regulatory fees, free protocol assistance and, importantly, 10 years of market exclusivity in the EU".

Neurizon was up one cent or 5.3 percent to 20 cents.

[ANTEOTECH](#)

Anteotech has requested a trading halt "pending an announcement by the company concerning a material capital raising".

Trading will resume on November 13, 2024, or on an earlier announcement.

Anteotech last traded at 2.7 cents.

[TRYPTAMINE THERAPEUTICS \(FORMERLY EXOPHARM\)](#)

Tryptamine says up-to 54.30 percent of its annual general meeting defeated the election and issue of options to director Peter Molloy.

In September, Tryptamine said that chief business officer and executive director Mr Molloy would transition to a non-executive director position (BD: Sep 23, 2024).

Last month, the company said its annual general meeting would vote to issue its managing-director, chair and directors up-to 55,000,000 options (BD: Oct 1, 2024).

Last week, Tryptamine said non-executive director Mr Molloy would resign, effective from November 8, 2024 (BD: Nov 6, 2024).

Today, the company said Mr Molloy's options were defeated by 87,766,533 votes (54.30%) with 73,874,780 votes (45.70%) in favor.

Tryptamine said the election of Mr Molloy as a director was lost, with 86,806,602 votes (53.95%) against and 74,103,161 votes (46.05%) in favor.

The company said the issue of options to director Gage Jull was opposed by 16.13 percent of the meeting, with all other resolutions passing easily with more than 97.57 percent in favor.

According to its annual report, Tryptamine had 1,138,921,906 shares on issue, meaning that the 87,766,533 votes against Mr Molloy's options amounted to about 7.7 percent of the company, sufficient to requisition extraordinary general meetings.

Tryptamine was up 0.4 cents or 9.8 percent to 4.5 cents with 11.3 million shares traded.

COCHLEAR

Pinnacle Investment Management Group Ltd says it has become a substantial shareholder in Cochlear with 3,279,259 shares, or 5.01 percent.

The Brisbane, Queensland and London, England-based Pinnacle said that between July 8 and November 5, 2024 it bought and sold shares in more than 60 transactions, with the single largest purchase 346,802 shares on October 31 for \$98,977,084, or \$285.40 a share.

Cochlear was up \$8.01 or 2.73 percent to \$300.93 with 165,917 shares traded.

AMPLIA THERAPEUTICS

Sydney's Platinum Investment Management Ltd says it has increased its substantial shareholding in Amplia from 35,337,132 shares (12.89%) to 51,183,323 shares (14.29%). Platinum said that between August 12 and September 3, 2024 it sold shares and on November 4, 2024 bought 17,391,304 shares for \$2,000,000, or 11.5 cents a share. Earlier this month, Amplia said it raised \$9.9 million in a placement and institutional rights offer at 11.5 cents a share, with a \$3.1 million retail offer to follow (BD: Nov 1, 2024). Amplia was up 0.1 cents or 1.1 percent to 9.4 cents with 9.3 million shares traded.

IMEX HEALTH SYSTEMS

Melbourne's JM Financial Group Ltd and No Plan B Pty Ltd say they have increased their holding in Imex from 6,387,989 shares (14.03%) to 6,903,346 shares (15.13%).

JM Financial and No Plan B said that they bought and sold shares between June 18 and September 26, 2024, with the single largest purchase 78,686 shares on June 26 for \$34,205, or 43.5 cents a share.

Imex was untraded at 42 cents.

NEUROTECH INTERNATIONAL

Neurotech says it has appointed Dr Anthony Filippis as its managing-director, effective from February 1, 2025, starting on \$468,300 a year salary.

Neurotech said Dr Filippis had 25 years of experience in biotechnology and was a director of Vivazome Therapeutics, co-founder of Senz Oncology and chief commercial officer of Percheron (formerly Antisense).

The company said Dr Filippis had been managing-director of Neurosciences Victoria and chief executive officer of Drawbridge Pharmaceuticals.

In 2011, Qponics said it appointed Dr Filippis as a director (BD: Nov 2, 2011).

According to his LinkedIn page, Dr Filippis held a Bachelor of Science and Master of Business Administration from La Trobe University as well as a Doctor of Philosophy from the University of Melbourne.

Neurotech said Dr Filippis would receive \$468,300 in annual pay inclusive of superannuation and up-to 20,000,000 long-term incentive options.

Neurotech chair Mark Davies said that following "an extensive search of potential candidates for the role, we are delighted that someone of the caliber of Dr Filippis has agreed to join the company as managing-director".

In 2022, Neurotech said it had appointed Dr Alexandra Andrews as its chief executive officer; and later, said Dr Andrews would "transition to a new position of chief operating officer" (BD: Aug 16, Sep 2, 2022).

Neurotech was up 0.1 cents or 1.9 percent to 5.4 cents with 1.3 million shares traded.

ISLAND PHARMACEUTICALS

Island says executive chair Dr Paul MacLeman and non-executive director Dr Anna Lavelle will resign at its annual general meeting on November 19, 2024.

Island did not disclose its plans for replacing Dr MacLeman and Dr Lavelle, but said it would “announce a new chair ... in due course”.

Island managing-director Dr David Foster said he thanked Dr MacLeman for “his many significant contributions and his leadership as executive chair at Island”.

“Dr MacLeman was instrumental in our ASX [initial public offer] and his dedication and his vision have been paramount in driving forward the company’s strategy, pipeline evolution and clinical program,” Dr Foster said.

“My thanks also goes to Dr Lavelle,” Dr Foster said, adding that “her stewardship and guidance provided across her many areas of expertise has helped us progress our strategic agenda and seen us deliver many clinical milestones.”

In 2018, Medicines Australia said it had appointed former 11-year Ausbiotech chief executive officer Dr Anna Lavelle as its independent chair (BD: Aug 13, 2018).

A media release from Medicines Australia on October 31, 2024 said that Dr Lavelle had announced she would retire as chair in 2025.

Island was unchanged at 12 cents.

RHYTHM BIOSCIENCES

Rhythm says it has appointed Gavin Fox-Smith as an independent, non-executive director, effective from December 2, 2024.

Rhythm said Mr Fox-Smith had more than 35 years of experience, including as managing-director Australia and New Zealand and head of Asia Pacific at Johnson & Johnson Medical Devices as well as chair of the Medical Technology Association of Australia and co-founder and chair of the Macquarie Park Business Coalition.

The company said Mr Fox-Smith was “currently transitioning out of his ... chief executive officer role at Omnigon” and was chair of the Australia National Digital Health Initiative (ANDHealth) and a director of Bowel Cancer Australia.

According to his LinkedIn page, Mr Fox-Smith held a Bachelor of Science from the University of Sydney and a Master of Business Administration from Melbourne’s Deakin University.

Rhythm was up 2.5 cents or 22.7 percent to 13.5 cents.

ORTHOCELL

Orthocell says it has appointed John Walker and Phillip Edmondson as its US-based head of sales and head of medical affairs, respectively.

Orthocell said Mr Walker and Mr Edmondson would support the US commercialization of its Remplir nerve repair product.

The company said the Texas-based Mr Walker and Florida-based Mr Edmondson had both worked for Axogen, a US supplier of peripheral nerve repair devices.

Orthocell said it expected US Food and Drug Administration 510(k) market authorization by April 2025 “with sales to commence ... soon thereafter”.

Orthocell was up 1.5 cents or 2.3 percent to 65.5 cents with 1.2 million shares traded.