



Biotech Daily

Wednesday November 27, 2024

Daily news on ASX-listed biotechnology companies

- * ASX, BIOTECH UP: ORTHOCELL UP 27%; STARPHARMA DOWN 9%
- * ISLAND: 'ISLA-101 SAFE, ANTI-DENGUE ACTIVITY'
- * PRO MEDICUS \$24m NEW YORK UNI LANGONE UPGRADE
- * LITTLE GREEN H1 REVENUE UP 37% TO \$17.5m; LOSS UP 123% TO \$5m
- * AMPLIA UNDERWRITTEN RETAIL RIGHTS RAISE \$459k OF \$3.1m; TOTAL \$13m
- * EMYRIA 'FIRM BIDS' FOR \$2.5m PLACEMENT
- * SOMNOMED EXPECTS FULL-YEAR REVENUE UP 5% TO \$105m
- * CYCLOPHARM 2 US VETERANS HOSPITALS TECHNEGAS ORDERS
- * ORTHOCELL: DEVICE TECHNOLOGIES SINGAPORE REPLIR DISTRIBUTOR
- * CLEO: ROYAL WOMEN'S HOSPITAL JOINS OVARIAN CANCER TRIAL
- * IMRICOR: LAUSANNE UNI PERFORMS 1st IMCR ABLATION
- * PYC: 'PYC-003 INCREASES PC1 KIDNEY PROTEIN, IN MONKEYS'
- * QBIOTICS RECEIVES \$7.4m FEDERAL R&D TAX INCENTIVE
- * ARCHER RECEIVES \$2.2m FEDERAL R&D TAX INCENTIVE
- * RADIOPHARM COMPLETES ADS NASDAQ LISTING
- * FTI: GENETIC TECHNOLOGIES REFUNDS RIGHTS OFFER
- * CANN \$900k NAB LOAN INTEREST, FEE REPAYMENT DEFERRED
- * OPYL TAKES \$305k GUOGA, IRWIN BIOTECH, MARYTON LOANS
- * STARPHARMA AGM 32% OPPOSE LYNDIA CHENG; REM REPORT DEFERRED
- * RENERVE DIRECTORS CHICK, RHODES, COOPER TAKE 9.8%, 8.1%, 7.2%
- * BIOTRON APPOINTS C14 CONSULTING FOR BIT225 COMMERCIALIZATION
- * CAMBIUM RE-APPOINTS PROF CHANDRA BALA DIRECTOR
- * SOMNOMED PROMOTES FINANCE HEAD YE-FEI GUO TO CFO
- * NUHEARA LOSES CO-SEC SUSAN PARK

MARKET REPORT

The Australian stock market was up 0.57 percent on Wednesday November 27, 2024, with the ASX200 up 47.3 points to 8,406.7 points. Seventeen of the Biotech Daily Top 40 companies were up, 14 fell and nine traded unchanged.

Orthocell was the best (see below), up 17 cents or 26.8 percent to 80.5 cents, with 4.3 million shares traded. Syntara climbed 14.3 percent; Paradigm improved 10.6 percent; Cyclopharm was up 8.15 percent; Imugene improved 5.3 percent; Dimerix and Percheron rose more than four percent; Aroa, Clarity, Mesoblast, Polynovo and Resonance were up three percent or more; Emvision and Proteomics rose more than two percent; with CSL, Nanosonics, Neuren and Opthea up by less than one percent.

Starpharma led the falls (see below), down one cent or 8.7 percent to 10.5 cents, with 274,312 shares traded. Amplia, Atomo and EBR lost five percent or more; 4D Medical fell 4.35 percent; Micro-X and Nova Eye were down more than three percent; Genetic Signatures and SDI shed more than two percent; Avita, Impedimed, Medadvisor and Telix were down one percent or more; with Clinuvel, Cochlear, Pro Medicus and Resmed down by less than one percent.

ISLAND PHARMACEUTICALS

Island says the four participants in the preventative arm of its 14-patient, phase IIa/b trial of ISLA-101 shows the drug's "safety and anti-dengue activity".

Last month, Island said it had dosed the four, phase IIa volunteers in the preventative arm of its phase IIa/b trial for dengue fever (BD: Oct 3, 2024).

Today, Island said the safety review committee noted "that blood levels of ISLA-101 were seen as expected, and given positive safety and efficacy signals, recommended that Island proceed with the therapeutic phase IIb cohort".

The company said the phase IIa trial dosed subjects with ISLA-101 before being infected with a weakened dengue virus developed by the US Army, with the aim "to assess whether ISLA-101 can prevent or reduce viremia and symptoms, compared to placebo".

The company said that following dosing of all subjects in the phase IIa prophylactic cohort, the data was consolidated for review by the safety review committee which had completed its process of evaluating the safety of ISLA-101.

Island said the committee found no safety concerns that necessitated implementing any defined individual or study stopping rules, confirming the study was safe and that a "reduction of viral load was seen in subjects treated with ISLA-101, showing there was evidence of ISLA-101 anti-dengue virus activity in the phase IIa cohort".

Island said it was in the process of preparing the safety review committee report for the US Food and Drug Administration and subject to FDA agreement it was "on target to start the phase IIb cohort in January 2025".

Island managing-director Dr David Foster said in the past 12 months the company had "recorded several important achievements, but this one stands out as the most exciting, and the very reason we started this company".

"While we are blinded to the full dataset, the unblinded safety review committee has clearly and unanimously stated there were no safety issues with ISLA-101 and also that the drug showed evidence of anti-dengue virus activity," Dr Foster said.

Island was up five cents or 30.3 percent to 21.5 cents with six million shares traded.

[PRO MEDICUS](#)

Pro Medicus says it has a \$24 million, five-year extension and upgrade of the New York University Langone Health's Visage 7 viewer contract.

In 2020, Pro Medicus said it had a seven-year, \$25 million contract with New York University's Medical Centre for its Visage imaging technology (BD: Sep 11, 2020).

Today, the company said the contract included the addition of the internet cloud-based Visage 7 open archive and the eventual transition of the New York University Langone's "entire current on-premise system to the cloud".

Pro Medicus said the Visage 7 viewer contract had been extended to 2029, as part of the deal, with planning for the rollout expected to begin immediately and would involve the migration of NYU Langone's current archive to the Visage 7 open archive.

Pro Medicus managing-director Dr Sam Hupert said the agreement was a "significant deal for us as it confirms our belief that there is opportunity for us to sell our archive and worklist modules back to our 'viewer only' clients; and, in time, we believe those customers with on premise solutions will join NYU and transition to cloud".

Pro Medicus fell \$1.59 or 0.7 percent to \$228.41 with 293,236 shares traded.

[LITTLE GREEN PHARMA](#)

Little Green says revenue for the six months to September 30, 2024 was up 36.9 percent to \$17,513,000, with net loss after tax up 123.0 percent to \$4,987,000.

The company said its revenue was primarily "from the sale of medicinal cannabis oil, flower and vaporizer products".

Little Green said diluted loss per share rose 57.5 percent to 1.15 cents, net tangible assets per share was down 11.5 percent to 22.93 cents a share, and it had cash and equivalents of \$4,832,000 on September 30, 2024, compared to \$6,192,514 the prior year.

Little Green Pharma fell one cent or 7.4 percent to 12.5 cents.

[AMPLIA THERAPEUTICS](#)

Amplia says has raised \$3.1 million in its fully-underwritten, one-for-6.45, retail entitlement offer at 11.5 cents a share, taking the total raised to \$13 million.

Earlier this month, Amplia said it had raised \$9.9 million in a placement and institutional rights offer, with a \$3.1 million retail entitlement offer to follow (BD: Nov 1, 2024).

Today, the company said investors subscribed for 3,994,284 shares under the retail rights offer, raising \$459,343, with the remaining 22,889,055 shortfall shares, worth \$2,632,241, taken up by the sub-underwriters Bell Potter Securities and Taylor Collison.

Amplia fell half a cent or 5.4 percent to 8.7 cents with 1.2 million shares traded.

[EMYRIA](#)

Emyria says it has "firm bids" to raise \$2,525,000 at 3.5 cents a share in a placement, with \$1.0 million to be raised from chair Greg Hutchinson, subject to shareholder approval.

Emyria said the issue price was a 3.13 percent discount to the 15-day volume weighted average price and a 10.26 percent discount to the last traded price.

The company said the funds would be used to expand its post-traumatic stress disorder and treatment-resistant depression treatment programs.

The company said 62 Capital Pty Ltd was lead manager to the placement and would receive its six percent capital raising fee in scrip at 3.5 cents a share.

Emyria fell 0.2 cents or 5.1 percent to 3.7 cents with 1.2 million shares traded.

SOMNOMED

Somnomed says it expects revenue for the year to June 30, 2025 to be up five percent to \$105 million, with Ebitda up 40 percent to \$7 million.

In August, Somnomed said revenue from sales of its Somnodent range for obstructive sleep apnoea and other sleep-related breathing disorders for the year to June 30, 2024 was up 9.6 percent to \$91,651,069, with net loss after tax up 53.0 percent to \$12,241,726, with guidance for 2024-'25 of \$100 million (BD: Aug 28, 2024).

Today, the company said it expected earnings before interest, taxation, depreciation and amortization (Ebitda) for the year of more than \$7 million, up 40 percent on the previous guidance of more than \$5 million.

Somnomed was up 12.5 cents or 46.3 percent to 39.5 cents.

CYCLOPHARM

Cyclopharm says it has received purchase orders for its Technegas lung imaging device from two US Government Veterans Health Administration hospitals.

Last month, Cyclopharm said it had an interim agreement to supply Technegas to 120 Veterans Health Administration hospitals (BD: Oct 3, 2024).

Today, the company said the purchase orders were for an initial five-year term and apply to the installation and annual charges associated with Technegas.

Cyclopharm said Technegas provided "highly accurate functional ventilation images" to aid in the diagnosis of chronic obstructive pulmonary disease and pulmonary fibrosis.

The company said Technegas would improve the Veterans Health Administration's "effective treatment and management of lung disease in affected veterans".

Cyclopharm managing-director James McBrayer said the orders would "allow for the first installations of Technegas within the [Veterans Health Administration] system during the first few weeks of 2025".

"Revenues will be generated immediately as our technology will be replacing existing nuclear medicine products," Mr McBrayer said. "These initial commercial agreements will also serve as a template for the remaining 118 nuclear medicine departments."

Cyclopharm was up 11 cents or 8.15 percent to \$1.46.

ORTHOCELL

Orthocell says it has appointed Device Technologies Asia as exclusive distributor of its Celgro-based Remplir for peripheral nerve repair in Singapore for an initial five years.

Last month, Orthocell said it had Singapore Health Sciences Authority approval for its Remplir collagen wrap for use in peripheral nerve repair (BD: Oct 8, 2024).

Orthocell said Device Technologies Asia provided "professionals with access to innovative, high-quality medical devices and solutions from around the world".

The company said it expected first sales in Singapore by April 2025.

Orthocell managing-director Paul Anderson said Device Technologies Asia was "a leading supplier of innovative medical solutions to hospitals and healthcare professionals throughout Singapore and Southeast Asia".

"We are delighted to extend our very successful distribution partnership with Device Technologies in Australia and New Zealand into Singapore," Mr Anderson said.

"They have a proven track record in successfully driving the market entry of high-quality products with specialist capabilities and resources, and in the marketing, promotion and distribution of Remplir," Mr Anderson said.

Orthocell was up 17 cents or 26.8 percent to 80.5 cents with 4.3 million shares traded.

CLEO DIAGNOSTICS

Cleo says that Melbourne's Royal Women's Hospital will join the 500-patient trial of its blood test for the early detection of ovarian cancer.

Earlier this year, Cleo said it had recruited the first of "a minimum of 500 patients" in a US trial of its ovarian cancer blood test (BD: Sep 6, 2024).

Today, the company said the Royal Women's Hospital would increase the cohort of patient samples, expand market awareness, verify and optimize its ovarian cancer blood test and potentially bolster the US trial.

Cleo said the trial would be used for a US Food and Drug Administration 510(k) submission which remained "on track for 2025".

Cleo managing-director Dr Richard Allman said that the addition of the Royal Women's Hospital was "important to our trials strategy in the context that Cleo is focused on working with leading organizations in the treatment of ovarian cancer".

Cleo fell one cent or 2.9 percent to 34 cents.

IMRICOR MEDICAL SYSTEMS

Imricor says Switzerland's Lausanne University Hospital has performed their first interventional cardiac magnetic resonance (ICMR) ablation procedure.

Earlier this year, Imricor said it had approval for an up-to 91-patient study of its cardiac ablation catheter and irrigation pump products at the Baltimore, Maryland's Johns Hopkins Hospital; and later, said it had Swiss regulatory authority approval to open the trial at Lausanne University Hospital (BD: Jan 21, Mar8, May 9, 2024).

Later, the company said that it completed the sale and installation of its (ICMR) imaging system to Lausanne University Hospital.

Today, Imricor said the procedure marked the activation of the University as its first customer site in Switzerland and added a third active site to its clinical trial supporting US Food and Drug Administration approval of its products.

The company said Lausanne University Hospital would be one of its "European centres of excellence, an important partnership where physicians from other hospitals can visit and be trained on real-time ICMR cardiac ablations and other future interventions, as the number of active sites across Europe continues to grow".

Imricor executive chair Steve Wedan said the company was "fortunate to be able to work with some of the key thought leaders in the field of cardiac [magnetic resonance imaging] and electrophysiology, and the highly regarded team at the [Lausanne University Hospital] sit firmly in that camp".

Imricor was up 19 cents or 21.6 percent to \$1.07.

PYC THERAPEUTICS

PYC says further pre-clinical data shows its PYC-003 for polycystic kidney disease increases "PC1 protein in the kidneys of non-human primates".

PYC said deficient PC1 protein was the underlying cause of polycystic kidney disease and restoring its expression had been shown to reverse the disease process in animal models.

Earlier this year, the company said it had completed dose range finding studies of PYC-003 for autosomal dominant polycystic kidney disease in monkeys, with human trials expected to begin by 2025 (BD: Apr 22, 2024).

PYC said it was "on track" to file regulatory submissions for human trials by January 2025, and, if successful, to have initial in-human data "in 2025".

PYC was up 13 cents or 6.95 percent to \$2.00 with 841,992 shares traded.

QBIOTICS

Qbiotics says it has received \$7.38 million from the Australian Taxation Office under the Federal Government's Research and Development Tax Incentive program.

Qbiotics said the incentive related to eligible domestic and international research and development expenditure for the year to June 30, 2024.

Qbiotics is a public unlisted company.

ARCHER MATERIALS

Archer says it has received \$2,189,556 from the Australian Taxation Office under the Federal Government's Research and Development Tax Incentive program.

Archer said the incentive related to research and development expenditure on its quantum and biosensor projects for the year to June 30, 2024, including eligible overseas expenditure covered by an advanced overseas finding by Ausindustry.

Archer was up half a cent or 1.7 percent to 30 cents.

RADIOPHARM THERANOSTICS

Radiopharm says it has completed its US listing of American depository shares (ADSs) and will trade on the Nasdaq under the ticker code 'RADX'.

Earlier this year, Radiopharm said it had launched an American depository receipt (ADR) program for shareholders to receive ADSs (BD: Sep 19, 2024).

Today, the company said each ADS would be equivalent to 300 Australian shares, with the Nasdaq listing secondary to its existing primary listing on the ASX.

Radiopharm said that US shareholders held 21 percent of the company.

Radiopharm managing-director Riccardo Canevari said the Nasdaq listing was "a very important strategic milestone for Radiopharm that will help increase our visibility with US and international investors".

Radiopharm was up 0.3 cents or 10.7 percent to 3.1 cents with six million shares traded.

GENETIC TECHNOLOGIES

Genetic Technologies administrator FTI Consulting says the company will refund all applications for its two-for-three rights issue at four cents a share.

In September, Genetic Technologies said its rights offer at four cents a share raised \$324,648, leaving a \$3,553,145 shortfall and later that week the ASX suspended the company (BD: Sep 12, 2024).

Last week, FTI Consulting said its Ross Blakeley and Paul Harlond were appointed as voluntary administrators of Genetic Technologies (BD: Nov 20, 2024).

Today, FTI said under the entitlement offer prospectus "if the offer is withdrawn or the minimum subscription amount is not achieved ... all application money received will be refunded in full, with no interest".

The administrator said it considered that its "appointment requires the offer to be withdrawn, and in this regard, all offers are closed, no issues of securities will be made, including the underwriting agreement, and all funds received under the offer ... will be returned to applicants".

Genetic Technologies was in a suspension and last traded at 3.9 cents.

CANN GROUP

Cann says the National Australia Bank (NAB) will defer \$900,000 in quarterly interest and facility fee payments for its construction loan, which was due November 22, 2024. Earlier this year, Cann said it had extended its fully-drawn \$15.6 million NAB loan to March 31, 2025, and NAB agreed to defer the quarterly repayment of the principal loan amounts of its \$49.4 million construction facility to May 2025 (BD: Mar 18, 2024). Today, the company said NAB was considering the deferment of the subsequent two quarterly interest and facility fee payments, as well as “not to call upon any of the outstanding loan balances during the period through to September 29, 2025”. Cann said the deferment of up-to three quarters of interest payments allowed it to redirect the funds to “accelerate revenue growth” through expanding its product offerings, pursuing export markets, optimizing productions costs and meeting customer demand effectively. Cann managing-director Jenni Pilcher said NAB's support had “been instrumental in positioning Cann for long-term success”. “This partnership underscores the shared commitment to the company's growth and operational excellence,” Ms Pilcher said. Cann was up 0.2 cents or 4.65 percent to 4.5 cents with 1.4 million shares traded.

OPYL

Opyl says it has taken three loans from Antanas Guoga, Irwin Biotech Nominees Pty Ltd and Maryton Australia Pty Ltd worth a total of \$305,000. Opyl said it had received a \$150,000 loan from Antanas ‘Tony’ Guoga, \$75,000 from Irwin Biotech and \$80,000 from Maryton Australia. The company said each loan was at 1.5 percent monthly interest and repayable by December 31, 2025, with the loans convertible to shares at 1.5 cents a share and including one attaching option per share, exercisable at 1.5 cents each within three years. Biotech Daily has previously reported that Irwin Biotech is a company associated with Genetic Technologies chair Peter Irwin Rubenstein (BD: Apr 24, 2020). Opyl said the loans and conversion terms were subject to shareholder approval at its next extraordinary general meeting. Opyl executive chair Saurabh Jain said the funding would allow the company “to continue innovating, improving Trialkey, and delivering outstanding value to stakeholders”. Opyl was untraded at 2.7 cents.

STARPHARMA HOLDINGS

Starpharma says its annual general meeting has voted 32.11 percent against the re-election of director Lynda Cheng and its remuneration report vote has been deferred. Starpharma said the re-election of Ms Cheng was opposed by 64,455,405 votes (32.11%) with 136,274,058 votes (67.89%) in favor. The company said the issue of performance rights to managing-director Cheryl Maley faced 8.70 percent dissent, with the proportional takeover provisions passed easily. Starpharma said the vote to adopt the remuneration report had been delayed to a reconvened meeting on November 29, 2024 due to “an offshore custodian needing additional time to amend votes on behalf of beneficial owners”. According to its most recent notice, Starpharma had 418,107,037 shares on issue, meaning that the 64,455,405 votes against Ms Cheng’s appointment amounted to 15.4 percent of the company, sufficient to requisition extraordinary general meetings. Starpharma fell one cent or 8.7 percent to 10.5 cents.

[RENERVE](#)

Renerve managing director Dr Julian Chick, executive director Dr David Rhodes and director Reginald Stephen Cooper say they have become substantial in the company. Yesterday, Renerve fell 17.5 percent to 16.5 cents following its \$7 million initial public offer at 20 cents a share to list on the ASX for its nerve repair products (BD: Nov 26, 2024). Today, in three separate substantial shareholder notices, Dr Chick, Dr Rhodes and Mr Cooper said they held 13,925,188 shares (9.82%), 11,527,500 shares (8.13%) and 10,170,788 shares (7.17%), respectively.

Dr Chick said that with Violeta Traicevski and Viomaj Pty Ltd he received 7,105,000 shares on February 23, 2017 and purchased shares between November 25, 2018 and November 22, 2024, with the single largest purchase 1,160,000 shares on November 25, 2018 for \$80,000, or 6.9 cents a share.

Dr Rhodes said that he received 11,165,000 shares on February 23, 2017 and purchased 290,000 shares on November 25, 2018 for \$25,001, or 8.6 cents a share, and 72,500 shares on May 28, 2020 for \$10,000, or 13.8 cents a share.

Mr Cooper said that with Zetland Road Pty Ltd he received 2,030,000 shares on February 23, 2017 and purchased shares between April 20, 2017 and November 22, 2024, with the single largest purchase 1,250,000 shares on December 5, 2020 for \$200,000, or 1.6 cents a share.

Renerve fell one cent or 5.3 percent to 18 cents with 1.8 million shares traded.

[BIOTRON](#)

Biotron says it has appointed the Philadelphia, Pennsylvania-based C14 Consulting Group to commercialize its anti-viral programs including lead clinical asset BIT225.

Biotron said that with C14 it would “refine its commercialization strategy and provide business development support over coming months”.

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

Biotron managing-director Dr Michelle Miller said the agreement allowed the company “to leverage internal expertise in a cost-effective, efficient manner”.

“With data from the recent clinical trials in hand, together with supporting preclinical and scientific data that demonstrate the potential utility of Biotron’s unique approach to treating serious viral infections, the company is now focused on achieving licencing or partnerships with its antiviral portfolio,” Dr Miller said.

Biotron has been developing BIT225 for hepatitis C, HIV and severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2) hoping to begin a phase I/II trial for HIV in 2007 and starting a phase I trial for hepatitis C in 2007 and a phase Ib/IIa trial for hepatitis C in 2008 (BD: Jul 12, 2006; Mar 22, 2007, Aug 7, 2008).

Biotron was up 0.3 cents or 16.7 percent to 2.1 cents with 6.1 million shares traded.

[CAMBIUM BIO \(FORMERLY REGENEUS\)](#)

Cambium says it has re-appointed Prof Chandra Bala as a director, effective from its annual general meeting on November 26, 2024.

Last week, Cambium said it had appointed Prof Bala as a director effective from November 22, but did not include his election at the annual general meeting, meaning Prof Bala had been forced to resign at the meeting, was reappointed and would be considered for re-election at its 2025 annual general meeting (BD: Nov 22, 2024).

Cambium was up four cents or seven percent to 61 cents.

SOMNOMED

Somnomed says it has appointed its head of finance Ye-Fei Guo as its chief financial officer, effective from November 27, 2024.

Somnomed said Ms Guo had more than 20 years of experience and had been an accountant at Pricewaterhousecoopers (PWC) as well as head of finance at Brookfield. The company said Ms Guo had been its head of finance since August and had “already proven to be a valuable asset to the team”.

NUHEARA

Nuheara administrator KPMG says Susan Park “has resigned from her role as company secretary” effective from November 7, 2024.

Earlier this year, Nuheara said it had appointed Klynveld Peat Marwick Goerdeler’s (KPMG) Martin Jones, Matthew Woods and Clint Joseph as joint and several voluntary administrators (BD: Aug 7, 2024).

Nuheara was in a suspension and last traded at 8.1 cents.