



Biotech Daily

Thursday December 14, 2023

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH UP: VOLPARA UP 41%; IMPEDIMED DOWN 7%**
- * **SEOUL'S LUNIT TO BUY VOLPARA FOR \$296m**
- * **RESPIRI PLACEMENT RAISES \$6.5m, \$20m FACILITY**
- * **MACH7 RENEWS 5-YEAR, \$10m SENTARA DEAL**
- * **RECCE \$43.8m ADVANCED OVERSEAS R&D FINDING**
- * **AUSTIN, FLOREY, BIONICS INSTITUTE IMPLANT 1st CROHN'S DEVICE**
- * **RECCE R327 'REDUCES 99% GONORRHOEAE SHEDDING', IN MICE**
- * **NUCLEUS NETWORK TO OPEN 1st NSW CLINICAL TRIAL SITE**
- * **MTP CONNECT, SOUTH KOREAN COOPERATION AGREEMENT**
- * **ATMO ENROLS 'PIVOTAL' GAS-SENSING CAPSULE TRIAL**
- * **BOTANIX REVISES SOFDA INSTRUCTIONS FOR NDA RESUBMISSION**
- * **TRUSCREEN WINS \$162k POLISH ICLOUD STORAGE GONG**
- * **NEUREN REQUESTS 'TRIAL RESULTS' TRADING HALT**
- * **PHEONIX TAKES 22% OF CONTROL BIONICS; NIGHTINGALE 15%**
- * **OPTISCAN TO RELEASE 6m VOLUNTARY ESCROW SHARES**
- * **LBT APPOINTS FORMER CO SEC DAN HILL DIRECTOR**
- * **DR TOM TAKUBO REPLACES RESPIRI DIRECTOR BRAD SNOW**
- * **RHYTHM APPOINTS JAMES BARRIE CO-CO SEC**

MARKET REPORT

The Australian stock market was up 1.65 percent on Thursday December 14, 2023, with the ASX200 up 120.1 points to 7,377.9 points. Twenty-four of the Biotech Daily Top 40 stocks were up, 12 fell, three traded unchanged and one was untraded.

Volpara was the best, up 32 cents or 41.3 percent to \$1.095, with 11 million shares traded. Dimerix climbed 25.9 percent; Syntara (Pharmaxis) rose 12.5 cents; Opthea was up 9.1 percent; Compumedics climbed 7.55 percent; Avita and Clinuvel were up more than five percent; Curvebeam was up 4.7 percent; Alcidion, Medical Developments, Mesoblast, Prescient, Starpharma and Telix rose more than three percent; Imugene, Nanosonics, Next Science and Orthocell improved more than two percent; Amplia, CSL, Immutep, Paradigm, Polynovo, Pro Medicus and Resmed were up one percent or more; with 4D Medical up by 0.7 percent.

Impedimed led the falls, down one cent or 6.9 percent to 13.5 cents, with 2.9 million shares traded. Genetic Signatures lost 6.25 percent; both Cynata and Nova Eye fell four percent; Antisense and Proteomics were down three percent or more; Atomo and Universal Biosensors shed more than two percent; Cyclopharm lost one percent; with Clarity, Cochlear, Emvision and SDI down by less than one percent.

[VOLPARA HEALTH TECHNOLOGIES](#)

Volpara says the Seoul, South Korea-based Lunit Inc will acquire the company for \$1.15 a share, valuing it at \$295.7 million, through a scheme implementation agreement.

Volpara said the offer was a 47.4 percent premium to its last closing share price of 78 cents a share and a 55.4 percent premium to its one-month volume weighted average price to December 13, 2023.

The company said the transaction was “expected to accelerate Volpara’s ability to serve its purpose of saving families from cancer”.

Volpara said Lunit was a medical company committed to accurately diagnosing and treating cancer patients with artificial intelligence-based medical image analytics and biomarkers, with its US Food and Drug Administration approved Lunit Insight suite used in more than 3,000 hospitals and institutions in more than 40 countries.

The company said that with the support of Lunit’s in-house radiologists and complementary technologies its “repository of more than 100 million images will be strategically augmented by additional [artificial intelligence] expertise”.

Volpara said the scheme was subject to shareholder and New Zealand High Court approvals, as well as other customary conditions including the absence of any ‘material adverse change’.

The company said shareholder approval would be sought at a scheme meeting expected to be held in mid-May 2024, with scheme information to be sent to investors by April, and if approved, the scheme would be implemented by July 2024.

Volpara said cornerstone shareholders Harbour Asset Management, director Roger Allen and founder Dr Ralph Highnam, who collectively held 25.92 percent of the company’s issued capital, would vote in support of the scheme.

The company said the board unanimously believed that the transaction was “in the best interests of shareholders” and recommended shareholders vote in favor of the scheme, in the absence of a superior proposal.

Volpara said it had appointed Grant Samuel and Associates Ltd as independent advisors, to assist shareholders in assessing the scheme.

Volpara chair Paul Reid said the board had “assessed the proposed scheme as providing compelling, risk-adjusted value and certainty for shareholders and unanimously support the proposed transaction”.

“In considering options for Volpara, including continuing to implement the company’s growth strategy as a publicly-listed company, the board adopted a long-term view of the risks and rewards of various alternatives,” Mr Reid said.

“The proposed transaction would accelerate the return of capital to shareholders and mitigate the risks that would otherwise be involved in delivering the opportunities from executing Volpara’s strategic plan over time,” Mr Reid said.

Volpara managing-director Teri Thomas said Lunit’s interest in acquiring the company was “a strong testament to the high quality of our products, our significant US market presence, and the hard work of our employees”.

“Working together, Lunit and Volpara would have the opportunity to develop products that very few companies are in a position to do,” Ms Thomas said.

“This is expected to put us at the forefront of cancer technology and position us as a global leader in our field,” Ms Thomas said.

Lunit chief executive officer Brandon Suh said that “Volpara’s established presence in the US and Lunit’s complementary global footprint and [artificial intelligence] expertise will create a compelling portfolio of advanced [artificial intelligence] enabled solutions for radiology and other healthcare specialties”.

Volpara was up 32 cents or 41.3 percent to \$1.095 with 11 million shares traded.

RESPIRI

Respiri says it has commitments to raise about \$6.5 million in a placement at 3.0 cents a share, and a \$20 million commitment facility from Principal Wealth Group.

Respiri said it would use the Sydney-based Principal Wealth facility to buy US remote patient monitoring operations to build on its Access Managed Services acquisition.

In August, the company said it bought Access Managed Services LLC for about \$4.5 million (BD: Aug 14, 2023).

Today, Respiri said the placement price was a three percent discount to the last traded price and a one percent premium to the 15-day volume weighted average price.

The company said cornerstone investor and Principal Wealth Group director Benjamin Richards was lead manager and had taken up about \$5 million in the placement.

Respiri said the funds would be for the final payment for Access and working capital and with the placement it expected to achieve a break-even cashflow by December 31, 2024.

The company said the \$20 million facility was subject to shareholder approval, and that Principal Wealth Group would receive a one percent management fee and a two percent placement fee of all amounts invested through the facility.

Respiri was unchanged at 3.1 cents with 1.8 million shares traded.

MACH7 TECHNOLOGIES

Mach7 says Sentara Healthcare has extended its contract for the Enterprise imaging platform and E-Unity diagnostic for a further five years, worth about \$10.2 million.

In 2017, Mach7 said the Norfolk, Virginia-based Sentara would use its vendor neutral archive system for data migration for its image management initiative (BD: Nov 17, 2017).

Today, the company said it expected \$2.0 million in annual recurring revenue, double the previous contract, with "further upside" if volumes continue to exceed contract minimums.

Mach7 said the renewed agreement was effective from January 1, 2024.

Mach 7 chief executive officer Mike Lampron said Sentara had been "a long-standing client ... and this renewal once again highlights the sticky nature of our customer base".

Mach 7 was up three cents or 4.2 percent to 74 cents.

RECCE PHARMACEUTICALS

Recce says that it has an Advanced Overseas Finding for up to \$43,774,907 for research and development on its synthetic antibiotics.

Recce said that the finding by the Federal Government's Department of Industry, Innovation and Science Ausindustry was "one of the largest awarded in Australian history as a pillar of the Federal [Research and Development] Tax Incentive Program.

The company said that the finding was for research and development expenditure from July 1, 2022 to June 30, 2025.

"This finding does not constitute a grant, or an upfront payment of the amount awarded," Recce said. "It is a binding, underwritten guarantee provided by the Australian Government, which affirms the company's [research and development] activities are of national interest and extends the 43.5 percent ... [Incentive] from locally, to cover those undertaken by the company anywhere in the world."

Recce chief executive officer James Graham said that the finding effectively said that if the company spent up to \$100,631,970 on the "development and testing of new synthetic antibiotic against superbugs" it would be guaranteed the full 43.5 percent Incentive.

Recce's recent Appendix 4C said the company had \$11,157,216 at September 30, 2023.

Recce was up two cents or 4.4 percent to 47 cents.

[AUSTIN HEALTH, BIONICS INSTITUTE FLOREY INSTITUTE OF NEUROSCIENCE AND MENTAL HEALTH](#)

Austin Health says its clinicians have implanted the first a Florey Institute and Bionics Institute developed electrical nerve stimulation device in a Crohn's disease patient.

A media release from Austin Health, said the device had been developed to prevent inflammation recurring after bowel surgery by the Florey and Bionics institutes in collaboration with the University of Melbourne.

Austin Health said Crohn's disease caused inflammation to the lining of the gut, with up-to 80 percent of patients eventually requiring bowel surgery to remove sections damaged by inflammation, and that even after surgery the disease frequently returned, requiring further surgery, with sufferers often at the mercy of life-long drug therapies to manage symptoms. The Bionics Institute's chief technical officer and head of research Prof James Fallon said the device was implanted onto the vagus nerve of a Crohn's patient.

"The vagus nerve controls many functions in the body, such as digestion, heart rate and the immune system," Prof Fallon said.

"The device is made up of tiny electrodes that stimulate the vagus nerve to trigger the body's natural defences and prevent inflammation from damaging the gut," Prof Fallon said.

"We have designed the device to be a set-and-forget treatment powered by a small battery under the skin, hopefully allowing patients to continue their lives without the fear of further surgery," Prof Fallon said.

The Florey Institute's Prof John Furness, a study co-investigator said "by stimulating anti-inflammatory nerves and addressing inflammation early, the recurrent inflammation and associated scar tissue development can hopefully be prevented altogether, meaning patients will avoid the cycle of surgery and recovery".

[RECCE PHARMACEUTICALS](#)

Recce says R327 led to a 99.9 percent reduction of bacterial shedding in mice vaginally inoculated with *Neisseria gonorrhoeae*.

Recce said the study at Melbourne's Murdoch Children's Research Institute administered bolus doses of R327 to groups of 10 mice intravenously, twice daily at 1,000mg/kg.

The company said antimicrobial resistance to *gonorrhoeae* was an increasing issue, rendering many classes of antibiotics ineffective, with current treatment involving combination therapy of at least two antibiotics but bacterial resistance having led to restriction for infections caused by resistant organisms.

Recce said that after five days, R327 showed a 99.9 percent reduction in bacterial shedding compared to the placebo-treated group.

The company said that a previous *gonorrhoeae* study showed a dose-dependent anti-bacterial effect in vaginal load at bolus doses of 100mg/kg, 500mg/kg and 1,000mg/kg. twice daily for seven days.

[NUCLEUS NETWORK](#)

Nucleus Network says it will expand its clinical trial services to New South Wales with the opening of a phase I clinic at Sydney's Royal North Shore public hospital.

Nucleus Network said the clinic would increase its bed capacity by more than 40 percent and was expected to add more than 100 jobs in the Sydney area.

The Network said the facility would cater to the needs of phase I trials, with amenities and technology, high standards of safety, efficiency and comfort.

MTP CONNECT

MTP Connect says it has an agreement with the Seoul-based Korea Health Industry Development Institute to support biotechnology companies in Australia and Korea. MTP Connect said the agreement supported cooperation between the two parties, including promotion and support for relevant funding and product development, in-market support in each party's respective jurisdictions and joint events and projects.

The Federally-funded industry organization said the first initiative was already underway, with MTP Connect representatives to meet South Korean medical technology companies in Seoul to discuss partnering with Australian companies.

MTP Connect said the Institute was a South Korean Government-funded organization that supported the country's life sciences sector.

MTP Connect chief executive officer Stuart Dignam said the agreement built "on the valuable relationship MTP Connect already enjoys with KHIDI and other links in Korea, including [Researcher Exchange and Development within Industry] fellowships with two companies, Cytiva and Yuhan Corp".

"Korea is Australia's third largest two-way trading partner ... trade is diversifying away from the traditional energy, resources and agriculture to technology and services, and life sciences and medical products, including ... trials is an example of this" Mr Dignam said.

Mr Dignam said an example of how the two organizations would work together was through KHIDI's International Cooperation Research and Development program.

"This new program requires Korean [medical technology] companies to partner with international companies to be eligible for grants up-to \$1.5 million," Mr Dignam said.

"It's a fantastic collaboration and funding opportunity for Australia's [medical technology small and medium-sized enterprises] to work with leading companies in Korea and we have staff on the ground in Seoul this week to help facilitate introductions, make connections and promote the benefits of Korea and Australia working more closely together," Mr Dignam said.

ATMO BIOSCIENCES

Atmo says it has recruited its target of more than 200 patients in its 'pivotal' trial of its gas-sensing capsule for diagnosing motility disorders such as gastro-paresis and constipation. In August, Atmo said it expected to recruit about 100 patients with gastro-intestinal symptoms and dysmotility for a "pivotal" trial of its gas-sensing capsule against Medtronic's Smartpill, with results to be used for a US Food and Drug Administration 510(k) application (BD: Aug 10, 2023).

Today, the company said the study was assessing the use of the gas capsule to measure gastrointestinal transit time in patients with suspected motility disorders by showing equivalence to a predicate device, the Smartpill.

Atmo said clinicians studied whole and regional gut transit to help diagnose motility disorders such as gastro-paresis, or delayed emptying from the stomach and slow transit constipation, or slow transit through the colon.

The company said the study took place at 11 sites in the US and one site in Australia, with more than 200 patients ingesting both its gas-sensing capsule and Medtronic's Smartpill to compare the two devices.

Atmo chief executive officer Malcolm Hebblewhite said the company was "delighted to have met our patient recruitment target ahead of schedule".

"It was a testament to the efforts of our 12 clinical partners who conducted the study at their institutions," Mr Hebblewhite said.

Atmo is a public unlisted company.

[BOTANIX PHARMACEUTICALS](#)

Botanix says it has revised the printed instructions of Sofdra for excessive sweating and will resubmit its US Food and Drug Administration new drug application (NDA).

Earlier this year, Botanix said the US Food and Drug Administration denied its new drug application of Sofdra, or sofipironium bromide, for excessive sweating, requesting printed instruction changes (BD: Sep 26, 2023).

Today, Botanix said it ran a 45-patient, "human factors" study to test participant use of Sofdra according to the revised instructions and that all participants successfully prepared and correctly applied Sofdra gel as per the printed instructions.

The company said it hoped to resubmit the new drug application by April and expected FDA approval by July 2024.

Botanix chief executive officer Dr Howie McKibbon said the company was "pleased with the outcome of the [human factors] study for Sofdra and the performance of the revised [instructions for use], in guiding patients to the safe and successful use of the product".

"The team will continue working over the holiday break to expeditiously assemble materials for resubmission, to allow a rapid turnaround and filing with FDA for Sofdra approval," Dr McKibbon said.

Botanix was unchanged at 14.5 cents with 5.3 million shares traded.

[TRUSCREEN GROUP](#)

Truscreen says it has won the Polish Mother and Child Institute Start Up Challenge and will receive EUR100,000 (\$A162,000) worth of internet cloud storage and support.

Truscreen said the seven-month competition was sponsored by 17 companies, including Poland's Ministry of Health, Iqvia, GE Healthcare, Astrazeneca and the European Union. The company said that as one of two winners it would receive one-year of support for the implementation of its technology in Poland, free access to an online course and 12 hours of mentoring support from the Chicago-based GE Healthcare.

Truscreen was up 01. cents or 4.55 percent to 2.3 cents.

[NEUREN PHARMACEUTICALS](#)

Neuren has requested a trading halt pending an announcement "in relation to the top line results of its phase II clinical trial in Phelan-McDermid syndrome".

Trading will resume on December 18, 2023, or on an earlier announcement.

Neuren last traded at \$17.14.

[CONTROL BIONICS](#)

Phoenix Development Fund says it has increased its substantial shareholding in Control Bionics from 8,019,581 shares (9.62%) to 31,269,581 shares (21.58%).

In a notice signed by former Control Bionics director Lindsay Phillips, the Sydney-based Phoenix said on December 12, 2023 it acquired 10,750,000 shares for \$430,000 through a rights issue shortfall at 4.0 cents a share and underwrote 12,500,000 shares for \$500,000.

In October, Control Bionics said it hoped to raise up-to \$2.73 million in a two-for-three, non-renounceable rights offer at 4.0 cents a share, with more than \$1 million underwritten (BD: Oct 30, 2023).

Control Bionics was up 0.8 cents or 24.2 percent to 4.1 cents.

CONTROL BIONICS

Sydney's Nightingale Partners says it has increased but been diluted from 19,537,595 shares (19.07%) to 21,287,595 shares (14.69%).

In a notice signed by former Control Bionics director Lindsay Phillips, Nightingale said that on December 12, 2023 it underwrote 1,750,000 shares for \$70,000, or 4.0 cents a share, in a rights issue (see above).

OPTISCAN IMAGING

Optiscan says it will release 6,000,000 voluntary escrow shares on December 20, 2023. According to its most recent filing, Optiscan had 835,140,803 shares on issue. Optiscan fell 0.1 cents or 1.2 percent to 8.1 cents.

LBT INNOVATIONS

LBT says it has appointed former company secretary Dan Hill as a non-executive director, effective from today.

In 2020, LBT said Mr Hill had stepped down as company secretary (BD: Feb 11, 2020).

Today, the company said Mr Hill became a substantial shareholder in the company after participating in its recent entitlement offer as a cornerstone sub-underwriter.

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 placed the shortfall (BD: Nov 20, Dec 8, 2023).

Today, LBT chair Rebecca Wilson said "as a substantial shareholder, Mr Hill has a confluence of interests with all shareholders and will take an active approach working with the board and management to execute our updated company strategy".

LBT was up 0.1 cents or 9.1 percent to 1.2 cents.

RESPIRI

Respiri says Dr Tom Takubo will replace Brad Snow as a non-executive director, effective from today.

Respiri said that Dr Takubo was a Republican Party West Virginia State Senator and vice chair of the West Virginia Senate Health and Human Resources and Senate Finance committees, and was chief of pulmonary and critical care medicine at the Charleston Area Medical Center and was head of provider relations at West Virginia University.

According to his LinkedIn page, Dr Takubo held a Bachelor of Science from the Huntington, West Virginia-based Marshall University and a Doctor of Osteopathy from the West Virginia School of Osteopathic Medicine.

RHYTHM BIOSCIENCES

Rhythm says it has appointed James Barrie as joint company secretary, to assist in the role alongside company secretary and general counsel Andrea Steele.

Rhythm was unchanged at 15 cents.