

Biotech Daily

Monday September 23, 2024

Daily news on ASX-listed biotechnology companies

- * ASX DOWN, BIOTECH UP: AMPLIA UP 26%; PARADIGM DOWN 9%
- * TELIX TO BUY RLS RADIOPHARMACY NETWORK FOR UP-TO \$366m
- * CONTROL BIONICS RAISES \$1.15m; RIGHTS OFFER FOR \$2.1m MORE
- * BTC CARDIO \$5m ROYAL CHILDREN'S HOSPITAL SUPPLY CONTRACT
- * RESPIRI: RECORD 2k PATIENTS; 2 HAWAII DEALS
- * AMPLIA: 6th PANCREATIC CANCER RESPONSE OPENS FINAL RECRUITMENT
- * MONASH UNIVERSITY: 'ANTIBODIES BOOST VACCINES, IN MICE'
- * PROTEOMICS OESOPHAGEAL CANCER TEST '94% ACCURACY'
- * BCAL: 'SYDNEY BREAST CLINIC FOR BREASTEST LAUNCH'
- * TAKEOVERS PANEL: TONY CHARARA WON'T SPILL TISSUE REPAIR BOARD
- * HERAMED, FOUNDA HEALTH PARTNERSHIP
- * FIREBRICK RECEIVES \$920k FEDERAL R&D TAX INCENTIVE
- * MA FINANCIAL (MOELIS) TAKES 8.5% OF TRAJAN
- * CRYOSITE APPOINTS HAMISH GEORGE, MICHAEL AUSTIN CO-CO SECS
- * TRUSCREEN APPOINTS DIRECTOR DR DEXTER CHEUNG TECHNOLOGY CHAIR
- * TRYPTAMINE CBO PETER MOLLOY TO NON-EXECUTIVE DIRECTOR

MARKET REPORT

The Australian stock market fell 0.69 percent on Monday September 23, 2024, with the ASX200 down 56.6 points to 8,152.9 points. Twenty of the Biotech Daily Top 40 stocks were up, 13 fell, six traded unchanged and one was untraded.

Amplia was the best for the second trading day in a row (see below), up 3.5 cents or 25.9 percent to 17 cents, with 7.9 million shares traded. Impedimed improved 17 percent; Micro-X was up 11.8 percent; Aroa and Proteomics climbed more than six percent; Percheron was up five percent; Dimerix was up 4.2 percent; Alcidion climbed 3.7 percent; Avita, Imugene, Nova Eye, Opthea and Prescient rose more than two percent; Clarity, Immutep, Medical Developments, Polynovo, Resmed and Telix were up more than one percent; with Emvision and Pro Medicus up by less than one percent.

Paradigm led the falls, down two cents or 9.1 percent to 20 cents, with 3.2 million shares traded. Actinogen lost 6.9 percent; Atomo shed five percent; Starpharma fell 4.8 percent; 4D Medical, Curvebeam, Genetic Signatures and Mesoblast shed more than two percent; CSL, Neuren and Resonance were down more than one percent; with Clinuvel, Cochlear, Nanosonics and SDI down by less than one percent.

TELIX PHARMACEUTICALS

Telix says it will acquire the Orlando, Florida-based RLS Inc Radiopharmacies network from RLS Group Ltd for up-to \$US250 million (\$A365.9 million).

Telix said RLS Radiopharmacies was the only US Joint Commission-accredited radiopharmacy networking distributing positron emission tomography (PET), single-photo emission computed tomography (SPECT) and therapeutic radiopharmaceuticals.

The company said it would pay \$US230 million upfront and up to \$US20 million pending milestones for RLS Radiopharmacies.

Telix said that RLS Radiopharmacies' revenue for the year to December 31, 2023 was \$US158 million.

The company said the acquisition would "significantly expand" its North American manufacturing footprint and establish the basis of a next generation radiometal production network for it and select commercial partners.

Telix said it would leverage RLS' 31 licenced radio-pharmacies in major US metropolitan areas to build a "radiometal production and distribution network for key therapeutics and diagnostic isotopes alongside last-mile delivery of finished unit doses in relevant markets". The company said the RLS acquisition included more than 100,000 square feet (9,290 square metres) of expansion space that could be used to meet increased production. Telix said it aimed to provide "additional supply chain backup and improve capacity to meet future demand" while increasing access for US patients, including under-served populations.

The company said RLS would service its existing customers and operate as an independent business unit under Telix Manufacturing Solutions, which included Telix brands like Artms, Isotherapeutics and Optimal Traces.

Telix chief executive officer Dr Christian Behrenbruch said "by combining the Artms platform and the RLS network, we can scale up the production of key isotopes and build a stable and consistent supply of PET and SPECT diagnostic tracers, along with therapeutic radiopharmaceuticals across the US for the benefit of Telix, our partners and the patients we serve".

"As we grow and commercialize new products, this investment ensures we can continue to deliver to this standard, alongside our key trusted distribution partners," Dr Behrenbruch said.

Telix said the purchase price included upfront cash consideration \$US230 million, "debt and debt equivalents', transaction expenses and working capital, and deferred cash consideration up to "a maximum of \$US20 million" contingent on achieving certain financial and operational performance milestones in the four quarters following closing, with the purchase expected to be funded from existing cash reserves.

Telix was up 38 cents or 1.9 percent to \$20.69 with 1.5 million shares traded.

CONTROL BIONICS

Control Bionics says it has raised \$1,150,000 through a placement, with one attaching option for every two shares subscribed, be exercisable at 10 cents each within two years. Last week, Control Bionics said it hoped to raise \$2,092,868 through a one-for-seven rights issue at 7.0 cents a share, and \$1 million in a placement (BD: Sep 20, 2024). Today, the company said the placement was subject to shareholder approval. Control Bionics said Lynx Advisors was lead manager for the placement and would receive a six percent fee on the funds raised and be granted 500,000 options also exercisable at 10 cents each, for three years.

Control Bionics fell 0.6 cents or 7.9 percent to seven cents.

BTC HEALTH

BTC says it has a \$5 million contract to supply extra corporal membrane oxygenation (Ecmo) equipment, consumables and services to Melbourne's Royal Children's Hospital. BTC Health said the five-year contract was through its BTC Cardio subsidiary with the Medolla, Italy-based Eurosets for its Ecmolife products.

The company said contract value included specified capital equipment and single-use consumable products was based on the expected number of patient cases each year. BTC said it would supply, commission and integrate the Eurosets Ecmolife equipment into the Royal Children's Hospital paediatric intensive care unit before the end of 2024. BTC Health chief executive officer Dr Richard Treagus said that "partnering with RCH and supporting their expert team in caring for vulnerable children is an absolute privilege". "This is the first implementation of our high-quality Ecmolife equipment in Australia, and we are excited about the opportunity to expand our national rollout further," Dr Treagus. BTC Health was up half a cent or 10 percent to 5.5 cents.

RESPIRI

Respiri says it has a record 2,000 patients enrolled in its programs as well as two remote patient monitoring deals in Hawaii, worth about \$US1 million (\$A1.46 million). Respiri said the agreements for its remote patient monitoring business were with two Honolulu-based nursing facilities, Liliha Healthcare Centre and Care Center of Honolulu. The company said about 1,000 patients were discharged to home-care from these two facilities each year, and its remote patient monitoring system could help ensure this transition was successful and that continuity of care was maintained.

Respiri said its team's patient engagement capacity was 1,000 a week, with a forecast enrolment rate of 33 percent or about 333, and its model "readily scalable".

The company said it expected about \$US1 million in revenue at a 33 percent recruitment rate, and at 100 percent recruitment revenue "could be as high as \$US2.4 million". Respiri said there were 42 skilled nursing facilities in Hawaii, which discharged about 5,000 patients each year, and that it was "in discussions to expand this model to a significantly larger proportion of these clinical facilities".

Respiri chief executive officer Marjan Mikel said "there are three major healthcare assets that work in concert to optimize healthcare delivery in the US: providers, hospitals and skilled nursing facilities and we now partner with all three in Hawaii".

Respiri was up 0.2 cents or 5.7 percent to 3.7 cents, with 2.9 million shares traded.

AMPLIA THERAPEUTICS

Amplia says six patients in its 50-patient, phase IIa, AMP945 pancreatic cancer trial have shown reduced tumor size with no new lesions, allowing it to recruit its 24 patients. In August, the company said five of six patients had a confirmed partial response in its trial of narmafotinib, or AMP945, with chemotherapy for advanced pancreatic cancer, with one more response needed to continue enrolment (BD: Aug 21, 2024).

Today, Amplia said it would begin recruiting the remaining 24 patients at existing trail sites in Australia and South Korea, with these patients expected to be completed by April 2025. Amplia managing-director Dr Chris Burns said that having confirmed the sixth partial response "we will move forward with recruiting the remaining 24 patients for the trial". "We are actively working with our clinical sites to ensure seamless reopening of enrolment with the goal of completing recruitment by the end of March 2025," Dr Burns said. Amplia was up 3.5 cents or 25.9 percent to 17 cents with 7.9 million shares traded.

MONASH UNIVERSITY

Monash University says it has developed a technique to increase vaccine effectiveness by adding vaccine antibodies to stimulate immune system B cells.

Monash University said that the mouse study showed that adding low doses of vaccinespecific antibody to a Covid-19 vaccine stimulated B cells, which were responsible for generating antibodies.

The University said the study, titled 'Conversion of vaccines from low to high immunogenicity by antibodies with epitope complementarity', was published in Immunity with an abstract at https://www.cell.com/immunity/abstract/S1074-7613(24)00416-3.

Monash University's Dr Isaak Quast said "a key challenge for vaccine design is to ensure sufficient activation and duration of B cell responses to achieve the quantity and quality of antibodies required for protection".

"Adding vaccine-specific antibodies is like adding a red flag, and making it really obvious to B cells that they need spring into action," Dr Quast said.

"This method stimulates B cells that would otherwise fail to be active participants in the immune response, potentially allowing new parts of invading viruses to be recognized, thus increasing protective immunity," Dr Quast said.

"While so far only tested in animal models, the research could also facilitate the development of vaccines to target structures of pathogens that are otherwise not recognized strongly enough by our immune system," Dr Quast said.

"In a diverse human population some people will always respond better than others, and this method could help ensure that a larger proportion of the population develops a 'good, sufficient' immune response for protection," Dr Quast said.

PROTEOMICS INTERNATIONAL LABORATORIES

Proteomics says its Promarker Eso blood test for oesophageal adenocarcinoma showed 94 percent accuracy in a 165-sample clinical validation study.

In 2022, Proteomics said a 302-patient study of its oesophageal cancer test had a "strong diagnostic performance" with an up-to 90 percent detection rate (BD: Sep 27, 2022). Last year the company said that the blood test correctly identified 89 percent of patients with the disease and 92 percent without the disease (BD: Sep 8, 2023).

In February, Proteomics said it presented further data confirming the biomarkers used in its endometriosis and oesophageal cancer blood tests (BD: Feb 1, 2024).

Today, the company said its oesophageal adenocarcinoma test had a 93.1 percent sensitivity and 96.6 percent specificity.

Proteomics said that the test used glycoprotein biomarkers to screen for oesophageal adenocarcinoma.

The company said it studied 165 patient samples from the Victoria Cancer Biobank, including 66 cancer patients and 99 healthy control patients.

Proteomics said the area under the receiver operating characteristic curve was 0.93, "indicating outstanding diagnostic performance" for identifying patients.

The company said the study also included assessment of its refined Promarker Eso test on a previously analyzed cohort from multi-state, US-based Ochsner Medical.

Proteomics said it would present the results at the 20th Annual International Society for Disease of the Esophagus (ISDE) World Congress for Esophageal Diseases in Edinburgh, Scotland today.

Proteomics was up 4.5 cents or 6.9 percent to 70 cents.

BCAL DIAGNOSTICS

Bcal says the Sydney Breast Clinic will assist building clinical validation evidence for the commercial launch of its Breastest breast cancer screening technology.

Bcal said Sydney Breast Clinic was a multi-disciplinary breast screening clinic and had been "an invaluable clinical study partner for Bcal over the past six years" including contributing samples to help Bcal develop and validate Breastest, with its clinicians collaborating with Bcal on clinical development.

The company said commercial terms of the agreement remained confidential, with Bcal executive chair Jayne Shaw absenting from the agreement negotiation and settlement due to having "an economic interest" in the clinic.

Bcal said the deal would help its soft launch this year and was on track to complete its National Association of Testing Authorities audit and accreditation in the coming weeks. Bcal was unchanged at 12 cents.

TAKEOVERS PANEL, TISSUE REPAIR

The Takeovers Panel says it won't take action on Tissue Repair following an undertaking from executive director Tony Charara not to spill the board.

In an email from the Takeovers Panel, posted on the Tissue Repair ASX site after the close of the ASX on Friday, September 20, 2024, Takeovers Panel chief executive Allan Bulman said the panel "declined to conduct proceedings on an application dated August 28, 2024 from Tissue Repair in relation to its affairs, after accepting an undertaking from Spark Capital Pty Ltd and Mr Charara".

In August, the Panel said it had an application from Tissue Repair relating to a potential board spill request concerning an alleged undisclosed association (BD: Aug 30, 2024). The Panel said on August 27, 2024, Tissue Repair's "non-executive directors received notices under sections 249D and 203D dated August 15, 2024 to requisition a general meeting ... for the removal of two ... directors and the appointment of a new director". Mr Charara is listed by Commsec as an executive director, with the company's three nonexecutive directors chair Jack Lowenstein, Bryan Gray and Dr Michael Silberberg. On Friday, Mr Bulman said Mr Charara was the co-founder and an executive director of Tissue Repair and a director Spark Capital and the section 249D and 203D notices "appeared to be signed by shareholders, including Spark Capital and Mr Charara, who together hold more than 50 percent of ... voting shares", with the notices provided to nonexecutive directors by a legal adviser who asserted the notices would be served if the company failed to provide a satisfactory proposal to give effect to the board changes. In June "Mr Charara had proposed to his fellow directors that TRP delist from the ASX," Mr Bulman said. "That proposal was not supported by the non-executive directors." "Mr Charara and Spark Capital Pty Ltd have undertaken not to give the notices to TRP and to inform each of the other shareholders who signed the notices that they are free to exercise their voting rights in their absolute discretion on any resolution put to TRP shareholders," Mr Bulman said. "Mr Charara also submitted that he had not discussed any delisting proposal with the other requisitioning shareholders and 'he is not considering, proposing or currently giving any consideration to any proposal to delist [Tissue Repair] and that he has no intention to do so in future'."

"Considering the undertaking and Mr Charara's submission, the Panel concluded there was no reasonable prospect that it would make a declaration of unacceptable circumstances," Mr Bulman said.

"Accordingly, the Panel declined to conduct proceedings," Mr Bulman said. Tissue Repair fell seven cents or 15.2 percent to 39 cents with 1.2 million shares traded.

HERAMED

Heramed says it has a letter of intent with Amsterdam's Founda Health to integrate its Heracare foetal heart monitor into Founda's platform.

Heramed said the letter of intent detailed its intention to "explore possible collaboration areas and, if commercially feasible, to negotiate and enter a subsequent ... agreement". The company said it would work with Founda Health to identify an initial hospital reference site, either in Europe or the US, to begin integrating its monitor into Founda's platform. Heramed was up 0.2 cents or 9.5 percent to 2.3 cents.

FIREBRICK PHARMA

Firebrick says it has received \$919,656 from the Federal Research and Development Tax Incentive program for expenditure for the year to June 30, 2024. Firebrick fell 0.4 cents or 7.1 percent to 5.2 cents.

TRAJAN GROUP HOLDINGS

Sydney's MA Financial Group Ltd (formerly Moelis) says it has increased its substantial shareholding in Trajan from 11,392,080 shares (7.48%) to 12,980,266 shares (8.53%). MA Financial said it bought shares between June 14 and September 18, 2024, with the largest purchase on September 17 of 600,000 shares for \$714,000 or \$1.19 a share. Trajan was up half a cent or 0.4 percent to \$1.25.

CRYOSITE

Cryosite says it has appointed Hamish George and Michael Austin joint company secretaries, following Dray Andrea's resignation, effective September 20, 2024. Cryosite said Mr George and Mr Austin worked with Bio101 Financial Advisory Pty Ltd. Cryosite was untraded at 80 cents.

TRUSCREEN GROUP

Truscreen says it has appointed director Dr Dexter Cheung as chair of its technology committee, effective immediately.

Truscreen said Dr Cheung and had more than 20 years of experience as a medical device engineer and in product research and development and was currently the respiratory humidification research and development manager for Fisher & Paykel Healthcare. According to his Linkedin page, Dr Cheung held a Masters of Engineering and Doctorate of Philosophy from the University of Auckland.

Truscreen fell 0.1 cents or 4.8 percent to two cents.

TRYPTAMINE THERAPEUTICS (FORMERLY EXOPHARM)

Tryptamine says that chief business officer and executive director Peter Molloy will transition to a non-executive director position, effective from September 23, 2024. Tryptamine fell 0.3 cents or 14.3 percent to 1.8 cents with 3.45 million shares traded.