



Biotech Daily

Tuesday November 19, 2024

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH UP: RESONANCE UP 55%; MEDADVISOR DOWN 7%**
- * **TELIX TO PAY UP-TO \$264m FOR 'FAP' CANCER THERAPIES**
- * **RESONANCE \$13.8m SUN PHARMACEUTICAL INDUSTRIES TRIAL CONTRACT**
- * **RHYTHM 'COMMITMENTS' FOR \$3.5m PLACEMENT**
- * **CENTENARY \$300k RT HALL CANCER RESEARCH GRANTS**
- * **4D MEDICAL, UC SAN DIEGO LUNG IMAGING DEAL**
- * **UNIVERSAL BIOSENSORS SIGNS 2nd US XPRECIA DISTRIBUTOR**
- * **QBIOTICS: 'TIGILANOL TIGLATE BEATS SARCOMA ENDPOINT'**
- * **RADIOPHARM ADDS 5 CANCERS TO PHASE I, RAD204 TRIAL**
- * **BLINKLAB PLATFORM '91% SENSITIVITY, 85% SPECIFICITY FOR AUTISM'**
- * **CURVEBEAM FILES 6-OF-10 HIRISE DATASETS**
- * **ISLAND 92% REMUNERATION REPORT 2nd STRIKE, 98% BACK BOARD SPILL**
- * **CANN 'MULTI-HEAD FILLER' PACKS 25k MARIJUANA UNITS**
- * **TRYPTAMINE FINDS UNSPECIFIED PHASE II TRP-8803 I.V. PSILOCYBIN DOSE**
- * **REGAL TAKES 11.8% OF IMMUTEP**
- * **QBIOTICS LOSES DIRECTORS PROF BRUCE ROBINSON, ANDREW DENVER**
- * **MICRO-X LOSES DIRECTOR DR ALEXANDER GOSLING**
- * **ALTERITY CFO ABBY MACNISH RELACES CO SEC PHILLIP HAINS**
- * **BIO-MELBOURNE TO OPEN MEDICAL RESEARCH CAREER PORTAL**

MARKET REPORT

The Australian stock market was up 0.89 percent on Tuesday November 19, 2024, with the ASX200 up 73.8 points to 8,374.0 points. Twenty-three of the Biotech Daily Top 40 companies were up, 13 fell and four traded unchanged.

Resonance was the best (see below), up 2.1 cents or 55.3 percent to 5.9 cents, with 5.5 million shares traded. Syntara was up 12.5 percent; Curvebeam climbed 10 percent; Starpharma rose 9.1 percent; Compumedics was up 7.0 percent; 4D and Paradigm were up more than six percent; Alcidion rose 5.2 percent; Universal Biosensors was up 4.2 percent; Aroa and Clarity were up more than three percent; Cochlear, Imugene, Polynovo and Pro Medicus rose two percent or more; Amplia, Avita, Genetic Signatures, Immutep, Mesoblast, SDI and Telix were up more than one percent; with Clinuvel, Cyclopharm, Orthocell and Resmed up by less than one percent.

Medadvisor led the falls, down two cents or 6.8 percent to 27.5 cents, with 974,772 shares traded. Neuren lost 5.3 percent; Dimerix and Emvision fell more than four percent; Actinogen and Percheron were down more than three percent; Cynata and Micro-X shed more than two percent; EBR, Medical Developments and Nova Eye were down one percent or more; with CSL, Opthea and Nanosonics down by less than one percent.

TELIX PHARMACEUTICALS

Telix says it will pay up-to EUR162 million (\$264 million) for a fibroblast activation protein (FAP)-targeting radio-pharmaceutical, initially for bladder cancer.

Telix said fibroblast activation protein was “one of the most promising pan-cancer targets in nuclear medicine” found in epithelial cancers, sarcomas and mesotheliomas, which would be developed for the treatment of bladder cancer.

The company said the FAP-targeting therapeutic and diagnostic radio-pharmaceutical candidates were developed by Prof Frank Roesch and others at the Mainz, Germany-based Johannes Gutenberg University.

Telix said Prof Roesch’s FAP-targeting radio-pharmaceuticals were “differentiated by a novel structure that drives extended tumor retention while minimizing off-target uptake, potentially overcoming the limitations seen with first generation compounds” and had been validated in more than 500 patients in a variety of solid tumors.

The company said it had signed an exclusive licence agreement to acquire the FAP assets, which were the joint intellectual property of Prof Roesch’s Berlin-based company SCV GmbH, and the Hamburg-based Medianeza GmbH.

Telix said it would pay EUR7,000,000 in cash, including EUR700,000 paid at or prior to the signing of the agreements, and a further EUR3,000,000 in 12 months, subject to any potential indemnity setoff.

The company said it would pay a further up-to EUR132 million, subject to achieving certain clinical development and regulatory milestones related to the FAP diagnostic and therapeutic products, and a further EUR20 million on achievement of certain commercial milestones as well as royalties; and subject to conditions including German approval.

Telix Therapeutics chief executive officer Richard Valeix said the company would “gain access to assets that are already significantly de-risked, with clinically demonstrated safety profile and efficacy,” Mr Valeix said.

“We will develop these assets in bladder cancer as a primary indication, in line with our focus on urological cancers, and explore the potential of FAP as a pan-cancer target, adding significant value to our pipeline,” Mr Valeix said.

Telix was up 24 cents or 1.05 percent to \$23.02 with 1.6 million shares traded.

RESONANCE HEALTH

Resonance says it has a \$13,775,000 agreement to provide clinical trials services to the Mumbai, India-based Sun Pharmaceutical Industries.

Resonance said that under the 24-month agreement it would be the Australian trial sponsor and provide clinical research organization services, trial site services and imaging analysis services the trial of a drug compound in Australia.

The company said it would receive first payment of \$2,066,000 within 30 days of signing the agreement, with its subsidiary CRO Services Pty Ltd to engage and make payments to the institutions, trial sites and vendors needed for the trial.

Resonance said the remaining payments were subject to, among other things, receipt of regulatory approvals to commence the trial including ethics approval.

The company said it would provide imaging analysis services through its recently acquired subsidiary Trialswest, with patient recruitment expected to begin “in early 2025, subject to receipt of regulatory approvals”.

Resonance chief executive officer Andrew Harrison said the agreement was “a direct result of the incredible work the team have done in executing the existing clinical trial with the customer”.

Resonance was up 2.1 cents or 55.3 percent to 5.9 cents with 5.5 million shares traded.

RHYTHM BIOSCIENCES

Rhythm says it has “commitments” to raise \$3.5 million at 10 cents a share in a placement, with investors to receive two options for every three shares purchased. Rhythm said the issue price was a 19.5 percent discount to the five-day volume weighted average price of 12.4 cents a share.

Rhythm said the options, subject to shareholder approval, would be exercisable at 20 cents each by March 31, 2026.

The company said the funds raised would be used for its Colostat multiplex test kit, continued research and development in other cancers and working capital.

Rhythm said PAC Partners and CPS Capital were joint lead managers.

Rhythm was up half a cent or 4.35 percent to 12 cents with 1.4 million shares traded.

CENTENARY INSTITUTE

Sydney’s Centenary Institute says two of its cancer research projects have received \$150,000 each in RT Hall Trust funding.

The Centenary Institute said one project would try to improve the safety and effectiveness of chimeric antigen receptor (Car)-T cell therapy in pancreatic cancer “by studying the molecular interactions between Car-T cells, cancer cells and the tumor micro-environment”.

The Institute said a second project was advancing research on liquid biopsies, a non-invasive blood test used for monitoring cancer.

The Centenary said the second project’s goal was to develop a test capable of detecting and analyzing rare cancer cells known as 'circulating tumor cells' in the blood of cancer patients to aid early cancer detection, predict cancer progression and anticipate relapse. The Institute said the research would include pancreatic, appendiceal, colorectal, mesothelioma and small cell lung cancers.

The Centenary Institute said the projects were led by the head of its Centre for Cancer Innovations, Dr Dannel Yeo.

Dr Yeo said This funding presents a remarkable chance for us to drive innovation and translation in cancer treatment and diagnostics, ultimately leading to improved patient outcomes,” said Dr Yeo.

4D MEDICAL

4D Medical says it has a three-year contract to supply its computed tomography-based lung imaging products to the University of California San Diego.

4D Medical said the agreement was “a significant achievement for the company, offering compelling validation of the diagnostic capabilities and clinical relevance of tis advanced lung imaging technology”.

The company said the terms of the contract were “commercial-in-confidence” but that the University would have access to its computed tomography-based products, with potential to expand into the rest of its portfolio.

4D Medical managing-director Prof Andreas Fouras said the agreement with the University of California San Diego underscored “the growing recognition of 4DMedical’s innovative technology in transforming respiratory care”.

“Not only are they a great customer for us, but their status as one of the best respiratory hospitals in the country will undoubtedly boost our commercialization efforts with the broader US healthcare system,” Prof Fouras said.

4D Medical was up three cents or 6.25 percent to 51 cents with 2.2 million shares traded.

UNIVERSAL BIOSENSORS

Universal Biosensors says Nashville, Tennessee's National Distribution & Contracting, Inc will distribute its Xprecia Prime blood coagulation test in the US.

Earlier this year, Universal Biosensors said it had US Food and Drug Administration 510(k) approval for Xprecia Prime (BD: Mar 19, 2024).

Earlier this month, the company said New York's Henry Schein would distribute and sell Xprecia Prime devices and test strips in the US (BD: Nov 8, 2024).

Today, Universal Biosensors said it sold its first Xprecia Prime product to National Distribution & Contracting as part of the deal.

The company said National Distribution & Contracting was "a healthcare supply chain solution, serving as one of the US's largest and most successful distributors of medical products representing over 1,900 distribution partners [in its] ... network".

Universal Biosensors said the two-year deal was non-exclusive with automatic one-year extensions unless otherwise terminated by either party.

Universal Biosensors chief executive officer John Sharman said the company had "been negotiating with [National Distribution & Contracting] for several months and we view [it as] a key partner for us in the US".

"[National Distribution & Contracting] undertook a comprehensive product review before agreeing to partner Xprecia Prime and will provide [the company] with direct access to thousands of coagulation clinics and hospitals throughout the US which can now access Xprecia Prime through the [National Distribution & Contracting] network." Mr Sharman said.

Universal Biosensors was up half a cent or 4.2 percent to 12.5 cents.

QBIOTICS

Qbiotics says its 11-patient, phase IIa trial of tigilanol tiglate for soft tissue sarcoma shows it exceeded "the primary endpoint for a promising response".

Earlier this year, Qbiotics said preliminary data from its 11-patient, open-label, single-arm trial of intra-tumoral tigilanol tiglate for soft tissue sarcoma showed the treatment was safe, with "early indications of efficacy" (BD: Sep 17, 2024).

Today, the company said further data presented in a poster included "additional observations made by the investigators outside of the clinical study showing that patients with metastatic [soft tissue sarcoma] ... who were originally non-responsive to systemic therapy responded to systemic therapy after [tigilanol tiglate] was used as the primary treatment of their primary tumor".

The poster said the trial showed that "efficacy was observed across numerous [soft tissue sarcoma] histologic types, exceeding the primary endpoint for a promising response".

The results concluded that "the tolerability and activity warrant further investigation" of tigilanol tiglate for soft tissue sarcoma either alone or in combination with other agents.

Qbiotics said the poster, titled 'A Pilot Phase II Study to Evaluate the Small Molecule Tigilanol Tiglate in Patients with Advanced Soft Tissue Sarcoma' was presented at the European Society for Medical Oncology meeting in Barcelona, September 13 to 17, 2024.

Qbiotics managing-director Stephen Doyle said the data supported the company's "hypothesis on possible mechanisms-of-action for tigilanol tiglate".

"The idea of introducing a novel therapeutic that activates the immune system to enhance the efficacy of standard treatments is highly compelling," Mr Doyle said.

"In our trial extension, we'll be closely monitoring for additional indications that the drug is functioning in this way," Mr Doyle said.

Qbiotics is a public unlisted company.

RADIOPHARM THERANOSTICS

Radiopharm says it has approval to enrol lung, breast, melanoma, head and neck and endometrial cancer patients in its about 23-patient, phase I trial of RAD204.

Earlier this year, Radiopharm said it had dosed the first of up-to 21 patients in its phase I, dose-escalation, study of RAD204 for lung cancer (BD: Jul 10, 2024).

Today, the company said it had ethics approval to include an additional five programmed death-ligand 1-expressing solid tumors beyond non-small cell lung cancer.

Radiopharm said these indications included small cell lung cancer, triple negative breast cancer, melanoma, head and neck cancer and endometrial cancer.

Radiopharm was up 0.1 cents or 3.85 percent to 2.7 cents with 10.8 million shares traded.

BLINKLAB

Blinklab says a 441-child study shows its smartphone platform “effectively identifies ... children with autism” with 91 percent sensitivity and 85 percent specificity.

Blinklab said the multi-centre study was conducted in 285 children diagnosed with autism and 156 children without autism aged four-to-12 years old in collaboration with Chicago’ Turning Pointe Autism Foundation, New Jersey’s Princeton University and Rabat, Morocco’s National Center for the Disabled.

Blinklab said the study showed “the potential of non-invasive digital biomarkers as a diagnostic aid for autism”.

The company said the study analyzed spontaneous and stimulus-evoked responses along with pre-pulse inhibition and startle habituation performance and its “machine learning algorithms achieved a sensitivity of 91 percent and specificity of 85 percent ... [with] robust and consistent performance across gender and age groups”.

Blinklab chair Brian Leedman said the results confirmed “the accuracy of our ... test for autism” and provided confidence for a forthcoming US Food and Drug administration trial.

Blinklab was up five cents or 19.2 percent to 31 cents with 2.4 million shares traded.

CURVEBEAM A.I.

Curvebeam says it has filed six patient datasets comparing its Hirise imaging device with standard computed tomography (CT) to validate with a robotic surgical system.

Curvebeam said as part of a validation of its Hirise weight bearing CT device for an unnamed “major robotic surgical system”, a vendor had requested 10 matched patient datasets pairing images on the Hirise and conventional CT.

The company said it was “delighted image quality to date and continues to receive positive feedback”, with the final four matched patient datasets scheduled to be collected by November 22, 2024 and then shared with the vendor for processing; and it expected to submit all requested documentation to the vendor for validation “by early December”.

The company said it believed the “submission should satisfy all requirements to complete the validation process and will update the market on the ongoing progress, including submission lodgment and the vendor’s response once received”.

Curvebeam managing-director Greg Brown said that “to be able to generate images at par with conventional CT on the enhanced Hirise is a fantastic outcome and I congratulate our [research and development] team on delivering this major achievement”.

“We are very close to completing the robotic system validation for the Hirise, and post-meeting this major milestone, we remain confident in the potential impact this will have on 2024-'25 Hirise placements,” Mr Brown said.

Curvebeam was up one cent or 10 percent to 11 cents.

ISLAND PHARMACEUTICALS

Island says 92.2 percent of its annual general meeting voted a remuneration report second strike with the conditional board spill approved by 98.43 percent of the meeting. Last year, Island said its annual general meeting defeated the remuneration report with a 90.41 percent vote against the report (BD: Nov 16, 2023).

Last month, the company said shareholders would vote to issue its chief executive officer, chair and non-executive directors 9,550,000 options, and vote on a potential spill resolution (BD: Oct 18, 2024).

Today, Island said that the remuneration report was opposed by 48,363,567 votes (92.22%) with 4,080,184 votes (7.78%) in support.

The company said the conditional board spill was passed with 51,547,849 votes (98.43%) in favor, with 820,902 votes (1.57%) opposition.

Last week, Island said that founding executive chair Dr Paul MacLeman and non-executive director Dr Anna Lavelle would resign at its annual general meeting on November 19, 2024 (BD: Nov 11, 2024).

On Friday, the company said it had appointed Phillip Lynch as its executive chair, effective from its annual general meeting (BD: Nov 15, 2024).

Today, Island published the proxy votes received for the resolutions to re-elect Dr MacLeman and issue options to Dr MacLeman and Dr Lavelle, with Dr MacLeman's options opposed by 95.48 percent of the proxy vote, with 4.52 percent in favor.

Shortly before the market closed, Island re-issued the meeting results and said that the resolutions relating to Dr MacLeman and Dr Lavelle "incorrectly showed incomplete proxy votes on resolutions that were withdrawn" with the revised votes showing the resolutions removed with no votes included.

The company said the resolutions to issue shares and options under a capital raising were opposed by between 3.42 percent and 37.51 percent of the meeting, with the approval of the increased placement capacity opposed by 17.56 percent.

Island said the issue of options to Chris Ntoumenopoulos was opposed by 5.17 percent, with the election of Mr Ntoumenopoulos as a director, the issue of options to managing director Dr David Foster and the issue of broker options passing easily.

According to its most recent filing, Island had 155,910,709 shares on issue, meaning that the 51,547,849 votes for the board spill amounted to about 33.1 percent of the company, more than sufficient to requisition extraordinary general meetings.

Island was up 1.5 cents or 9.1 percent to 18 cents.

CANN GROUP

Cann says it has packed 25,000 units of 10g, 15g or 28g of marijuana using its multi-head packaging filler.

Cann said 17,500 of the units packed by the multi-head filler were for external customers, with the remaining 30 percent for its Botanitech range.

The company said the installation and operation of its multi-head filler was "one of numerous efficiency activities undertaken by Cann over the past eight months".

Cann said the filler was capable of 9,000 units per shift and reduced operational costs by lowering the labor costs to filling by about 90 percent.

Cann managing-director Jenni Pilcher said that the implementation of the multi-head filler was "another key milestone in our plans to accelerate revenue growth and reduce overheads".

"Also, we can better support our customers by reducing our turn-around times," she said.

Cann was up 0.2 cents or 4.35 percent to 4.8 cents.

TRYPTAMINE THERAPEUTICS

Tryptamine says its 11-participant, phase Ib study of intra-venous TRP-8803 psilocybin has confirmed the required dose for a phase II trial, but did not state the specific dose. Last month, Tryptamine said that the 11-healthy volunteer, phase Ib trial showed TRP-8803 was “generally safe and well-tolerated” (BD: Oct 18, 2024).

Today, the company said the optimal doses and infusion rates of psilocin were achieved and target psilocin blood levels were found, with greater control of psilocin blood levels compared to oral psilocybin formulations.

Tryptamine said the data optimized dosing for the desired pharmaco-kinetics for a future phase II trial using TRP-8803, and that all trial participants achieved rapid onset of the psychedelic state, compared to one or two hours with oral psilocybin.

The company said the rapid reversibility of TRP-8803 was shown when “one subject encountered an elevated heart rate outside of study criteria ... the [intra-venous] infusion was able to be quickly halted which resulted in the subject’s heart rate returning to normal”.

Tryptamine said planning for additional clinical trials using TRP-8803 for specific indications was underway with a further phase Ib study in an obese subject population was set to begin this week with the results designed to confirm TRP-8803’s safety in obese patients as a treatment for binge eating disorder.

Tryptamine chief executive officer Jason Carroll said the results “exceeded all expectations and allows the company to advance its clinical trial pipeline immediately”.

“We are very pleased to have achieved all of the key objectives from the phase Ib, including safety and optimized blood psilocin levels, all of which further highlight the potential of the treatment to achieve improved health outcomes at scale,” Mr Carroll said. Tryptamine was up 0.1 cents or 2.1 percent to 4.8 cents with 4.2 million shares traded.

IMMUTEP

Regal Funds Management Pty Ltd says it has increased its substantial shareholding in Immutep from 153,864,135 shares (10.59%) to 171,522,666 shares (11.79%).

The Sydney-based Regal said that it bought shares between October 1 and November 14, 2024, with the single largest purchase 6,000,000 shares on November 14 for \$2,019,600, or 33.66 cents a share.

Immutep was up half a cent or 1.6 percent to 32 cents with 6.9 million shares traded.

QBIOTICS

Qbiotics says non-executive directors Prof Bruce Robinson and Andrew Denver “will retire from the board” following its annual general meeting on November 22, 2024.

Earlier this year, Qbiotics said it had appointed Mark Fladrich and David Phillips as non-executive directors (BD: May 20, 2024).

Today, Qbiotics chair Mark Fladrich said Mr Denver and Prof Robinson had “served on the Qbiotics board in a variety of roles since 2016” and extended “gratitude and our thanks to Prof Robinson and Mr Denver for their contributions, commitment and service”.

MICRO-X

In an Appendix 3Z, Micro-X says non-executive director Dr Alexander Gosling has resigned, effective from November 12, 2024.

Micro-X fell 0.2 cents or 2.9 percent to 6.7 cents.

ALTERITY THERAPEUTICS

Alterity says it has appointed chief financial officer Abby Macnish Niven as its company secretary, replacing Phillip Hains from November 18, 2024.

In September, Alterity said Ms Macnish Niven would replace chief financial officer Mr Hains, with Mr Hains to remain as its company secretary (BD: Sep 30, 2024).

Alterity was unchanged at 0.3 cents with 6.4 million shares traded.

BIO-MELBOURNE NETWORK

The Bio-Melbourne Network says with the Victorian Government it will conduct a one-year project to develop a digital health sciences workforce resources portal.

The Bio-Melbourne Network said with contributions from its members it would “map Victorian medical research careers, including what skills, qualifications and experience are really needed when applying for roles”.

The Network said it would publish the ‘career maps’ on its portal, which would show the career opportunities available in the life sciences sector, including “direct research roles, supporting roles such as clinical trials or lab technicians, and professional roles such as intellectual property and regulatory affairs specialists”.

The Bio-Melbourne Network said the portal would include an “online community to support engagement, jobs and opportunities boards, and mentoring between members of the ecosystem”.

Deputy Premier of Victoria and Minister for Education and Medical Research Ben Carroll said the state was “a world leader in medical research because of our dedicated and talented workforce”.

“The Victorian Government is proud to support the Bio-Melbourne Network to deliver resources so more young people can think about a career in medical research, and to support the current workforce to understand career opportunities and pathways,” Mr Carroll said.

"A spokesperson for the industry-organization said that the Government support included 'financial support', but did not disclose the amount."