



Biotech Daily

Monday November 18, 2024

Daily news on ASX-listed biotechnology companies

- * **ASX UP, BIOTECH DOWN: ACTINOGEN UP 13%; CURVEBEAM DOWN 17%**
- * **QUEENSLAND UNI DEVELOPS ORAL OXYTOCIN FOR STOMACH PAIN**
- * **RADIOPHARM RAD-301 'SAFE FOR IMAGING PANCREATIC CANCER'**
- * **CLINUVEL SUSPENDS STROKE, PARKINSON'S, XP PROGRAMS**
- * **ANATARA INCREASES PLACEMENT UP-TO \$750k**
- * **ECHO IQ: ECHOSOLV IN 5 U.S. HOSPITALS**
- * **ONCOSIL APPOINTS NORDIC, EGYPT DISTRIBUTORS**
- * **OPTISCAN SIGNS MINNESOTA UNI FOR ANIMAL CANCER RESEARCH**
- * **CLARITY, ST VINCENT'S CU-64 SAR-BIS-PSMA IMAGING TRIAL**
- * **ISLAND COLLECTS PHASE IIa ISLA-101 DENGUE TRIAL SAMPLES**
- * **MICROBA RECEIVES \$6m FEDERAL R&D TAX INCENTIVE**
- * **RESONANCE REQUESTS 'TRIAL SERVICES' TRADING HALT**
- * **BLINKLAB REQUESTS 'STUDY RESULTS' TRADING HALT**
- * **IMMURON AGM 23% OPPOSE DIRECTOR OPTIONS**
- * **MESOBLAST AGM 14% OPPOSE BOARD OPTIONS**
- * **AUSTRALIAN ETHICAL TAKES 14.5% OF MACH7**
- * **PLATINUM INCREASES, DILUTED TO 9.6% OF PERCHERON**
- * **MICHELLE BURKE, IAIN ROSS REPLACE ADALTA'S DR ROBERT PEACH**
- * **MESOBLAST LOSES DIRECTOR JOSEPH SWEDISH**
- * **VAXXAS CEO DAVID HOEY WINS AMCHAM GONG**

MARKET REPORT

The Australian stock market was up 0.18 percent on Monday November 18, 2024, with the ASX200 up 15.0 points to 8,300.2 points. Ten of the Biotech Daily Top 40 companies were up, 21 fell, seven traded unchanged and two were untraded.

Actinogen was the best, up 0.3 cents or 13.0 percent to 2.6 cents, with 25.9 million shares traded. Starpharma climbed 4.8 percent; Clinuvel, Genetic Signatures, Percheron and Prescient rose more than two percent; Cyclopharm, Nanosonics and Resmed were up more than one percent; with Mesoblast and Orthocell up by less than one percent.

Friday's best, Curvebeam, led the falls, down two cents or 16.7 percent to 10 cents, with 157,094 shares traded.

Clarity fell 15.4 percent; Cynata lost 8.2 percent; Neuren was down 6.5 percent; Amplia, Atomo, Dimerix, Immutep, Paradigm, SDI and Syntara fell four percent or more; Medical Developments was down 3.4 percent; Avita shed 2.9 percent; 4D Medical, Compumedics, CSL, Medadvisor, Nova Eye and Polynovo were down one percent or more; with Cochlear, Emvision, Opthea, Pro Medicus and Telix down by less than one percent.

UNIVERSITY OF QUEENSLAND

The University of Queensland says it has developed an oxytocin-based oral painkiller to suppress chronic abdominal pain.

The University of Queensland said that oxytocin was a peptide hormone produced in the brain and known as the 'bonding hormone' or the 'love molecule' due to its effects on relationship building, empathy and trust as well as the key hormone that induces uterine contractions during labor and facilitates milk release during breast-feeding.

The University said its researchers had "changed the chemical structure of oxytocin to make it gut-stable after earlier work revealed the hormone could treat abdominal pain".

The University of Queensland said that the developed oxytocin molecules worked "in the colon and do not need to cross the gut barrier into the bloodstream to suppress abdominal pain ... [and there was] "an urgent need for new treatments for the chronic pain caused by gastrointestinal disorders such as irritable bowel syndrome and irritable bowel diseases".

The University said the research by its Institute for Molecular Biosciences' Prof Markus Muttenthaler, was titled 'Oxytocin Analogues for the Oral Treatment of Abdominal Pain' published in Angewandte Chemie and available at: <https://bit.ly/3ZdGPrv>.

Dr Muttenthaler said chronic abdominal pain affected "up-to 15 percent of adults in their lifetime, and all we have are anti-inflammatories and opioids which can cause side effects and addiction".

"Our research focuses on peptides that are highly potent and selective molecules and have few side effects," Dr Muttenthaler said. "However, nearly all peptide drugs must be injected as they are rapidly digested in the gut."

"We have now developed a way of making peptides gut-stable so they can be given orally," Dr Muttenthaler said. "This is an exciting new mode of action to prevent pain."

"We are currently looking for investors to accelerate pre-clinical studies, with the goal of taking it into the clinic," Dr Muttenthaler said.

"Now that we have perfected making peptides stable, we are looking at other gut drugs to improve treatment options for gastrointestinal disorders, an unmet medical need," Dr Muttenthaler said.

RADIOPHARM THERANOSTICS

Radiopharm says a retrospective, 44-patient study of its gallium-68-labelled RAD-301 (gallium-68-trivehexin) shows it is “safe and suitable” for imaging in pancreatic cancer. Radiopharm said “the primary tumor, as well as metastases in the liver, lymph nodes, peritoneum, lung, bone, spleen, pleural cavity, and soft tissues, were visualized with a high tumor-to-background ratio”.

The company said no adverse events were recorded and that the findings showed that RAD-301 was a suitable and safe diagnostic agent for imaging ‘ $\alpha\beta6$ -integrin’ or alpha-v-beta-6-integrin expression in pancreatic cancer.

Radiopharm said RAD-301 was “a peptide that targets ‘ $\alpha\beta6$ -integrin’, a cellular marker for tumor invasion and metastatic growth, the expression of which correlates with decreased survival in several carcinomas, particularly pancreatic”.

The company said the ‘ $\alpha\beta6$ -integrin’ receptor was “found in high density on most pancreatic carcinoma and head and neck squamous carcinoma cells, making it an attractive potential diagnostic and therapeutic target in pancreatic ductal adenocarcinoma (PDAC) and head-and-neck squamous cell carcinoma”.

The study, titled ‘ $\alpha\beta6$ -integrin targeted PET/CT imaging in pancreatic cancer patients using 68Ga-Trivehexin’ was published in *Frontiers in Nuclear Medicine*, with the full article available at: <https://bit.ly/4exzv3>.

Radiopharm managing-director Riccardo Canevari said that the “current imaging standards-of-care for the detection of PDAC have significant limitations, making this one of the highest areas of unmet medical need and posing a major challenge for healthcare providers in imaging PDAC patients”.

“These findings reinforce the clinical potential of RAD-301 as an imaging agent for the more sensitive and selective detection of pancreatic cancer and its metastases, ultimately advancing PDAC patient management,” Mr Canevari said.

Radiopharm was up 0.1 cents or four percent to 2.6 cents with 4.7 million shares traded.

CLINUVEL PHARMACEUTICALS

Clinuvel says it has “temporarily suspended” its stroke, Parkinson’s disease and xeroderma pigmentosum (XP) clinical programs, “streamlining the current operations”.

Clinuvel said it would prioritize “its resources towards three key areas of clinical development” including vitiligo and adreno-cortico-tropic hormone as well as erythropoietic protoporphyria and variegate porphyria; and continue “photo-cosmetic” development.

The company said the decision was based on “new clinical guidelines in [central nervous system] disorders, chances of reimbursement and the need to use internal resources more efficiently”.

Clinuvel said that it had determined that a consolidation of its activities would lead to more research, development and innovation catalysts “which public markets will find easier to follow with progression along valuable milestones”.

The company said along with its three clinical programs its photo-cosmetic product development continued and it was preparing to commercialize three product lines.

Clinuvel said its existing team was “being redeployed to maximize efficiency”.

Clinuvel chair Dr Jeffrey Rosenfeld said the board with its recently appointed members had “deliberated extensively as to the short- and long-term objectives of the company”.

“By providing clear priorities we can accelerate development and generation of meaningful milestone news for public investors,” Dr Rosenfeld said. “Today’s decision is the first of a number of far-reaching changes that we invoke.”

Clinuvel was up 29 cents or 2.2 percent to \$13.57 with 121,013 shares traded.

ANATARA LIFE SCIENCES

Anatara says it has increased its placement at five cents a share by \$90,000, from \$660,000 to \$750,000.

Last week, Anatara said it had “firm commitments” to raise \$660,000 at five cents a share, a 10 percent discount to the 30-day volume weighted average price, in a placement, with a share purchase plan for up-to \$500,000 to follow (BD: Nov 15, 2024).

Today, the company said the shares would be issued using its 15 percent placement capacity and that the details of its share purchase plan and the use of the funds raised remained unchanged.

Anatara was untraded at 5.8 cents.

ECHO IQ

Echo IQ says five US hospitals will use its artificial intelligence-based Echosolv decision support software for assessing aortic stenosis with echo-cardio-graphy.

Last month, Echo IQ said it had US Food and Drug Administration 510(k) clearance to market and sell Echosolv for detecting aortic stenosis (BD: Oct 8, 2024).

Today, the company said that the Boston, Massachusetts’ Beth Israel Deaconess Medical Center would integrate its Echosolv software following a 31,000-patient, historical study of the software conducted by the Harvard Medical School health facility.

Echo IQ said Beth Israel would use Echosolv on a no-cost basis while it pursued the relevant reimbursement codes for users of the technology under insurance.

The company said reimbursement codes were expected “to be secured in the coming quarters, marking an important commercial milestone which when achieved will allow for first revenues to be recognized”.

Echo IQ said four additional, unnamed hospitals located in New York, Alabama, Dallas and Oklahoma would integrate Echosolv as part of their existing use of Core Sound Imaging’s Studycast.

Last year, Echo IQ said it had an agreement with the Raleigh, North Carolina-based Core Sound Imaging to integrate its Echosolv aortic stenosis diagnostic system with Studycast, a picture archiving and communication system used in 49 US states and territories and seven countries (BD: Jun 13, 2023).

Today, the company said the partnerships marked “the commencement of a broader roll-out across the US through integration partners”.

Echo IQ did not disclose the commercial terms of the agreements.

The company said it would begin “a medical device pilot trial of Echosolv this year which will be rolled out as a quality assurance and patient recall program to highlight at-risk patients for further review across Australia and New Zealand”.

Echo IQ chief executive officer Dustin Haines said that securing Beth Israel as a “flagship deployment hospital in the US marks an early vote of confidence in the company’s Echosolv-[aortic stenosis] technology”.

“Furthermore, it follows an independent trial undertaken by [Beth Israel] researchers which validated the key performance metrics and accuracy of Echosolv across the hospital’s extensive historical patient population,” Mr Haines said.

“We look forward to providing further updates as this integration and others progress over the coming months,” Mr Haines said.

Echo IQ was up two cents or 8.9 percent to 24.5 cents with 7.4 million shares traded.

ONCOSIL MEDICAL

Oncosil says the Cardirad and Femto Trade will distribute its pancreatic cancer device in the Nordic region and Egypt, respectively.

Oncosil said the Lohja, Finland-based Cardirad was “a prominent distributor of innovative medical technologies in the Nordics, renowned for its strong expertise and extensive network in the fields of oncology and nuclear medicine” and would distribute its technology in Sweden, Denmark, Norway, and Finland, “further enhancing cancer treatment capabilities in the region”.

The company said the Giza, Egypt-based Femto Trade specialized in nuclear medicine and interventional oncology.

Oncosil did not disclose the commercial terms of the partnerships.

Oncosil fell 0.1 cents or 12.5 percent to 0.7 cents with 14.9 million shares traded.

OPTISCAN

Optiscan says it has a research agreement with the University of Minnesota College of Veterinary Medicine to research its endo-microscope for cancer detection in animals.

In August, Optiscan said it had a memorandum of understanding with the Minneapolis-based College for its endo-microscopic for cancer in animals (BD: Aug 19, 2024).

Today, the company said it had a five-year agreement to use the University’s research facilities to study clinical applications of its technology in veterinary medicine, with an initial focus on companion animals.

Optiscan fell 0.25 cents or 1.5 percent to 16.75 cents.

CLARITY PHARMACEUTICALS

Clarity says Sydney’s St Vincent’s Hospital will conduct an investigator-led, 50-patient, phase II trial of its copper-64 Sar-Bis-PSMA for imaging prostate cancer recurrence.

Clarity said the trial would evaluate copper-64 Sar-Bis-prostate specific membrane antigen (PSMA) compared to standard-of-care gallium-68 PSMA-11 for detecting prostate cancer recurrence.

The company said the primary objective of the study was to compare the detection rate of sites of prostate cancer recurrence as determined by the number of lesions per patient, between copper-64 Sar-Bis-PSMA and gallium-68 PSMA-11 with positron emission tomography (PET) and/or computed tomography (CT).

Clarity chair Dr Alan Taylor said “the head-to-head comparison between copper-64 Sar-Bis-PSMA and gallium-68 PSMA-11 PET presents a significant opportunity to continue demonstrating the superior diagnostic capabilities of our proprietary copper-based and Bis-PSMA platforms”.

“Copper-64 Sar-Bis-PSMA’s excellent performance has already been demonstrated in the ‘Cobra’ trial, where we were able to image lesions more than six months prior to other standard-of-care imaging, identifying lesions with a diameter smaller than two millimetres,” Dr Taylor said.

Earlier this year, Clarity said its phase I/II trial showed copper-64 Sar-Bis-PSMA was safe and well-tolerated and could detect “much smaller lesions than anticipated” including a lesion with a less than 2.0mm diameter (BD: Feb 15, Mar 6, 2024).

“We know very well that early detection of cancer provides the best opportunities for better treatments, and this capability, coupled with the extended imaging window and logistical advantages, make it an ideal candidate to revolutionize care in these patients,” he said.

Clarity fell \$1.10 or 15.4 percent to \$6.04 with 2.4 million shares traded.

ISLAND PHARMACEUTICALS

Island says it has collected blood samples from the four participants in the preventative component of its 14-patient, phase IIa/b trial of ISLA-101 for dengue fever.

Last month, Island said it had dosed the four, phase IIa volunteers in the preventative arm of its 14-patient, phase IIa/b trial of ISLA-101 for dengue fever (BD: Oct 3, 2024).

Today, the company said the samples would be analyzed to determine how viral load levels in the blood of trial subjects infected with a weakened dengue virus had changed through the study.

Island said other samples were being analyzed for pharmaco-kinetic data as well as other blood analyses.

The company said the data was being consolidated for review by the safety review committee who would meet in the coming weeks, and that following analysis the committee would make a recommendation about whether to advance the trial to the 10-patient, treatment cohort "before the end of the calendar year".

Island managing-director Dr David Foster said the company was "very pleased to be able to report that 46 days into the trial, we've collected the key data required for evaluation by the safety review committee".

"From here, while we will continue to check in with patients up-to 90 days post-dosing, we look forward to providing all the data to the [safety review committee] for evaluation in the coming weeks," Dr Foster said.

"Importantly, this means we remain on track to report data before the end of the year from our phase IIa component, and next steps for the phase IIb cohort before the end of the year," Dr Foster said.

Island fell one cent or 5.7 percent to 16.5 cents.

MICROBA LIFE SCIENCES

Microba says it has received \$6,019,829 from the Australian Taxation Office under the Federal Government's Research and Development Tax Incentive program.

Microba said the incentive related to research and development for the year to June 30, 2024.

The company said it had four separate advanced overseas findings from Ausindustry, which pre-approved eligible overseas research and development expenditure for each year from June 30, 2023 to June 30, 2026.

Microba was untraded at 16.5 cents.

RESONANCE HEALTH

Resonance has requested a trading halt pending the announcement of a contract "for the provision of [clinical trial] services ... [to] a major pharmaceutical company".

Trading will resume on November 20, 2024, or on an earlier announcement.

Resonance last traded at 3.8 cents.

BLINKLAB

Blinklab has requested a trading halt "pending an announcement in relation to autism study results".

Trading will resume on November 20, 2024, or on an earlier announcement.

Blinklab last traded at 26.0 cents.

IMMURON

Immuron says its annual general meeting passed all resolutions but with up-to 22.96 percent against the issue of director options and the placement capacity.

Last month, Immuron said investors would vote to issue directors Prof Ravi Savarirayan, Dr Jeannette Joughin and Daniel Pollock 1,000,000 options, each (BD: Oct 18, 2024).

Today, the company said Mr Pollock's options were opposed by 8,535,037 votes (22.96%), with 28,639,332 votes (77.04%) in support, with Prof Savarirayan's options opposed by 19.30 percent and Dr Joughin's options by 10.36 percent.

Immuron said the special resolution to approve the increased placement capacity, was opposed by 7,679,102 votes (19.41%), with 31,882,051 votes (80.59%) in favor.

The company said the re-election of director Mr Pollock was opposed by 15.70 percent of the meeting, with Dr Joughin's election and the remuneration report passing more easily.

According to its most recent notice, Immuron had 229,145,429 shares on issue, meaning that the 8,535,037 votes against Mr Pollock's options amounted to about 3.7 percent of the company, not sufficient to requisition extraordinary general meetings.

Immuron was up 0.4 cents or 5.3 percent to 7.9 cents.

MESOBLAST

Mesoblast says investors passed all resolutions with up-to 13.6 percent opposition to options for chief executive officer Prof Silviu Itescu and director Dr Eric Rose.

Last month, Mesoblast said its annual general meeting would vote to issue Prof Itescu 3,108,000 long-term incentive options for the year to June 30, 2025, as well as 1,010,000 options and 1,212,000 options as part of his short-term incentive for the years to June 30, 2023 and June 30, 2024 (BD: Oct 17, 2024).

At that time, the company said the meeting would vote to issue Dr Rose 946,000 long-term incentive options for the year to June 30, 2025, as well as 1,829,502 options as part of his short-term incentive for the two years to June 30, 2024 and 436,686 options in lieu of 30 percent of his annual pay.

Today, Mesoblast said Prof Itescu's short-term incentive options were opposed by 54,150,139 votes (13.59%), with 334,353,177 votes (86.41%) in support, with Dr Rose's short-term options opposed by 54,158,159 votes (13.57%).

The company said the remuneration report was opposed by 12.74 percent of the meeting with long-term options and options in lieu of Prof Itescu's and Dr Rose's salaries passed more easily, along with options to Dr Philip Krause as consultancy fees, the issue of options to directors and ratification of prior issue of securities.

The company said the remaining resolutions were passed more easily.

According to its most recent notice, Mesoblast had 1,141,784,114 shares on issue, meaning that the 54,158,159 votes against Dr Rose's options amounted to about 4.74 percent of the company, not sufficient to requisition extraordinary general meetings.

Mesoblast was up half a cent or 0.3 percent to \$1.575 with 4.7 million shares traded.

MACH7 TECHNOLOGIES

Australian Ethical says it has increased its substantial shareholding in Mach7 from 32,342,776 shares (13.41%) to 34,886,014 shares (14.46%).

The Sydney-based Australian Ethical said it bought shares between September 19 and November 14, 2024, with the single largest purchase 1,000,000 shares for \$530,875, or 53.1 cents a share.

Mach7 fell half a cent or 1.35 percent to 36.5 cents.

PERCHERON THERAPEUTICS

Platinum Investment Management Ltd says it has increased and been diluted in Percheron from 96,266,694 shares (10.68%) to 101,464,483 shares (9.57%).

The Sydney-based Platinum said that between September 17 and October 15, 2024 it sold 7,302,211 shares for \$832,384, or an average of 11.4 cents a share, and on October 21, 2024 bought 12,500,000 shares for \$1,000,000, or 8.0 cents a share.

Last month, Percheron said it raised \$13.0 million in an institutional placement at 8.0 cents a share, with an up-to \$2.0 million share plan to follow (BD: Oct 18, 2024).

Percheron was up 0.2 cents or 2.5 percent to 8.1 cents with 1.5 million shares traded.

ADALTA

Adalta says it has appointed Michell Burke and Iain Ross as non-executive directors, with eight-year director Dr Robert Peach to retire, effective from November 20, 2024.

Adalta said Ms Burke had worked for Bristol-Myers Squibb and the then Smith Kline Beecham, now Glaxosmithkline, and was a former chair and director of Ausbiotech and currently a non-executive director of Cell Therapies Pty Ltd and the Olivia Newton-John Cancer Research Institute.

The company said Mr Ross had worked for Sandoz, Hoffman La Roche, Reed Business Publishing and Celltech Group and was currently chair of Silence Therapeutics and Reneuron Group, a director of Tern plc and Fivephusion as well as an Adalta shareholder.

Adalta said Ms Burke and Mr Ross' appointments would be effective following its annual general meeting on Wednesday, with director Dr Peach to retire at the end of the meeting.

The company said Dr Peach's retirement came "as he continues to wind back his board portfolio to spend more time working in family businesses" and he remained an investor.

Adalta chair Dr Paul MacLeman thanked "Dr Peach for his extensive contribution to the company's scientific and product development over his eight years as a non-executive director. Everyone at Adalta wishes him every success in his future endeavors."

Adalta was up 0.15 cents or 8.6 percent to 1.9 cents.

MESOBLAST

In an Appendix 3Z, Mesoblast says former chair Joseph Swedish has resigned as a non-executive director on November 15, 2024.

In April, Mesoblast said that it had appointed director Jane Bell as non-executive chair, replacing Mr Swedish (BD: Apr 30, 2024).

VAXXAS PTY LTD

Vaxxas says its chief executive officer David Hoey has won the American Chamber of Commerce in Australia 'Amcham Alliance Award for Excellence in Biotechnology'.

Vaxxas said Mr Hoey's award was "for his contribution in shaping future economic collaboration between Australia and the US".

Mr Hoey said the company was "proud to be working closely with the US Government and the Coalition for Epidemic Preparedness Innovations as we aim to enable pandemic vaccines to be distributed more efficiently".

Vaxxas is a private company.