

Biotech Daily

Tuesday April 29, 2025

Daily news on ASX-listed biotechnology companies

- * ASX, BIOTECH UP: MEDICAL DEVELOPMENTS UP 31%;
 MICRO-X DOWN 10.5%
- * AROA RECEIPTS UP 18% TO \$72m
- * MEDICAL DEVELOPMENTS 9-MONTH RECEIPTS UP 11% TO \$30m
- * MACH7 9-MONTH RECEIPTS UP 12% TO \$27m
- * NOVA EYE \$19.5m 9-MONTH RECEIPTS
- * RESONANCE 9-MONTH RECEIPTS UP 159% TO \$11.2m
- * LUMOS 9-MONTH RECEIPTS DOWN 50% TO \$7.1m
- * RADIOPHARM \$4.5m 9-MONTH RECEIPTS FROM LANTHEUS DEAL
- * 4D MEDICAL 9-MONTH RECEIPTS UP 146% TO \$3.8m
- * AMPLIA: 11 PARTIAL RESPONSES IN 29 PANCREATIC CANCER PATIENTS
- * WEHI STARTS ORGANOID BOWEL CANCER TESTING TRIAL
- * QUEENSLAND UNI OPENS TYPE 1 DIABETES IMMUNO-THERAPY TRIAL
- * PACIFIC EDGE: US MEDICARE PRICES CXBLADDER TRIAGE AT \$1.6k
- * ORTHOCELL REQUESTS 'NEW REMPLIR APPROVAL' TRADING HALT
- * BLINKLAB REQUESTS 'CAPITAL RAISING' TRADING HALT
- * DIMERIX REQUESTS 'LICENCING AGREEMENT' TRADING HALT
- * MEDADVISOR TAKES 'CLEANSING NOTICE' HALT TO SUSPENSION
- * PYC CHAIR ALAN TRIBE, AUSTRALIAN LAND INCREASE, DILUTED TO 32%
- * ADVANCE TAKES 11% OF OSTEOPORE
- * TELIX LOSES 3-WEEK US DIRECTOR ANNE WHITAKER
- * MESOBLAST APPOINTS LYN COBLEY DIRECTOR

MARKET REPORT

The Australian stock market was up 0.92 percent on Tuesday April 29, 2025, with the ASX200 up 73.5 points to 8,070.6 points.

Twenty-two of the Biotech Daily Top 40 stocks were up, 10 fell, five traded unchanged and three were untraded.

Medical Developments was the best, up 14.5 cents or 31.2 percent to 61 cents, with 1.8 million shares traded.

Impedimed improved 16.7 percent; Resonance rose 14.3 percent; Nova Eye climbed 6.1 percent; 4D Medical and Neuren were up more than five percent; Alcidion, Aroa, Clarity, Clinuvel, Genetic Signatures, Nanosonics, Orthocell, Polynovo, SDI and Syntara were up more than four percent; Avita and Immutep improved three percent or more; Mesoblast and Pro Medicus rose more than two percent; Emvision and Telix were up one percent or more; with Cochlear, CSL and Cyclopharm up by less than one percent.

Micro-X led the falls, down 0.7 cents or 10.45 percent to six cents, with 293,604 shares traded. Curvebeam and Universal Biosensors lost five percent or more; Paradigm fell 4.8 percent; Actinogen and Imugene were down more than three percent; EBR shed 2.5 percent; Amplia, Compumedics and Proteomics were down more than one percent; with Resmed down by 0.5 percent.

AROA BIOSURGERY

Aroa says customer receipts for the year to March 31, 2025 were up 17.75 percent to \$NZ77,331,000 (\$A71,770,000), compared to the prior corresponding period. Aroa said receipts from sales of its Ovitex sheep fore-stomach-based bio-scaffold for hernia repair and its Myriad Matrix and Morcells products for soft tissue reconstruction and complex wounds for the three months to March 31, 2025 were up 12.1 percent to \$NZ20,127,000, compared to the previous corresponding period.

Aroa said that it had a positive cash flow of \$NZ1,060,000 for the three months, with cash and cash equivalents of \$NZ21,992,000 at March 31, 2025 compared to \$NZ29,522,000 at March 31, 2024.

Aroa was up two cents or 4.8 percent to 44 cents with 1.2 million shares traded.

MEDICAL DEVELOPMENTS INTERNATIONAL

Medical Developments says receipts from customers for the nine months to March 31, 2024 rose 11.1 percent to \$29,838,000, compared to the prior corresponding period. Medical Developments said receipts from sales of its Penthrox non-opioid pain management and respiratory products for the three months to March 31, 2025 were up 50.15 percent to \$10,619,000, compared to the prior corresponding period. The company said it had a positive cash flow of \$1,690,000 for the three months, with cash and cash equivalents of \$19,119,000 at March 31, 2025 compared to \$10,722,000 at March 31, 2024.

Medical Developments was up 14.5 cents or 31.2 percent to 61 cents with 1.8 million shares traded.

MACH7 TECHNOLOGIES

Mach7 says receipts from customers for the nine months to March 31, 2025 were up 12.1 percent to \$27,280,000, compared to the prior corresponding period.

Mach7 said receipts from licencing contracts for its Enterprise imaging product and diagnostic workflow applications were up 28.4 percent to \$11,361,000, compared to the previous corresponding period.

The company said it was \$2,598,000 cash flow positive for the three months, with cash and equivalents of \$24,859,000 at March 31, compared to \$24,801,000 the prior year. Mach7 fell one cent or three percent to 32 cents.

NOVA EYE MEDICAL

Nova Eye says receipts from customers for the nine months to March 31, 2025 were \$19,468,000 compared to \$23,325,000 in revenue for the year to June 30, 2024. Last year, Nova Eye did not lodge an Appendix 4C with the ASX for the nine months to March 31, 2024.

Today, the company said receipts from sales of its Itrack microcatheter for ocular drug delivery for the three months to March 31, 2025 were \$6,644,000.

Nova Eye said full year revenue was expected to be between \$27.5 million and \$29.1 million, excluding sales in China, with improved margins and sales expected to "drive a continued reduction in cash outflows, with steady progress toward breakeven".

The company said it had a cash burn of \$1,377,000 for the three months, with cash and equivalents of \$6,265,000 at March 31, 2025 compared to \$6,151,000 at June 30, 2024. Nova Eye was up 0.6 cents or 6.1 percent to 10.5 cents.

RESONANCE HEALTH

Resonance says receipts from customers for the nine months to March 31, 2025 were up 159.3 percent to \$11,243,000, compared to the previous corresponding period.

Resonance said receipts from its clinical trial services, imaging analysis services and clinical trial site services contracts were up 157.0 percent to \$2,955,000, compared to the prior corresponding period.

The company said it was \$77,000 cash flow positive for the three months, with cash and equivalents of \$3,196,000 at March 31, 2025 compared to \$5,324,000 at March 31, 2024. Resonance was up half a cent or 14.3 percent to four cents.

LUMOS DIAGNOSTICS

Lumos says customer receipts for the nine months to March 31, 2025 fell 50.1 percent to \$US4,548,000 (\$A7,075,000), compared to the prior corresponding period.

Lumos said receipts from sales of its Febridx, Viradx and other tests for the three months to March 31, 2025, fell 77.0 percent to \$US1,539,000, compared to the prior period. The company said the decrease was "primarily due to the reduced monthly revenue recognition rate of the [Hologic] intellectual property agreement".

Last year, Lumos said the Marlborough, Massachusetts' Hologic Inc would pay it \$US10 million to improve its women's health products (BD: Jan 21, 2024).

The company said that it had a cash burn of \$US1,324,000 for the three months, with cash and equivalents of \$3,974,000 at March 31, 2025 compared to \$US3,366,000 at March 31, 2024.

Lumos was up 0.2 cents or 7.7 percent to 2.8 cents with 9.2 million shares traded.

RADIOPHARM THERANOSTICS

Radiopharm says it has receipts from customers for the nine months to March 31, 2025 of \$4,537,000, related to its partnership with Lantheus.

A spokesperson for the company told Biotech Daily the receipts related to its \$3.2 million agreement with North Billerica, Massachusetts' Lantheus (BD: Jan 19, 2025). Radiopharm fell 0.1 cents or 4.55 percent to 2.1 cents with 1.3 million shares traded.

4D MEDICAL

4D Medical says receipts from customers for the nine months to March 31, 2025 were up 146.4 percent to \$3,772,000, compared to the prior corresponding period.

4D said sales and licencing of its computed tomography lung ventilation assessment software (CT Lvas) and other lung function imaging products for the three months to March 31, 2025 were up 6.6 percent to \$1,208,000, compared to the prior period. The company said it had a cash burn of \$11,245,000 for the three months, with cash and equivalents of \$16,805,000 at March 31, compared to \$41,162,000 at March 31, 2024. 4D Medical was up 1.5 cents or 5.3 percent to 30 cents with 2.2 million shares traded.

AMPLIA THERAPEUTICS

Amplia says that of 29 advanced pancreatic cancer patients, 11 have had partial responses following treatment with narmafotinib, or AMP945, and chemotherapy. In March, Amplia said that interim data from its 55-patient, phase IIa trial of narmafotinib for pancreatic cancer showed that 13 patients had more than 30 percent tumor size reduction (BD: Mar 27, 2025).

Last year, Amplia said six of 26 enrolled patients in its phase IIa, trial of AMP945 for pancreatic cancer showed reduced tumor size with no new lesions, allowing it to begin recruitment of the remaining 24 patients (BD: Sep 23, 2024).

Today, Amplia chief executive officer Dr Chris Burns told Biotech Daily that the 29 patients in the trial had been recruited between January and October 2024 and the data was from the 29 patients, of which 26 were evaluable, at March 7, 2025.

Yesterday, Amplia said the data was being presented in a poster at the American Association of Cancer Research (AACR) meeting in Chicago, from April 25 to 30, 2025. The company said that the 11 partial responses was a rate of 38 percent compared to 23 percent in historical data for 431 patients receiving chemotherapy alone.

Amplia said median duration on trial for the narmafotinib and chemotherapy combination in its trial was 208 days compared to 117 days for the chemotherapy alone group.

The company said that 21 patients recorded a reduction in tumor size, with 15 of those showing a more than 30 percent tumor shrinkage.

Amplia said that of the 15 patients, 11 recorded a sustained reduction in tumor size for more than two months, which was recorded as "a confirmed partial response".

The company said that safety and tolerability data for 39 patients showed that narmafotinib was "well tolerated, [with] the most common treatment emergent adverse events, which were typically assessed as related to the chemotherapy rather than narmafotinib, included nausea, diarrhoea, fatigue, and constipation".

Amplia said that the most common narmafotinib-related treatment related adverse events were nausea, diarrhoea, and gastro-oesophageal reflux which were predominantly mild to moderate.

Amplia fell 0.1 cents or 1.85 percent to 5.3 cents.

THE WALTER AND ELIZA HALL INSTITUTE OF MEDICAL RESEARCH

The Walter and Eliza Hall Institute says it has begun a 140-patient trial of its tumor organoids for predicting treatment outcomes in bowel, or colorectal, cancer.

WEHI said its tumor organoids were miniature cancers the size of a grain of sand, grown in a laboratory from a patient's own tissue samples and mimicked the characteristics of the cancer from which they were created.

The Institute said that a previous study of chemotherapy drugs on the organoids of 30 patients with advanced bowel cancer and found that organoid drug testing could predict the treatments that won't work for the individual patient, with 90 percent accuracy and the treatments that would work, with 83 percent accuracy.

The article, titled 'Unified framework for patient-derived, tumor-organoid-based predictive testing of standard-of-care therapies in metastatic colorectal cancer' was published in Cell Reports Medicine and is available at: https://bit.ly/4jwRFR6.

The Institute said the trial would take tissue samples from bowel cancer patients to create eight tumor organoids per patient, which could then be tested with different drug combinations to determine the patient's optimal treatment.

WEHI said the trial would look at whether the previous results would be replicated in people and would open at Peter MacCallum Cancer Centre, Eastern Health, Northern Health, the Royal Melbourne Hospital and Western Private "in the coming months". The Institute said the trial could "transform current treatment selection practices for bowel cancer patients, improving their survival rates and quality of life".

WEHI co-lead researcher Prof Peter Gibbs said "each time you give a patient an ineffective treatment, you lose up to three months on a treatment that won't work". "Our research to date shows that if a drug has no effect on the organoid, then this treatment would also have no effect on the patient," Prof Gibbs said.

THE UNIVERSITY OF QUEENSLAND, LIPERATE THERAPEUTICS

The University of Queensland says it has dosed the first five of up-to 36-patients in a trial of its ASITI-201 immuno-therapy for type 1 diabetes.

The University of Queensland said the drug had been "designed to rebalance the body's immune response to protect insulin-producing pancreatic cells".

The University said the trial was funded by the Federal Government through Cureator "which helped form spin-out company Liperate Therapeutics", founded by Uniquest.

The University of Queensland said ASITI-201's pre-clinical proof-of-concept was supported by multiple grants from Breakthrough T1D (formerly the Juvenile Diabetes Research Foundation) totalling \$2.54 million between 2003 and 2015.

The University said that the drug "aimed to preserve as much pancreatic function for as long as possible in people recently diagnosed with type 1 diabetes, to reduce the amount of insulin they need to administer".

The University of Queensland said the Leona M and Harry B Helmsley Charitable Trust awarded two grants totalling \$5.33 million to complete the pre-clinical development of the drug candidate, including safety studies and manufacturing.

University of Queensland researcher Prof Ranjeny Thomas said that "in people with type 1 diabetes, the immune system starts to recognize pancreatic cells as something it needs to attack, and right now the only available treatment is insulin replacement".

"We've taken a new approach and developed ASITI-201 using a protein from the pancreas, along with vitamin D to calm the immune response," Prof Thomas said.

"This potential treatment uses the immune system's ability to heal and has been successful in controlling the disease in mice," Prof Thomas said.

PACIFIC EDGE

Pacific Edge says the US Centers for Medicare and Medicaid Services (CMS) have proposed a draft 'gap-fill' price for its Cxbladder Triage Plus of \$US1,018 (\$A1,586). Yesterday, Pacific Edge said that local coverage determination changes by its Medicare Administrative Contractor Novitas halting US Medicare coverage of its Cxbladder urine test became effective on April 24, 2025 (BD: Apr 28, 2025).

At that time, the company said it would "focus on the paths available" including reconsideration requests for its Cxbladder Triage and Monitor products, but not for its Cxbladder Detect product.

Today, Pacific Edge said "when finalized, the CMS price for Triage Plus sets the amount Pacific Edge will be reimbursed for all patients with Medicare and Medicare Advantage insurance".

The company said the price was subject to its Medicare Administrative Contractor, Novitas, providing coverage of the test.

Pacific Edge said the seven Medicare Administrative Contractors responsible for processing Medicare claims across various jurisdictions in the US published their draft pricing for Triage Plus.

The company said that Novitas priced Triage Plus at \$US1,588 and due to its agreements with multiple contractors, the price provided by Palmetto was the de facto median price, because Palmetto's pricing was used in 28 of the 50 US states.

Pacific Edge said that the draft pricing for Palmetto was US\$1,018, and subject to public comments that were due by June 28, 2025, and some possible adjustment based on those comments, the CMS was expected to make that price effective on January 1, 2026. Pacific Edge said it expected to submit a reconsideration request for Triage Plus coverage as soon as additional analytical validation and clinical validation studies were published. Pacific Edge chief executive officer Dr Peter Meintjes said the company had "invested significant resources in Triage Plus, a multi-modal test that combines DNA and RNA workflows with the outputs analysed by a novel algorithm ... to assist clinicians to manage their haematuria patients as high, intermediate or low risk".

"The resources needed to develop, validate and operate Triage Plus commercially are substantial, thus necessitating a higher price," Dr Meintjes said. "Importantly, when Triage Plus' performance characteristics are used in our existing budget impact model we observe that the improved performance characteristics have the potential for even greater savings to the Medicare system by reducing more unnecessary procedures and allowing clinicians to spend more time and clinical resources on those who need it most." Pacific Edge was untraded at 7.5 cents.

ORTHOCELL

Orthocell has requested a trading halt pending the release of "an announcement by the company regarding a new regulatory approval for Remplir".

Trading will resume on May 1, 2025, or on an earlier announcement.

Orthocell was up 6.5 cents or 4.6 percent to \$1.465 with 669,528 shares traded.

BLINKLAB

Blinklab has requested a trading halt "pending an announcement in relation to a capital raising".

Trading will resume on May 1, 2025, or on an earlier announcement.

Blinklab last traded at 36 cents.

DIMERIX

Dimerix has requested a trading halt "pending the release of an announcement regarding a licencing agreement".

Trading will resume on May 1, 2025, or on an earlier announcement.

Dimerix last traded at 48 cents.

MEDADVISOR

Medadvisor has requested a suspension following last week's trading halt in relation to a cleansing notice lodged to the ASX (BD: Apr 24, 2025.

Earlier this month, Medadvisor said it had raised \$5 million at 10 cents a share and hoped for \$2 million from a share plan (BD: Apr 1, 2025) and in a cleansing notice filed last week, said it had issued 45,750,000 shares under the placement.

The company said it expected trading to resume on May 2, 2025, or on the earlier announcement about the outcome of the court application.

Medadvisor last traded at 9.6 cents.

PYC THERAPEUTICS

PYC chair Alan Tribe says with Australian Land Pty Ltd he has increased and been diluted from 158,726,741 shares (34.02%) to 186,726,741 shares (32.01%).

Mr Tribe said that through Australian Land, Pagham Pty Ltd, Runcton Pty Ltd, Trexon Pty Ltd and Stockbridge Corporation Pty Ltd he bought 28,000,000 shares in an entitlement offer on February 27, 2025 for \$35,000,000, or \$1.25 a share and was diluted on March 21 and April 23, 2025.

In February, PYC said it hoped to raise up-to \$146 million at \$1.25 a share in a one-for-four, non-renounceable institutional and retail rights offer, with the issue price a 4.9 percent discount to the five-day volume weighted average price (BD: Feb 17, 2025). Earlier this month, the company said it raised the total \$146 million in its fully-subscribed, underwritten, one-for-four rights offer at \$1.25 a share (BD: Apr 17, 2025). PYC fell half a cent or 0.4 percent to \$1.195.

OSTEOPORE

Advance Opportunities Fund says it has increased its substantial shareholding in Osteopore from 14,327,621 shares (10.21%) to 17,097,777 shares (11.23%). The Cayman Islands-based Advance said that it sold 3,723,350 shares on April 24 and April 28, 2025 for \$66,367, or 1.8 cents a share and converted 6,493,506 shares for \$100,000, or 1.5 cents a share.

Last year, Osteopore said that it expected to raise \$20 million from Advance for a redeemable convertible note at four percent a year, issuing in four equal tranches of 20 equal sub-tranches of \$250,000 each (BD: Sep 27, 2024).

Earlier this year, the company said Advance had subscribed for \$2.0 million worth of the \$20 million redeemable convertible note; and last week, said Advance subscribed for a further \$1.0 million (BD: Feb 17, Apr 8, 2025).

Osteopore fell 0.2 cents or 11.8 percent to 1.5 cents with 6.8 million shares traded.

TELIX PHARMACEUTICALS

Telix says its US-based non-executive director Anne Whitaker has submitted her resignation, effective immediately "due to unforeseen personal and family reasons". Earlier this month, Telix said it had appointed Anne Whitaker as a US-based non-executive director, effective from April 7, 2025 (BD: Apr 4, 2025).

The company said it regretted "Ms Whitaker's decision to step down from the Telix board and wishes her all the best in her personal and professional endeavors".

Telix was up 27 cents or one percent to \$26.95 with 1.9 million shares traded.

MESOBLAST

Mesoblast says it has appointed Lyn Cobley as an independent non-executive director. Mesoblast said Ms Cobley had been chief executive officer of Westpac Institutional Bank, treasurer of Commonwealth Bank of Australia (CBA), worked for Barclays Capital and Citibank, was a former director of the Australian Financial Markets Association and was currently a director of the Commonwealth Bank of Australia.

According to her Linkedin page, Ms Cobley held a Bachelor of Economics from Sydney's Macquarie University.

Mesoblast was up 4.5 cents or 2.5 percent to \$1.835 with 5.2 million shares traded.