Biotech Daily

Monday May 26, 2025

Daily news on ASX-listed biotechnology companies

*** ASX EVEN, BIOTECH DOWN: 4D MEDICAL UP 17%; CYNATA DOWN 8%**

*** PROTEOMICS PROMARKER ENDO: '83% SENSITIVITY, 95% SPECIFICITY'**

*** IMMUTEP EFTI COMBINATION MEETS SOFT TISSUE SARCOMA ENDPOINT**

*** ONCOSIL RAISES $6.7m; $2m SHARE PLAN TO GO**

*** 4D MEDICAL FILES CT:VQ FDA 510(k) SUBMISSION**

*** RHYTHM VALIDATES 2nd GENERATION COLOSTAT CANCER TEST**

*** CHINA ACCEPTS RECCE ANTI-INFECTIVES PATENT**

*** PYC OKAY TO DOSE 2nd PHASE Ia PYC-003 KIDNEY DISEASE COHORT**

*** INOVIQ REQUESTS 'ASX PRICE QUERY' TRADING HALT**

*** OSTEOPORE TAKES $500k MORE of $20m ADVANCE NOTE**

*** IMEX M-D DR GERMAN ARANGO INCREASES, DILUTED TO 12%**

*** IMEX CHAIR DOUGLAS FLYNN TAKES 6.5%**

MARKET REPORT

The Australian stock market was flat on Monday May 26, 2025, with the ASX200 up 0.1 points to 8,361.0 points. Fourteen of the Biotech Daily Top 40 companies were up, 18 fell, six traded unchanged and two were untraded.

4D Medical was the best (see below), up 4.5 cents or 17.3 percent to 30.5 cents, with 1.7 million shares traded. Emvision, Genetic Signatures and Neuren climbed more than four percent; Syntara was up three percent; Amplia and Botanix rose two percent or more; Alcidion, Aroa, Micro-X, Paradigm, Prescient and Telix were up more than one percent; with Clarity, Cochlear, CSL and Pro Medicus up by less than one percent.

Cynata led the falls, down 1.5 cents or 7.7 percent to 18 cents, with 297,785 shares traded. Compumedics lost 6.7 percent; Immutep and Mesoblast were down more than five percent; Actinogen and Optiscan fell more than four percent; Avita, Medical Developments and Proteomics were down more than three percent; Clinuvel, Dimerix, Nanosonics, Orthocell, Resmed and SDI shed more than two percent; Curvebeam, Cyclopharm and EBR were down more than one percent; with Polynovo down by 0.4 percent.

PROTEOMICS INTERNATIONAL LABORATORIES

Proteomics says a 704-sample clinical validation cohort shows its Promarker Endo blood test had an overall 83 percent sensitivity and 95 percent specificity for endometriosis.
Proteomics said the study, with the Royal Women's Hospital and the University of Melbourne, showed Promarker Endo accurately distinguished "endometriosis from both symptomatic and general population controls … across all stages".
Last year, the company said a study of 805 samples showed its Promarker Endo blood test identified "all stages of endometriosis with high accuracy" (BD: Jan 19, 2025).
Today, Proteomics managing-director Dr Richard Lipscombe told Biotech Daily that "the first set of 805 samples [reported on December 30, 2024] included a discovery cohort of 56 samples".
"The further reduction of 45 samples in today's results was due to a better characterization of the samples compared to the early results last year," Dr Lipscombe said.
The company said its validated Promarker Endo test had integrated "prototype models using a sequential two-step approach to calculate individual risk … [and that] the algorithm combines the concentration of a panel of protein biomarkers with age and [body mass index] to generate a risk score for endometriosis".
Proteomics said the results provided 95 percent specificity for all groups with 75 percent sensitivity for stage I endometriosis, rising to 86 percent for stage II, 89 percent for stage III and 98 percent for stage IV.
The company said it had patents for Promarker Endo "pending in all major jurisdictions" and would continue with regulatory applications, clinical studies and partner engagement.
Proteomics said the study, titled 'Validation of a novel plasma protein biomarker test for diagnosing endometriosis' was presented at the Congress on Endometriosis in Sydney.
Dr Lipscombe said the results were "a major step forward in making non-invasive endometriosis diagnosis a reality".
"Promarker Endo has the potential to dramatically reduce diagnostic delays with its simplicity, accuracy, and broad applicability, including in fertility care," Dr Lipscombe said.
"The advances support our commercialization strategy and reinforce the potential for Promarker Endo to become a standard part of the clinical diagnostic pathway."
Proteomics fell 1.5 cents or 3.6 percent to 40.5 cents.

IMMUTEP

Immutep says the investigator-initiated 40-patient, phase II trial of 'efti' with radio-therapy and pembrolizumab, or Keytruda, for soft tissue sarcoma has met its primary endpoint.
In 2023, Immutep said it would provide eftilagimod alpha, or 'efti', formerly IMP321, to Warsaw, Poland's Maria Skłodowska-Curie National Research Institute of Oncology to for an up-to 40-patient, open-label, phase II trial in combination with radio-therapy and pembrolizumab, or Keytruda, for soft tissue sarcoma (BD: Apr 17, 2023).
Last year, the company said efti had shown "significant efficacy" in 21 soft tissue sarcoma patients and improvement in 40 non-small cell lung cancer patients (BD: Nov 14, 2024).
At that time, Immutep said efti led to "a greater than threefold increase in tumor hyalinization/fibrosis … at the time of surgical resection as compared to a historical median 15 percent", which was the primary endpoint in the study.
Today, the company said the efti combination "exceeded the study's pre-specified median of 35 percent tumor hyalinization/fibrosis versus 15 percent for historical data from radio-therapy alone in patients with resectable soft tissue sarcoma".
Immutep said the trial investigators would present detailed results at a future meeting.
Immutep fell 1.5 cents or 5.1 percent to 28 cents with 6.7 million shares traded.

ONCOSIL MEDICAL

Oncosil says it has raised $6.7 million at 0.3 cents a share in a placement, with a share purchase plan for $2.0 million to follow for a total of $8.7 million.
Biotech Daily calculates the placement price as a 19.3 percent discount to the 5-day volume-weighted average price, with the last closing price 0.3 cents on May 21, 2025.
Oncosil said investors would receive one option for each share, exercisable at 0.3 cents by July 31, 2027; with shares under the plan to be issued at the lower of 0.3 cents and a 2.5 percent discount to the five-day volume weighted average price to the closing date.
The company said the funds raised would be used for ongoing commercialization of its pancreatic cancer device, clinical trials and working capital.
Oncosil said the share plan was “not underwritten, but the company has received binding commitments from institutional funds to subscribe for up-to $2.0 million”.
The company said Pengana Capital was a cornerstone investor and would increase its holding following the transaction; and Bell Potter Securities was lead manager.
Oncosil said $3.45 million worth of the placement as well as the options and the share purchase plan shares and options were subject to shareholder approval at an upcoming extraordinary general meeting.
The company said the share purchase plan had a record date of May 23, would open on June 4 and close on July 4, 2025.
Oncosil fell 0.05 cents or 14.3 percent to 0.3 cents with 57.6 million shares traded.

4D MEDICAL

4D Medical says it has filed a US Food and Drug Administration 510(k) submission for its computed tomography (CT) ventilation perfusion (VQ) lung imaging software.
Last year, 4D Medical said the Federal Government granted it $1.9 million for its non-nuclear CT:VQ imaging device, which measured both the regional motion and local density changes of lung tissue (BD: Oct 23, 2024).
Earlier this year, the company said it would conduct an 80-participant study of CT:VQ for lung health with the US Department of Defense (BD: Jan 19, 2025).
Today, 4D Medical said the submission followed “extensive technical development, internal validation and regulatory documentation” including quantitative and qualitative assessment and case-based reviews.
4D Medical said VQ scans were “highly effective” in diagnosing several lung conditions, including primarily pulmonary embolism, or blood clots in the lungs, as well as chronic thromboembolic pulmonary hypertension, chronic obstructive pulmonary disease, asthma, and other airway diseases.
The company said reimbursement was expected to align with its existing CT lung ventilation analysis software (LVAS) CPT code of $US650 ($A997).
4D Medical said its computed tomography VQ scan worked without the need for any radio-tracer or contrast agent, instead using a routine CT scan to measure both regional motion and local density changes of lung tissue.
The company said its CT:VQ scans improved scheduling and accessibility and was integrated with routine CT imaging, had higher resolution and quantification and could be used with about 14,500 installed CT scanners in the US.
4D Medical managing-director Prof Andreas Fouras said the FDA submission was “a defining moment … [and] CT:VQ has the potential to completely transform how respiratory disease is diagnosed and managed, offering clinicians a faster, more convenient, and more accessible tool for functional lung assessment”.
4D Medical was up 4.5 cents or 17.3 percent to 30.5 cents with 1.7 million shares traded.

RHYTHM BIOSCIENCES

Rhythm says it has completed verification and validation testing of its second generation Colostat assay kits for colorectal cancer.

Last year, Rhythm said its second-generation Colostat colorectal cancer test showed "superior performance" compared to the first-generation test ($p < 0.0001$) and that it would work with its contract manufacturing organization Quansys to develop, verify and validate a commercial version of the algorithm (BD: Oct 7, 2024).

Today, the company said more than 96 percent of the second generation, 'beta' assay kits tested "comfortably met the performance targets for the operation use and the remaining four percent will be compensated for in the final, manufactured product".

Rhythm said validation was conducted in previously collected patient samples and assessed for "analytical variables including precision, reliability and robustness … [and] to meet or exceed the proposed clinical use as a triage test for patients symptomatic for bowel disease".

The company said the redesign was intended to simplify the "for a routine laboratory, reduce turnaround times, improve the quality and performance of the assay and reduce overall cost of goods for the assay" and the kit met its performance objectives.

The company said Quansys would produce pilot kits, "followed by final testing with an independent set of clinical samples", before the test would be commercialised.

Rhythm managing-director Dr David Atkins said it was "the first time the company has had a truly stable and reliable, simple to use Colostat assay with the necessary consistency of demonstrated performance".

Rhythm was up 0.6 cents or 9.8 percent to 6.7 cents.

RECCE PHARMACEUTICALS

Recce says the China National Intellectual Property Administration has accepted its patent family four protecting its anti-infectives, including R327 and R529.

Recce said the patent, titled 'Process for Preparation of Biologically Active Copolymer' would protect its intellectual property until 2041.

The company said the patent related to its anti-infectives' process of preparation, use as a treatment of bacterial and viral infections as well as their administration by oral, inhalation, transdermal delivery, aerosol, gel, topical foam or ointment.

Recce said it had received its family four patent in Australia, Canada, Israel and Japan, "with further patent cooperation treaty country submissions in respective stages".

Recce was up half a cent or 1.7 percent to 29.5 cents.

PYC THERAPEUTICS

PYC says it has approval to proceed to the second, 1.2mg/kg dose cohort of its phase Ia single-ascending dose study of PYC-003 for polycystic kidney disease.

Earlier this year, PYC said it had approval to begin human trials of PYC-003 for polycystic kidney disease in a single ascending dose study, with a primary endpoint of safety, with data expected by 2026 (BD: Feb 10, 2025).

At that time, the company said it would study 0.4mg/kg, 1.2mg/kg and 2.4mg/kg doses in three cohorts of eight patients, with an optional fourth cohort to receive 4.0mg/kg.

Today, the company said it had completed dosing the first cohort and it had begun dosing the second cohort, with the trial's safety review committee scheduled to meet again in July to review the second cohort's four-week safety data.

PYC was up three cents or 2.5 percent to $1.23.

INOVIQ

Inoviq has requested a trading halt “pending an announcement in relation to an ASX price query response”.
Trading will resume on May 28, 2025, or on an earlier announcement.
Inoviq last traded at 44 cents.

OSTEOPORE

Osteopore says the Cayman Island’s Advance Opportunities Fund has subscribed for a further $500,000 worth of its $20 million redeemable convertible note agreement.
Last year, Osteopore said it expected to raise $20 million from Advance Opportunities for a redeemable convertible note at 4.0 percent a year, issuing in four equal tranches of 20 equal sub-tranches of $250,000 each (BD: Sep 27, 2024).
At that time, the company said the note had a conversion price at 80 percent of the average closing price on “any five consecutive business days” as selected by the noteholder during the 45 business days immediately preceding the conversion date.
Earlier this year, Osteopore said Advance Opportunities subscribed for $2,000,000 worth of the note, then a further $1,000,000, and last week, an additional $500,000 worth of convertible notes (BD: Feb 17, Apr 8, May 19, 2025).
Today, the company said funds would be used for the business and future developments.
Osteopore was unchanged at 1.4 cents.

IMEX HEALTH SERVICES

Imex managing-director Dr German Arango says he has increased and been diluted in the company from 5,506,372 shares (14.13%) to 6,572,254 shares (12.25%).
The Bogota, Colombia-based Dr Arango said with Digital Imaging Solutions and Jorge Marin he was diluted in a placement on April 14 and May 22, 2025 and bought 328,572 shares on May 22, 2025 for $115,000, or 35.0 cents a share.
Last month, Imex said it raised $1.5 million in a placement at 35 cents a share, a 13.2 percent discount to the five-day volume weighted average price, as well as $1.0 million in a conditional placement and up-to $1.0 million in a share plan (BD: Apr 3, 2025).
Later, the company said it raised $103,000 in the up-to $1.0 million, non-underwritten share plan; and last week, said it raised $1.0 million in the conditional placement to its directors following annual general meeting approval (BD: May 15, 22, 2025).
Imex fell one cent or 2.9 percent to 33 cents.

IMEX HEALTH SERVICES

The Sydney-based Imex chair Douglas Flynn says he has become a substantial shareholder in the company with 3,492,116 shares, or 6.51 percent.
Mr Flynn said that with Dai Yat Pty Ltd and Auxino Partners Pty Ltd he bought 1,328,572 shares on May 22, 2025 for $465,000, or 35.0 cents a share (see above).