Biotech Daily

Monday February 10, 2025

Daily news on ASX-listed biotechnology companies

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*** BREAKTHROUGH VICTORIA APPOINTS ROD BRISTOW CEO**

*** INOVIQ APPOINTS 4 ADVISORS**

MARKET REPORT

The Australian stock market fell 0.34 percent on Monday February 10, 2025, with the ASX200 down 28.6 points to 8,482.8 points. Seven of the Biotech Daily Top 40 companies were up, 21 fell and 12 traded unchanged.

Paradigm was the best, up four cents or eight percent to 54 cents, with 1.5 million shares traded. Compumedics and Medical Developments climbed more than three percent; Prescient rose two percent; EBR and Nanosonics were up more than one percent; with Clinuvel, CSL, Pro Medicus and Resmed up by less than one percent.

Genetic Signatures led the falls, down four cents or 7.1 percent to 52.5 cents, with 185,191 shares traded. Curvebeam lost 6.1 percent; 4D Medical was down 5.45 percent; Immutep fell 4.5 percent; Aroa, Avita, Mesoblast, Micro-X, Nova Eye and Opthea were down more than three percent; Alcidion, Amplia, Imugene, Neuren and SDI shed more than two percent; Clarity, Syntara and Telix were down more than one percent; with Cochlear, Cyclopharm, Orthocell and Polynovo down by less than one percent.

EDITORIAL: US PRESIDENT TRUMP AND AUSTRALIAN BIOTECHNOLOGY

Biotech Daily has been asked about the impact of US President Donald Trump on Australian biotechnology. In the immortal words of Douglas Adams: “Don’t Panic”.

Australia’s greatest asset is that it is not Canada, Mexico or China. Last week, Adalta announced it was licencing Chinese assets to develop and sell to “the West”, namely Europe and North America. Every challenge is an opportunity.

The tariffs on aluminium and steel may increase prices on some items, but they might also increase the incentive for Australian companies to manufacture both more affordably.

What we know, so far.
The imminent confirmation of Robert F Kennedy Junior as the head of US health is a concern. Not just because he is known as an anti-vaxxer and has joined lawsuits against pharmaceutical companies, but that he is as unpredictable as his President.

There was a possibility that the new Republican US Government might be ‘libertarian’, but all the statements so far indicate that it will be interventionist and protectionist.

Instead of letting everything through the US Food and Drug Administration, we might find greater restrictions on approvals, especially pharmaceuticals. That could affect a number of companies including CSL, Telix and Neuren, but most other Australian drug developers are years from final FDA applications - most likely long after the Trump administration has completed its term.

NIH cuts
There has been concern over the cuts announced at the US National Institutes of Health (NIH). The NIH said that last year, $US9 billion of the $US35 billion granted for research was for administrative overheads, known as “indirect costs”.

From February 7, 2025, the NIH lowered the maximum indirect cost rate to 15 percent “above what many major foundations allow and much lower than the 60 percent plus that some institutions charge the government today”.

“This change will save more than $US4 billion a year effective immediately,” the NIH said.

The NIH said that of 72 universities surveyed “67 were willing to accept research grants that had zero percent indirect cost coverage” while Harvard required 15 percent and the California Institute of Technology required 20 percent and three universities, “refused to accept indirect cost rates lower than their Federal indirect rate”.

We shall have to wait and see what develops, but the current outlook is that the Trump administration will have little or no impact on Australian biotechnology.

In 2015, a US investment organization subscribed to Biotech Daily. When asked the firm’s interest in Australian biotechnology, the response was illuminative: “You guys fail phase II at the same rate as American companies … but you do it 10 to 90 percent cheaper.”

David Langsam, Editor

MAYNE PHARMA

Mayne Pharma says it expects revenue for the six months to December 31, 2024 to be up 11.7 percent to 14.4 percent to between $210 million and $215 million.
Last year, Mayne Pharma said revenue for the six months to December 31, 2023 was up 259.8 percent to $187,926,000 and that it had a loss of $70,552,000 compared to a profit of $289,927,000 in the prior corresponding period (BD: Feb 26, 2024).
Today, the company said it expected to see “continued growth, some seasonal cost impacts from patient payment programs as deductibles reset, and an increase in promotional expenses for women’s health products to drive additional growth”.
Mayne Pharma said it expected underlying earnings before interest, taxation, depreciation and amortization (Ebitda) of $30 million to $32 million, “as a result of continued growth across women’s health portfolio with increased operating leverage”.
The company said its dermatology business “saw improvement of margin primarily through product mix”.
Mayne Pharma managing-director Shawn O’Brien said the company had “experienced solid trading conditions in the first half as we execute against our corporate strategies, with robust revenue growth recorded particularly within our women’s health segment”.
Mayne Pharma was up $1.14 or 24.4 percent to $5.82 with 1.1 million shares traded.

ALTERITY THERAPEUTICS

Alterity says it has “binding commitments” to raise $40.0 million in a placement at 1.1 cents a share, with one attaching option for every share issued.
Alterity said the issue price was an 8.3 percent discount to the last closing price and that the options were exercisable at 2.8 cents each by February 26, 2027.
The company said the funds would be used for clinical development of ATH434, including planned advancements in multiple system atrophy, research efforts in neuro-degenerative diseases, including Parkinson’s disease, and working capital.
Alterity said about $12.8 million would be raised in a first tranche under its existing placement capacity, with the remaining $27.2 million subject to shareholder approval at an extraordinary general meeting “expected to be held in late March 2025”.
The company said MST Financial Services was sole manager of the offer.
Alterity fell 0.1 cents or 8.3 percent to 1.1 cents with 65.3 million shares traded.

MICRO-X

Micro-X says it has raised $3.3 million at 7.0 cents a share through its institutional placement and one-for-10 rights offer, with a $2.7 million retail rights offer to go.
Last week, Micro-X said it would raise $6.0 million at seven cents a share in a non-underwritten $2.0 million placement and $4.0 million one-for-10 institutional and retail entitlement offer (BD: Feb 6, 2025).
Today, the company said its placement raised $2.0 million and its institutional entitlement offer raised $1.3 million.
Micro-X said Morgans Corporate and Hawkesbury Partners acted as joint lead managers to the placement and institutional entitlement offer.
The company said the non-underwritten retail offer had a record date of February 10, would open on February 13, and close on February 28, 2025.
Micro-X fell 0.3 cents or 3.85 percent to 7.5 cents.

RADIOPHARM THERANOSTICS

Radiopharm says its 22-patient, phase IIb trial shows RAD101 detects all brain metastases, regardless of the tumor of origin, with a high tumor-to-background ratio.

Last year, Radiopharm said it had approval from the US Food and Drug Administration for a phase IIb/III trial of fluorine-18 (18F)-pivalate, or RAD101, and positron emission tomography (PET) for imaging brain metastasis (BD: May 29, 2023, Jul 23, 2024).

Later, the company said the Grand Rapids, Michigan-based BAMF Health would produce doses of RAD101 and run the first site for its phase IIb imaging study in brain metastasis (BD: Oct 21, 2024).

Today, Radiopharm said the trial was currently open and recruiting in the US and designed to evaluate the diagnostic performance of RAD101 in 12 patients with no prior radio-therapy and 10 patients with previously treated with brain radiation.

The company said the study results, titled 'A hybrid [18F] fluoropivalate PET-multiparametric MRI to detect and characterise brain tumour metastases based on a permissive environment for monocarboxylate transport' were published in the European Journal of Nuclear Medicine and Molecular Imaging, with the full article available at: https://link.springer.com/article/10.1007/s00259-025-07118-0.

The research article said that high uptake of RAD101 was seen in all intra-cranial metastatic disease compared to contra-lateral white matter, regardless of extra-cranial disease tumor-of-origin ($p = 0.0001$).

The article said RAD101-PET volumes extended beyond contrast-enhanced magnetic resonance imaging (MRI) volumes in treatment-naïve but not stereotactic radiosurgery-treated tumors.

Radiopharm managing-director Riccardo Canevari said that "the rising incidence of brain metastases is largely attributed to improved systemic cancer treatments leading to longer patient survival". "Contrast-enhanced MRI is the current standard-of -care but provides limited sensitivity for distinguishing disease progression from radio-therapy versus treatment effects."

"This is the first clinical study with 18F-RAD101 PET-[multiparametric] MRI that demonstrates potentially more sensitive detection of brain metastases compared to current standard-of-care, offering a strong potential to improve diagnostic accuracy of suspected recurrent brain metastases," Mr Canevari said.

Radiopharm was unchanged at 2.5 cents with 46 million shares traded.

HYDRIX

Hydrix says client and investee company Gyder Surgical has received US Food and Drug Administration 510(k) clearance for its Gyder hip surgery navigation system.

Hydrix said Gyder's hip system was the "world's first commercially available pin-less and image-less navigation solution for accurate positioning of the acetabular cup during anterior hip arthroplasty".

The company said the FDA approval triggered a milestone equity payment to its subsidiary Hydrix Ventures and increased its investment in Gyder by $300,000 to a total value of $2.65 million.

Hydrix head of marketing Alan Morris said the FDA clearance for the Gyder hip system was "a testament to the ingenuity of Gyder Surgical and the value of Hydrix's product development expertise".

"This approval significantly enhances Gyder Surgical's commercial prospects in the US market," Mr Morris said.

Hydrix was up one cent or 66.7 percent to 2.5 cents with 15.7 million shares traded.

BTC HEALTH

BTC says it has indefinitely extended its licencing deal to sell the Sydney-based Arna Pharma's Bronchitol and Aridol products in Singapore and Malaysia.
BTC said its subsidiary BTC Pharma had amended its initial 10-year licence of Arna Pharma's Bronchitol, or mannitol, dry powder for cystic fibrosis and Aridol dry powder asthma test, effective from February 1, 2025.
In 2023, the then Pharmaxis, now Syntara, said Arna Pharma bought its mannitol business including Bronchitol and Aridol products (BD: Oct 3, 2023).
Today, BTC said Arna would pay a single-digit royalty on sales for the first three years and had granted it an indefinite licence to the products for Australia and New Zealand.
The company said Arna Pharma had granted it the first right of refusal to commercialize its products in the Australian and New Zealand markets.
BTC executive chair Dr Richard Treagus said the "expanded partnership agreement with Arna Pharma combines the established strengths of Arna Pharma's product development and manufacturing capabilities and BTC Pharma's distribution and marketing expertise".
BTC was up 0.1 cents or 1.8 percent to 5.7 cents with one share traded.

CLINUVEL PHARMACEUTICALS

Clinuvel says its 28-patient trial of Scenesse for erythropoietic protoporphyria (EPP) shows it has an "equivalent safety profile between adults and adolescents".
In 2022, Clinuvel said it had applied to the European Medicines Agency (EMA) to expand the Scenesse, or afamelanotide 16mg, label to include adolescent patients with erythropoietic protoporphyria light intolerance (BD: Sep 5, 2022).
In 2023, the company said the EMA wanted more data for its application to expand Scenesse to 12-to-17-year-old EPP patients (BD: Sep 5, 2023).
Last year, Clinuvel said it withdrew the submission to expand marketing authorization for Scenesse to adolescent EPP patients in Europe and said it was "preparing a future submission containing additional data" (BD: Jun 3, 2024).
Today, Clinuvel said preliminary data showed Scenesse was well-tolerated and that "biochemical analyses showed that the controlled-release profile of the Scenesse implant in adolescent patients was similar to that observed in earlier studies in adults".
The company said the study assessed 14 adults and 14 adolescents, with all treatment-related adverse events mild in severity and resolved during the study and no treatment-related serious adverse events reported.
Clinuvel said biochemical analysis "found that active drug detectable in blood samples was higher in adolescents compared to adults, although consistent with historical data captured in healthy volunteer studies".
The company said all eligible patients in the study requested further treatment under a special access scheme, with final data expected "in the second half of 2025".
Clinuvel said it would use the data to seek label expansions in jurisdictions where the drug is approved, including a resubmission to the European Medicines Agency.
Clinuvel chief scientific officer Dr Dennis Wright said the company had "collected and analyzed data which support a positive risk-benefit profile of Scenesse in adolescent EPP patients, following demand from patients and physicians to broaden access to treatment".
"Initial data from the … study demonstrate that the drug is well tolerated, consistent with that seen under conditions of use in adults," Dr Wright said.
"Adolescents seem to have slightly higher drug exposure in this study but these results are consistent with historical ranges in earlier adult studies," Dr Wright said.
Clinuvel was up three cents or 0.3 percent to $11.50 with 104,913 shares traded.

PYC THERAPEUTICS

PYC says it has approval to begin human trials of PYC-003 for polycystic kidney disease, with human safety and efficacy data expected within 2025.
PYC said it would conduct an up-to 24-volunteer, single-ascending dose study of PYC-003 with a primary endpoint of the study would be safety, with all patients to be monitored for 24-weeks following dosing.
The company said it would study 0.4mg/kg, 1.2mg/kg and 2.4mg/kg in three cohorts of eight patients, with an optional fourth cohort to receive 4.0mg/kg, if required.
PYC said it would conduct an open-label part B of the single ascending dose trial in polycystic kidney disease patients, subject to safety review committee approval following completion of part A of the trial.
PYC said part B of the trial would include three cohorts of six-patients, with an optional additional cohort and would include exploratory endpoints of efficacy including urinary biomarkers and magnetic resonance imaging to assess total kidney volume, total cyst number and cyst parenchyma surface area.
The company said the study formed the basis of the clinical trial pathway aligned with the US Food and Drug Administration during a pre-investigational new drug meeting in 2024, with dosing expected to be completed in 12 months and cost about $10 million.
PYC was up 4.5 cents or 3.6 percent to $1.30 with 808,700 shares traded.

CHIMERIC THERAPEUTICS

Chimeric says the University of Chicago Medicine has opened its phase I/II trial of CHM CDH17 Chimeric antigen receptor (Car) T-cells for various cancers.
Last year, Chimeric said it had dosed the first of 15-patients in its phase I/II trial of CHM CDH17, formerly CHM2101, Car T-cells for various cancers (BD: Aug 28, 2024).
Today, the company said the two-stage study would recruit 15 patients in the phase I part of the trial and “lead to dose selection and expansion with indication-specific phase II cohorts” but did not state the number of phase II patients it expected to enrol.
Chimeric chief executive officer Dr Rebecca McQualter said that “following five successful manufacturing runs of CHM CDH17, we’ve now seen three patients dosed across the Sarah Cannon and [University of Pennsylvania] sites and look forward to bringing announcing further updates on progress as soon as we’re able”.
Chimeric was up 0.1 cents or 14.3 percent to 0.8 cents with 26.4 million shares traded.

BLINKLAB

Blinklab says Chicago’s North Shore Pediatric Therapy has joined its up-to 1,000-patient registrational study of its smartphone autism diagnostic.
Last week, the company said it had opened the first US site in its 1,000-children, registrational trial of its artificial intelligence (A.I.)-based smartphone platform autism diagnostic at Dayton, Ohio’s Primed Clinical Research (BD: Feb 5, 2025).
Today, Blinklab said North Shore Pediatric Therapy provided comprehensive paediatric services in the Chicago area, specializing in the evaluation and treatment of autism.
Blinklab said North Shore Pediatric Therapy was selected due to its experience in administering the autism diagnostic observation schedule (ADOS)-2 diagnostic tool, which was “widely recognized as the gold-standard for autism diagnosis”.
The company said enrolment of the 100-patient initial phase of its study was expected at the second site was expected to begin “in the coming weeks”.
Blinklab was up 3.5 cents or 8.2 percent to 46 cents with 1.8 million shares traded.

CLEO DIAGNOSTICS

Cleo has told the ASX that it is not aware of any information it has not announced which, if known, could explain the recent trading in its securities.
The ASX said Cleo's share price rose 25.7 percent from a low of 35 cents to a high of 44 cents on February 7, 2025, and noted a significant increase in the volume of shares traded.
Cleo said it was "the only known medical technology company on the ASX focussed on the development of its simple and accurate blood test for the early diagnosis of ovarian cancer" (sic).
Cleo fell three cents or 6.9 cents to 40.5 cents.

AROVELLA THERAPEUTICS

Arovella has requested a suspension following last week's trading halt for its 'announcement to the market in connection with the capital raising' (BD: Feb 6, 2025).
Arovella said it expected to make the announcement before February 17, 2025.
Arovella last traded at 19.5 cents.

BREAKTHROUGH VICTORIA

Breakthrough Victoria says it has appointed Rod Bristow as its chief executive officer.
Breakthrough Victoria said Mr Bristow had more than 30 years of experience in stock-broking, asset and wealth management, agriculture and not-for-profits and had been chief executive officer of Sydney-based venture capital firm Investible.
According to his Linkedin profile, Mr Bristow held a Bachelor of Science from Canberra's Australian National University.
Breakthrough Victoria chair John Brumby said the company was "thrilled to welcome Mr Bristow to Breakthrough Victoria, with his proven track record in venture and leadership, we are confident that he will build on our strong foundations, continuing our work investing in innovation and delivering positive and sustainable environmental, social and economic impact for Victorians".

INOVIQ

Inoviq says it has appointed Prof Miles Prince, Prof Phillip Darcy, Prof Carlos Salomon and Dr James McCracken to its medical and scientific advisory board.
Inoviq said Prof Prince was a clinical haematologist and oncologist, a professor at the University of Melbourne and Monash University and Prof Darcy was the head of the Peter MacCallum Cancer Centre's cancer immune-therapy laboratory.
The company said Prof Salomon was the director of the University of Queensland Centre for Extracellular Vesicle Nanomedicine and Dr McCracken was head medical oncologist in breast cancer at Epworth Health and the Peter MacCallum Cancer Centre.
Inoviq fell half a cent or 1.2 percent to 42.5 cents.