Biotech Daily

Tuesday January 28, 2025

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: RESONANCE UP 13.5%; CLARITY DOWN 8%**

*** PROF TONY HAYMET REPLACES DR CATHY FOLEY AS CHIEF SCIENTIST**

*** CSL: TGA OKAYS ANDEMBRY FOR HEREDITARY ANGIOEDEMA**

*** TELIX COMPLETES $400m RLS PURCHASE**

*** BIOXYNE H1 REVENUE RECEIPTS UP 168% TO $12.6m**

*** IDT EXPECTS UNAUDITED H1 REVENUE UP 83% TO $10.5m**

*** RESONANCE H1 RECEIPTS UP 157% TO $8m**

*** HYDRIX H1 RECEIPTS DOWN 16% to $6m**

*** ZELIRA RECEIVES FINAL $1.1m HOPE MARIJUANA AUTISM TRIAL NOTE**

*** EBR WISE FACTORY LEASE**

*** ONCOSIL: BSI OKAYS PANCREATIC CANCER MEDICAL DEVICE**

*** CURVEBEAM, STRYKER AUSTRALIA, NZ HIRISE CT DEAL**

*** PACIFIC EDGE CXBLADDER US COVERAGE CONTINUES TO APRIL**

*** TRIVARX, FDA AGREE ON MEB-001 PIVOTAL TRIAL DESIGN**

*** ANATARA WINS AUSTRALIA GARP PATENT**

*** ISLAND 81% EGM OPPOSE DIRECTOR ALBERT HANSEN RE-ELECTION**

*** AUSTRALIAN ETHICAL INCREASES, DILUTED TO 9% OF CYCLOPHARM**

*** ALTERITY REQUESTS 'TRIAL RESULTS' TRADING HALT**

MARKET REPORT

The Australian stock market fell 0.12 percent on Tuesday January 28, 2025, with the ASX200 down 9.8 points to 8,399.1 points. Eighteen of the Biotech Daily Top 40 companies were up, 20 fell and two traded unchanged. The four Big Caps were mixed.

Resonance was the best, up 0.7 cents or 13.5 percent to 5.9 cents, with 1.1 million shares traded. Percheron climbed 11.1 percent; EBR was up 7.95 percent; Medadvisor and Opthea were up five percent or more; Starpharma improved 4.8 percent; Actinogen was up 3.85 percent; Amplia, Aroa, Imugene, Resmed and Telix rose more than two percent; Avita, Cyclopharm, Genetic Signatures, Medical Developments and SDI were up one percent or more; with Clinuvel, CSL and Mesoblast up by less than one percent.

Clarity led the falls, down 32 cents or 7.8 percent to $3.78, with 2.6 million shares traded. Syntara fell 7.0 percent; Orthocell lost six percent; Curvebeam and Nanosonics fell more than four percent; Alcidion, Compumedics, Emvision and Micro-X were down three percent or more; 4D Medical, Neuren, Nova Eye, Polynovo and Universal Biosensors shed more than two percent; Dimerix, Immutep, Impedimed, Paradigm, Prescient, Pro Medicus and Proteomics were down more than one percent; with Cochlear down by 0.2 percent.

FEDERAL GOVERNMENT

The Federal Government says it has appointed Prof Tony Haymet as the Chief Scientist replacing Dr Cathy Foley (BD: Jan 19, 2025).
A media release from the Federal Minister for Industry and Science Ed Husic said that Prof Haymet was “a world-leading oceanographer, chemist and entrepreneur”.
The media release said that Prof Haymet was previously the chair of the Antarctic Science Foundation and the Australian Academy of Technological Sciences and Engineering (ATSE) Climate Change Working Group.
The Federal Government said Prof Haymet was a professor, director and vice-chancellor emeritus at the Scripps Institution of Oceanography at the University of California, San Diego, had worked for the Commonwealth Scientific and Industrial Research Organisation, was the founder of an ocean robot manufacturing company, and the author of 177 peer-reviewed publications.
The Government said that Prof Haymet’s three-year term would begin today.

CSL

CSL says the Australian Therapeutic Goods Administration has approved its Andembry, or garadacimab, for the prevention of recurrent hereditary angioedema.
In an announcement, dated January 24, 2025, and posted on its website, but not disclosed to the ASX, CSL said “the regulatory approval for registration in Australia is the first in the world for Andembry”.
The company said the TGA had approved the use of its mono-clonal antibody Andembry in patients aged 12 years and older with C1-esterase inhibitor deficiency or dysfunction.
CSL said hereditary angioedema was a form of bradykinin-mediated angioedema, and was a “rare, debilitating and potentially life-threatening genetic disorder affecting approximately one in 50,000 people globally”.
The company said Andembry inhibited the plasma protein factor XIIa and was dosed subcutaneously using a pre-filled auto-injector which allowed for self-administration.
CSL said it Andembry was discovered and developed by its scientists at its Melbourne laboratories and manufactured for clinical trials at its factory in Broadmeadows, Victoria.
According to the Australian Department of Health and Aged Care product and consumer medicine information documents on Andembry, the approval followed a 64-patient, placebo-controlled, pivotal phase III trial as well as a 161-patient open-label extension study of Andembry for angioedema.
CSL said Andembry was recommended by the Pharmaceutical Benefits Advisory Committee for funding on Australia’s pharmaceutical benefits scheme.
The company said that Andembry was “also under review by regulatory agencies in the European Union, US, Japan, Switzerland, Canada and the UK”.
CSL managing-director Paul McKenzie said that the approval was “a significant milestone for people living with hereditary angioedema and exemplifies the CSL patient-centric ambition of improving quality-of-life through novel treatment options and convenient administration.”
“As an Australian company with a global footprint, we take great pride that Andembry is our first mono-clonal antibody treatment and was discovered in our labs in Australia,” Mr McKenzie said.
“We look forward to making this medicine accessible to patients in the future, to address unmet needs in the [hereditary angioedema] community,” Mr McKenzie said.
CSL was up 48 cents or 0.2 percent to $272.48 with 917,745 shares traded.

TELIX PHARMACEUTICALS

Telix says it has completed its acquisition of the Orlando, Florida-based RLS Inc Radiopharmacies network for up to $US250 million ($A399.5 million).

Last year, Telix said it would buy RLS Inc Radiopharmacies network from the RLS Group Ltd for up-to $US250 million, including $US230 million in up-front cash, “debt and debt equivalents”, transaction expenses and working capital as well as a deferred payment of $US20 million (BD: Sep 23, 2024).

Today, the company said RLS was the US’s “only joint commission-accredited radio-pharmacy networking distributing [positron emission tomography], [single-photon emission computed tomography] and therapeutic radio-pharmaceuticals”.

Telix said the acquisition “immediately enhances [its] presence in the US with a network of over 30 radio-pharmacies dispensing radio-pharmaceuticals manufactured by Telix and other companies, while bringing a team of highly-skilled and multi-disciplinary radio-pharmaceutical professionals into the company”.

The company said RLS would continue to operate under the same name and as a stand-alone business within Telix Manufacturing Solutions, which included its other brands ARTMS, Isotherapeutics and Optimal Tracers.

Telix said the deferred cash payment of up-to $US20 million was still payable, pending the “achievement of certain milestones related to demonstration of accretive financial and operational performance” during the year following the acquisition.

Telix managing-director Dr Chris Behrenbruch said the completion of the acquisition was “a milestone in our journey to become the leader in radio-pharmaceuticals, as the RLS network significantly boosts our existing in-house and partner capabilities”.

Telix was up 77 cents or 2.8 percent to $28.30 with two million shares traded.

BIOXYNE

Bioxyne says revenue for the six months to December 31, 2024 was up 167.8 percent to $12,596,000 compared to the previous corresponding period.

Bioxyne said customer receipts from sales of its medical cannabis products for the six months were up 182.5 percent to $13,211,000, compared to the previous corresponding period, with receipts for the three months to December 31, 2024 up 214.0 percent to a record $7,439,000, and the increase was a result of “several major contracts, a growing customer base and an expanding product range”.

Bioxyne said it was $1,546,000 cash flow positive for the three months, with cash and equivalents of $2,679,000 at December 31, 2024 compared to $1,525,000 the prior year.

Bioxyne was up 0.3 cents or 10 percent to 3.3 cents with 5.95 million shares traded.

IDT AUSTRALIA

IDT says it expects unaudited revenue for the six months to December 31, 2024 was up 83.2 percent to $10.5 million, compared to the previous corresponding period.

IDT said unaudited revenue from its drug development and commercial drug manufacturing contracts for the three months to December 31, 2024 was up 97.7 percent to $5.3 million, with the increase “largely driven by significant increase in the Advanced Therapies business”, with its specialty orals business and active pharmaceutical ingredient manufacturing business down 26.4 percent and 83.7 percent, respectively.

The company said the pipeline and its ability to secure contracts supported expectations that for the year to June 30, 2025 it would “comfortably surpass that of the prior year”.

IDT was up 1.5 cents or 14.3 percent to 12 cents with 1.1 million shares traded.

RESONANCE HEALTH

Resonance says receipts from customer for the six months to December 31, 2024 were up 157.3 percent to $8,197,000, compared to the prior corresponding period.
Resonance said receipts from its clinical trial contracts and sales of its Feriscan liver iron concentrate diagnostic, Hepafat liver fat scan, cardiac T2 heart iron loading scan and other software for the three months to December 31, 2024 were up 141.9 percent to a record $5,009,000, compared to the previous corresponding period.
The company said that “continued strong demand in diagnostics, clinical trials, and milestone clinical trial service delivery payments earned in the company’s [contract research organization] services business, contributed to [its] record receipts”.
Resonance said it was $1,080,000 cash flow positive for the three months, with cash and equivalents of $3,512,000 at December 31, 2024 compared to $5,898,000 the prior year.
Resonance was up 0.7 cents or 13.5 percent to 5.9 cents with 1.1 million shares traded.

HYDRIX

Hydrix says receipts from customers for the six months to December 31, 2024 were down 16.1 percent to $5,955,000, compared to the previous corresponding period.
Hydrix said receipts from its Hydrix Services, which provided medical technology consulting services, and sales of its software-as-a-service products including remote cardiac patient monitoring for the three months to December 31, 2024 fell 5.5 percent to $3,275,000, compared to the prior corresponding period.
Hydrix chair Gavin Coote said “consecutive profitable quarters, from the services business, reflects a relentless drive to convert sales opportunities and to deliver highly complex and regulated new product development projects”.
“Sales growth coupled with a significantly lower cost base underpins confidence for the future,” Mr Coote said.
Hydrix said it was $131,000 cash flow positive for the three months, with cash and cash equivalents of $1,118,000 at December 31, 2024 compared to $843,000 the prior year.
Hydrix fell 0.2 cents or 8.3 percent to 2.2 cents with 1.2 million shares traded.

ZELIRA THERAPEUTICS

Zelira says it has received the final tranche of $US681,000 ($A1,086,065) from the Forman Trust to fund clinical trials of its Hope marijuana product for autism.
In 2023, Zelira said the Dallas, Texas-based Cantheon Capital LLC would provide $US8.6 million for phase II and III trials of Hope (BD: Feb 15, 2023).
Later, the company said the Philadelphia, Pennsylvania-based Forman Family Foundation would give $US3 million to fund the Hope clinical trials (BD: May 22, 2023).
Today, the company said with the final tranche it had received the total funding provided by the Forman Trust, and continued to manage the special purpose vehicle.
Last year, Zelira said it had a “positive response” from the US Food and Drug Administration for an investigational new drug application for its Hope ZEL-HOP1 marijuana for autism (BD: Jul 11, 2024).
Today, the company said the FDA feedback had “confirmed support for the program and outlined key guidance for the design of the [investigational new drug]-opening phase I study in health volunteers”.
Zelira said it expected to have “subsequent rounds of closings from its continuing fund-raising efforts to support the Hope formal FDA clinical program”.
Zelira was up 2.5 cents or 4.35 percent to 60 cents.

EBR SYSTEMS

EBR says it has an 11-year lease on a 51,000 square foot (4,751m^2) factory in San Jose, California to manufacture its Wise wireless pacemaker.

EBR said the facility would allow it to increase its manufacturing scale and capabilities to ensure there was "sufficient room to accommodate future growth and demand for Wise".

Last week, the company said the US Food and Drug Administration manufacturing inspection had been completed, with regulatory approval expected on or before April 13, 2024 and commercial launch by 20265 (BD: Jan 20, 2025).

Today, EBR said the plant was 4.2km from its headquarters, and it would transfer its manufacturing, storage and distribution and research and development to the facility.

The company did not disclose the commercial terms of the lease, but said the landlord would finance about $US4 million ($A6.4 million) in tenant improvements and it budgeted $US1.3 million ($A2.1 million) for furniture, equipment and contingencies for the build-out.

EBR said once the build-out and installation of key equipment was completed, the FDA would need to conduct another manufacturing post-approval inspection.

EBR managing-director John McCutcheon said the company had "been working on identifying an appropriate property and negotiating the terms of the lease for the better part of a year".

"This will be great for our shareholders, our employees, and our future customers as we develop this state-of-the-art facility in Silicon Valley," Mr McCutcheon said. "We are confident that the new facility allows us to control the company's direction as we transition into a commercial medical devices business addressing a significant unmet need."

EBR was up 13 cents or eight percent to $1.765 with 1.3 million shares traded.

ONCOSIL MEDICAL

Oncosil says the British Standards Institution has granted its device for pancreatic cancer medical device regulation certification in the European Union.

Oncosil said the certification included "the lifting of existing post-market restrictions" including local ethics and hospital governance approvals, which simplified "the initiation of commercial treatments, enabling smoother operations and allowing teams to focus on advancing commercial activities".

The company said the removal of operational constraints was "projected to yield significant cost savings over the next three years, which will be reinvested in growth initiatives and strategic advancements of the Oncosil device".

Oncosil said the approval "accelerated market access, shortening sales cycles and expanding the reach of the Oncosil device across the [European Union] and UK, enhancing patient access and driving commercial success".

The company said the certification provided "a critical opportunity to re-submit our application to the Therapeutic Goods Administration for approval in Australia".

Oncosil managing-director Nigel Lange said the approval was "a pivotal achievement for Oncosil".

"It underscores the strength of our clinical evidence and the safety profile of the Oncosil device," Mr Lange said.

"With the lifting of post-market restrictions, we are now in a stronger position to streamline operations, focus on commercial growth, and accelerate market access across key European markets," Mr Lange said. "Importantly, this milestone allows us to revisit opportunities in the Australian market, reinforcing our mission to bring life-changing treatments to more patients worldwide."

Oncosil was unchanged at half a cent with 13.7 million shares traded.

CURVEBEAM A.I.

Curvebeam says Stryker Australia Pty Ltd will promote its Hirise weight-bearing computed tomography (CT) scanner in Australia and New Zealand.
Curvebeam said the Portage, Michigan-based Stryker had more than 25 sales-persons in Australia which could “assist in the education of local surgeons to the benefits of weight bearing CT”.
The company said its previous distribution agreement for the Australian market with a local distributor expired in 2024 and that the three-year deal with Stryker was “a material expansion of its market opportunity in Australia and New Zealand”.
Curvebeam said the agreement had no minimum volumes for referrals that result in a sale and commission in order of the exclusive agreement to continue.
Curvebeam fell half a cent or 4.35 percent to 11 cents.

PACIFIC EDGE

Pacific Edge says the effective date for local coverage determination changes ceasing reimbursement for its Cxbladder urine test has been delayed to April 24, 2025.
Earlier this month, Pacific Edge said its US Medicare administrative contractor Novitas would cease reimbursement of its Cxbladder urine tests for bladder cancer from February 23, 2025, following an extension to finalize or withdraw changes to coverage of the tests last year (BD: Jul 29, 2024; Jan 19, 2025).
Today, the company said the two-month delay was observed “after an off-schedule update to the Medicare coverage database” and contained no explanation.
Pacific Edge said the delay followed representations by the company “to Novitas, its parent company Guidewell, the [US] Centers for Medicare and Medicaid Services, the US Department of Health and Human Services Office of the General Counsel and incoming political leadership to have the changes revised or withdrawn”.
Pacific Edge was up 0.1 cents or 1.9 percent to 5.3 cents.

TRIVARX (FORMERLY MEDIBIO)

Trivarx says the US Food and Drug Administration has “provided clear validation” of its study design for a 563-patient, pivotal trial of MEB-001 sleep signal analysis algorithm.
Last year, Trivarx said it requested a pre-submission meeting with the FDA to approve a trial for its MEB-001 depression screening algorithm, with the trial to be the final step before applying to the FDA under its De Novo pathway in 2025 (BD: Sep 24, 2024).
Today, the company said the trial would recruit a minimum 563 patients, between 22 years of age and 75 years of age who had been referred to a sleep clinic for sleep disturbances.
Trivarx said the trial would be conducted at five or more study sites in the US and would compare its MEB-001 artificial intelligence-based algorithm as a diagnostic of current major repressive episode to the gold-standard Mini module A.
The company said the trial was the final requirement before it could submit MEB-001 for FDA approval through the De Novo pathway.
Trivarx said it was “progressing discussions with several prominent US sleep centres and hospitals to determine key study sites” which was well advanced and was expected “to unlock a number of high-volume locations for the trial”.
Trivarx was up 0.3 cents or 17.65 percent to two cents with 6.9 million shares traded.

ANATARA LIFE SCIENCES

Anatara says the Australian Patent Office has granted it a patent for its gastro-intestinal reprogramming, or Garp, product.
Anatara said the patent, titled 'Gastrointestinal Health Composition' would protect its intellectual property until October 9, 2040.
The company said the Australian patent followed protection of its product in the European Union, with further patents being processed in further jurisdictions.
Anatara fell 0.4 cents or 7.7 percent to 4.8 cents.

ISLAND PHARMACEUTICALS

Island says its extraordinary general meeting defeated the re-election of director Albert Hansen with 81.34 percent of the vote.
Island said that investors passed the re-election and issue of options to director Phillip Lynch with more than 99 percent support, but opposed Mr Hansen's re-election with 61,553,605 votes (81.34%) against and 14,124,496 votes (18.66%) in favor.
According to its most recent filing, Island had 181,686,795 shares on issue, meaning that the 61,553,605 votes against Mr Hansen amounted to 33.9 percent of the meeting, sufficient to requisition extraordinary general meetings.
Island was up one cent or 6.1 percent to 17.5 cents.

CYCLOPHARM

Australian Ethical says it has increased and been diluted in Cyclopharm from 9,220,165 shares (10.04%) to 9,867,556 shares (8.88%).
The Sydney-based Australian Ethical said that it bought shares between May 27 and November 12, 2024, with the single largest purchase 1,056,338 shares on May 27 for $1,500,000, or $1.42 a share, and sold shares between January 6 and 23, 2025, with the single largest sale 342,564 shares on January 23 for $798,328, or $2.33 a share.
Last year, Cyclopharm said it raised $20 million at $1.42 a share in a placement and $4 million in an oversubscribed share plan (BD: May 24, Jun 25, 2024).
Cyclopharm was up three cents or 1.3 percent to $2.39.

ALTERITY THERAPEUTICS

Alterity has requested a trading halt pending an announcement "in relation to the results of its phase II clinical trial".
Trading will resume on January 30, 2025, or on an earlier announcement.
Alterity last traded at 0.8 cents.