Biotech Daily

Thursday February 27, 2025

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: CYNATA UP 13%; NOVA EYE DOWN 9%**

*** TRAJAN H1 REVENUE UP 6% TO $81m, LOSS UP 9-FOLD TO $3.5m**

*** SDI H1 REVENUE DOWN 1% TO $51.5m, PROFIT UP 3.5% TO $4m**

*** CLINUVEL H1 REVENUE UP 10.5% TO $36m; PROFIT UP 29% TO $14m**

*** AUSTCO RECORD H1 REVENUE UP 62% TO $37m, PROFIT UP 150% TO $3m**

*** MACH7 H1 REVENUE UP 33% TO $18m, LOSS DOWN 60% TO $2m**

*** ALCIDION H1 REVENUE DOWN 7.5% TO $18m, LOSS DOWN 59% TO $2m**

*** LUMOS H1 REVENUE UP 128% TO $10m, LOSS DOWN 56% TO $4.5m**

*** MESOBLAST H1 REVENUE DOWN 6.8% TO $5m, LOSS UP 47% TO $76m**

*** UNIVERSAL BIO REVENUE DOWN 5% TO $6m, LOSS UP 111% TO $14m**

*** CHIMERIC $4m FROM UNNAMED US CHARITY**

*** NEUREN: ACADIA DAYBUE SALES UP 97% TO $553m; ROYALTY $56m**

*** QUEENSLAND UNI PREGNANCY COMPLICATION BLOOD TEST**

*** BIONOMICS BECOMES 'NEUPHORIA THERAPEUTICS'**

*** NEUROTECH 'POSITIVE' EMA NTI164 ORPHAN STATUS FEEDBACK**

*** TELIX FOUNDERS DR BEHRENBRUCH, DR KLUGE SELL 4m SHARES**

*** TRUSCREEN TO SELL HANGZHOU DALTON HPV, CERVICAL CANCER TESTS**

*** MESOBLAST RYONCIL $308k PER INFUSION; US LAUNCH 'IN WEEKS'**

*** IMUGENE INDIA PATENT FOR CF33**

*** RENERVE, IMBIOMEX MEXICO NERVALIGN DEAL**

*** RESPIRI REQUESTS 'CAPITAL RAISING' TRADING HALT**

*** PHEONIX TAKES 19.85% OF CONTROL BIONICS; NIGHTINGALE 19%**

MARKET REPORT

The Australian stock market was up 0.33 percent on Thursday February 27, 2025, with the ASX200 up 27.5 points to 8,268.2 points. Twenty-one of the Biotech Daily Top 40 companies were up, 12 fell, six traded unchanged and one was untraded.

Cynata was the best, up three cents or 13.0 percent to 26 cents, with 840,799 shares traded. Starpharma climbed 9.1 percent; Neuren was up 8.9 percent; Actinogen, Alcidion, Imugene and Orthocell were up more than five percent; Clarity and Polynovo improved more than four percent; Cyclopharm, EBR, Proteomics and Resonance were up more than three percent; Clinuvel, Emvision, Medadvisor and Opthea rose more than two percent; SDI and Syntara were up more than one percent; with Avita, Nanosonics and Resmed up by less than one percent.

Nova Eye led the falls, down one cent or 8.7 percent to 10.5 cents, with 1.3 million shares traded. Dimerix lost 5.2 percent; Amplia, Curvebeam and Prescient fell four percent or more; Pro Medicus was down 3.7 percent; Genetic Signatures, Impedimed and Telix shed two percent or more; 4D Medical, Aroa, Cochlear and CSL were down one percent or more; with Medical Developments and Paradigm down by less than one percent.

TRAJAN GROUP HOLDINGS

Trajan says revenue for the six months to December 31, 2024 was up 6.0 percent to $81,004,000, with net loss after tax up 9.3-fold from $378,000 to $3,530,000.
Trajan said revenue was from sales of its products and devices for the analysis of biological, food and environmental samples.
The company said this year it paid $851,000 tax, with a $2,905,000 tax benefit last year.
Trajan said diluted loss per share rose 828.0 percent to 2.32 cents, net tangible assets per share was up 33.3 percent to eight cents, and it had cash and equivalents of $10,441,000 at December 31, 2024 compared to $11,194,000 at December 31, 2023.
Trajan was up seven cents or 8.4 percent to 90 cents.

SDI (FORMERLY SOUTHERN DENTAL INDUSTRIES)

SDI says revenue for the six months to December 31, 2024 was down 1.3 percent to $51,541,000 with net profit after tax up 3.5 percent to $3,827,000.
SDI said sales of its dental aesthetics products was up 2.5 percent to $26,960,000, whitening products revenue down 0.1 percent to $15,170,000, amalgam sales down 15.0 percent to $6,525,000 and equipment sales down 5.9 percent to $2,886,000.
The company said that an unchanged interim fully-franked dividend of 1.5 cents a share for holders at the record date of April 16 would be paid on April 30, 2025.
SDI chief executive officer Samantha Cheetham said the company increased aesthetic products sales, had improved product margins and managed its operating expenses well.
“The product margin improvements, while benefitting from product mix, is also due to some efficiency measures we are beginning to see, and we expect this positive trend to continue for the remainder of the year,” Ms Cheetham said.
SDI said diluted earnings per share were up 3.5 percent to 3.22 cents, with net tangible assets per ordinary security up 6.15 percent from 50.60 cents to 53.71 cents.
The company said it had cash and cash equivalents of $4,871,000 at December 31, 2024 compared to $7,087,000 at December 31, 2023.
SDI was up one cent or 1.2 percent to 85.5 cents.

CLINUVEL PHARMACEUTICALS

Clinuvel says revenue for the six months to December 31, 2024 was up 10.5 percent to $35,645,883, with net profit after tax up 28.7 percent to $14,075,335.
Clinuvel said its revenue was up due to a “combined increase in commercial sales and reimbursements from the distribution of Scenesse”, or 16mg afamelanotide, for erythropoietic protoporphyria, as well as sales of its photo-cosmetic products.
The company said that it would not pay a dividend for the six months to December 31, 2024, following the 5.0 cents fully franked dividend in the prior corresponding period.
The company said diluted earnings per share rose 32.1 percent to 28.0 cents, net tangible asset backing per share was up 22.9 percent to $4.35, and it had cash and equivalents at December 31, 2024 of $16,820,595 compared to $38,817,216 at December 31, 2023.
Clinuvel was up 33 cents or 2.9 percent to $11.75 with 478,900 shares traded.

AUSTCO HEALTHCARE

Austco says record revenue for the six months to December 31, 2024 was up 61.6 percent to $36,909,000, with net profit up 150.1 percent to $2,931,000.
Austco said revenue was from sales of its healthcare communication and clinical workflow management systems, and the increase in revenue was “underpinned by the successful integration of the two recently acquired businesses, Teknocorp and Amentco, who combined, contributed $11.9 million of revenue” (BD: Nov 28, 2023; May 1, 2024).
Austco said $21,295,000 of its revenue was from equipment sales, with $11,039,000 from installation services and $4,575,000 from its software and related services.
Austco said diluted earnings per share rose 101.5 percent to 0.792 cents, net tangible assets per share was up 20.9 percent to 6.08 cents, and it had cash and equivalents of $10,190,000 at December 31, 2024 compared to $4,973,000 at December 31, 2023.
Austco fell one cent or 3.3 percent to 29 cents with 1.3 million shares traded.

MACH7 TECHNOLOGIES

Mach7 says revenue for the six months to December 31, 2024 was up 33.05 percent to $17,739,317, with net loss after tax down 59.7 percent to $1,868,692.
Mach7 said revenue came from subscriptions, support and maintenance for sales of its medical imaging and data management software solutions.
The company said diluted loss per share fell 57.9 percent to 0.8 cents, net tangible assets per share were up 15.1 percent to 11.11 cents, and it had cash and cash equivalents of $23,596,825 at December 31, 2024 compared to $22,729,147 at December 31, 2023.
Mach7 was unchanged at 44 cents.

ALCIDION GROUP

Alcidion says revenue for the six months to December 31, 2024 was down 7.5 to $17,638,000, with net loss after tax down 59.2 percent to $1,698,000
Alcidion said revenue came from licencing its Miya Precision task management and patient administration software, with the reduced loss due to a company restructure in 2024 that resulted in “a decrease in employee benefits expense of $3,352,000”.
The company said diluted loss per share fell 79.4 percent to 0.07 cents, negative net tangible assets per share rose 62.9 percent to negative 0.57 cents, and it had cash and equivalents of $7,681,000 at December 31, 2024 compared to $7,914,000 last year.
Alcidion was up half a cent or 5.6 percent to 9.5 cents with 3.7 million shares traded.

LUMOS DIAGNOSTICS

Lumos says that revenue for the six months to December 31, 2024 was up 128.0 percent to $US6,306,000 ($A10,001,620) with net loss after tax down 56.3 percent to $US2,804,000 ($A4,447,279).
Lumos said its revenue was from sales, contract development and manufacturing services of its Febridx for viral and bacterial infections and Viradx for severe acute respiratory syndrome point-of-care tests in the US.
The company said diluted loss per share fell 68.05 percent to 0.46 US cents, with last year's negative net tangible assets per share of 0.37 US cents turned to a positive 0.31 US cents, and it had cash and equivalents of $US5,532,000 at December 31, 2024 compared to $US1,379,000 at December 31, 2023.
Last year, Lumos said that its net tangible assets per share was negative 0.13 cents.
Lumos fell 0.2 cents or 6.7 percent to 2.8 cents with 2.4 million shares traded.

MESOBLAST

Mesoblast says revenue for the six months to December 31, 2024 fell 6.8 percent to $US3,156,000 ($A4,999,950) with net loss after tax up 47.3 percent to $US47,934,000 ($A75,940,303).
Mesoblast said $US3.0 million in revenue came from royalty income from Temcell for graft-versus-host disease in Japan, and did not include US sales of Ryoncil (see below).
The company said diluted loss per share was up 14.0 percent to 4.2 US cents, negative net tangible asset backing per share was up 41.1 percent to negative 7.59 US cents.
Mesoblast said it had cash and equivalents of $US38,029,000 at December 31, 2024, compared to $US77,554,000 at December 31, 2023.
Mesoblast was unchanged at $2.46 with 11.2 million shares traded.

UNIVERSAL BIOSENSORS

Universal Biosensors says revenue for the year to December 31, 2024 fell 5.3 percent to $6,282,738 with net loss after tax up 111.2 percent to $14,239,743.
Universal Biosensors said the loss was "impacted due to slightly lower sales in 2024 as well some price discounting in competitive markets".
The company said revenue for its Siemens Health Xprecia blood coagulation tests was up 10 percent to $2,879,106, Sentia wine analyzer revenue fell 4.7 percent to $2,409,979, Petrackr veterinary diabetes test sales fell 78.4 percent to $108,247, with laboratory test services down 11.1 percent to $885,406.
The company said that its diluted loss per share was up 66.7 percent to 5.0 cents with net tangible assets per share down 33.3 percent to 6.0 cents.
Universal Biosensors said it had cash and cash equivalents of $8,544,105 at December 31, 2024 compared to $10,240,429 at December 31, 2023.
Universal Biosensors was unchanged at 7.2 cents.

CHIMERIC THERAPEUTICS

Chimeric says it has $4.0 million in non-dilutionary funding "from an undisclosed US-based philanthropic family office" to develop its CHM CDH17 for cancers.
Chimeric said it would use the funds to continue its trial of CHM CDH17 chimeric antigen receptor (Car) T-cells in colorectal, gastric and intestinal cancers.
Chimeric requested a trading halt for a capital raise and last traded at 0.65 cents.

NEUREN PHARMACEUTICALS

Neuren says Acadia Pharmaceuticals has announced Daybue US sales for the year to December 31, 2024 up 96.6 percent to $US348.4 million ($A552.5 million).
Neuren said it expected $56.2 million in royalties for the year, up 109.7 percent on the prior corresponding period.
In 2023, Neuren said its North American partner, the San Diego-based Acadia had US Food and Drug Administration approval for Daybue, or trofinetide, for Rett syndrome for people over the age of two years (BD: Mar 13, 2023).
Last year, Neuren said net sales of Daybue for Rett syndrome since the April launch to December 31 was $US177.2 million and Acadia guidance for full-year net sales in 2024 was between $US370 million and $US420 million (BD: Feb 28, 2024).
Today, the company said Daybue sales in the three months to December 31, 2024 were a record $US96.7 million, and Acadia expected US sales of Daybue for the year to December 31, 2025 to be between $US380 million and $US405 million, with its royalties expected to be between $62 million and $67 million.
Neuren was up $1.16 or 8.9 percent to $14.20 with 1.2 million shares traded.

THE UNIVERSITY OF QUEENSLAND

The University of Queensland says a study of 201 pregnant women shows its blood test can detect pregnancy complications “as early as 11 weeks”.
The University of Queensland said its ‘nanoflower sensor’ screened blood samples for cell biomarkers, which “could help reduce neonatal hospital admissions and save the healthcare system millions [of dollars] each year”.
The University said the test analyzed extracellular vesicles, which carried critical signals between maternal and foetal cells during pregnancy.
The University of Queensland said “about 30,000 babies born in Australia each year experience growth and developmental impairments due to pregnancy complications”.
The University said the technology could “save the healthcare system millions [of dollars] annually by reducing neo-natal intensive care unit admissions, which cost about $5,000-to-$10,000 per day, and prevent emergency interventions, including caesarean sections which cost about $10,000-to-$20,000 each”.
The University of Queensland said it would conduct a trial with “at least 2,000 women”.
The University said the study was conducted with the New Orleans, Louisiana-based Ochsner Medical Centre and supported by the Federal Government’s National Health and Medical Research Council, Cancer Council Queensland and the JST-Erato Yamauchi Materials Space-Tectonics project.
The University of Queensland said the research, titled ‘Rapid and high-sensitivity screening of pregnancy complications by profiling circulating placental extracellular vesicles’ was published in the journal Science Advances, with the full article available at: https://www.science.org/doi/10.1126/sciadv.adr4074.
Researcher Prof Carlos Salomon Gallo said the sensor was able to detect health complications that usually weren't picked up until the second or third trimesters.
“We detected possible complications, such as pre-term birth, gestational diabetes and pre-eclampsia, which is high blood pressure during pregnancy,” Prof Gallo said.
“Currently, most pregnancy complications cannot be identified until the second or third trimester, which means it can sometimes be too late for effective intervention,” Prof Gallo said.
“However, with this technology, pregnant women will be able to seek medical intervention much earlier,” Prof Gallo said.

BIONOMICS (NOW NEUPHORIA THERAPEUTICS)

Bionomics says it has re-domiciled to the US, changed its name to Neuphoria Therapeutics and is trading on the Nasdaq under the ticker code 'NEUP'.
In a media release on December 23, 2024, the Burlington, Massachusetts-based Neuphoria said it completed a scheme of arrangement in which it became "the ultimate parent company of Bionomics", with Nasdaq trading expected to begin the following day.
On February 15, Neuphoria said it would receive a $US15 million ($A23.8 million) milestone payment from Merck & Co (Merck, Sharp and Dohme) following the opening of a phase II trial to evaluate the safety and efficacy of MK-1167, an alpha-7 nicotinic acetylcholine receptor positive allosteric modulator for Alzheimer's disease symptoms.
In 2014 and 2017, Bionomics said Merck & Co would pay $US506 million including milestones, but not royalties on sales, for a collaboration on BNC375, a modulator of the alpha-7 nicotinic acetylcholine receptor, a target for the improvement of memory and learning deficits in illnesses like Alzheimer's disease (BD: Jun 24, 2014; Feb 3, 2017).
Today, Neuphoria said it was eligible to receive up to $US450 million in additional milestone payments for development and commercial milestones associated with the progress of multiple candidates, plus royalties on net sales of any licenced medicines.
In 2021, Bionomics said it raised about $US20 million in an initial public offering of 1,622,000 ADS on the Nasdaq (BD: Jan 16, 2022), and in 2023, the ASX said the company was removed from the ASX official list (BD: Aug 28, 2023).
At January 31, 2025, the then Bionomics had a market capitalization of $8 million dollars. Last night it had a market capitalization of $28 million.
On the Nasdaq, Neuphoria was unchanged at $US5.14 ($A8.15) with 94,223 shares traded.

NEUROTECH INTERNATIONAL

Neurotech says the European Medicines Agency has issued a "positive opinion" on its orphan medicinal product application of NTI164 marijuana for Rett syndrome.
Last year, Neurotech said it had US Food and Drug Administration orphan drug designation for the use of NTI164 for Rett syndrome (BD: Nov 26, 2024).
Today, the company said it filed for orphan medicinal product designation "in late October 2024 … [and expected] an official decision by the European Commission in due course".
Neurotech said orphan stratus would grant it "protocol assistance, a type of scientific advice specific for designated orphan medicines, and 10 years' market exclusivity once the medicine is on the market", with regulatory fee reductions also available.
Neurotech fell 0.2 cents or 5.4 percent to 3.5 cents.

TELIX PHARMACEUTICALS

Telix says founders managing-director Dr Christian Behrenbruch and former director Dr Andreas Kluge have sold 2,000,000 shares, each, at $29.50 a share.
Telix said the 4,000,000 shares, sold for a total of $118,000,000, were sold in block trades and were subject to a 12-month lock-up arrangement.
The company said both Dr Behrenbruch and Dr Kluge had confirmed they had "no intention to sell further shares in the foreseeable future".
Telix said Dr Behrenbruch's sale was less than 10 percent of his holdings and was conducted for "divorce settlement and estate planning purposes" and that he would hold about 6.30 percent of the company following the sale.
Telix fell 62 cents or two percent to $30.38 with 2.1 million shares traded.

TRUSCREEN GROUP

Truscreen says it will potentially sell the Hangzhou, China-based Dalton Bioscience's human papillomavirus tests in exchange for Dalton distributing its cervical cancer test.
Truscreen said it had a non-binding memorandum of understanding with Dalton Bioscience, a manufacturer of human papillomavirus (HPV) DNA tests and laboratory equipment for cervical cancer screening.
The company said that under the deal it would distribute and market complementary HPV-related, in-vitro diagnostic products under its brand, while Dalton would "explore opportunities to assist" Truscreen's artificial intelligence (A.I.)-enabled cervical screening device in its distribution network, particularly in China and South America.
Truscreen said it would formalize a distribution agreement within three months, with the proposed deal to begin with due diligence on Dalton's products, namely the HPV-DNA tests and self-sampling tests, before it was appointed a distributor of Dalton's products in all jurisdictions except the US and Canada.
The company did not disclose the commercial terms of the agreement.
Truscreen chief executive officer Marty Dillon said the deal was "a significant step forward in our mission to provide innovative and accessible cervical cancer screening solutions".
"Dalton Biosciences HPV screening tests complement Truscreen's A.I.-enabled real-time cervical screening technology," Mr Dillon said.
Truscreen was up 0.1 cents or 3.6 percent to 2.9 cents.

MESOBLAST

Mesoblast says Ryoncil will cost $US194,000 ($A307,600) wholesale per intravenous infusion, and be available in the US in the "coming weeks".
Last year, Mesoblast said the US Food and Drug Administration approved Ryoncil, or remestemcel-L, for steroid-refractory acute graft versus host disease (GvHD) in children aged two months and older (BD: Dec 19, 2024).
Today, the company said Ryoncil was the first therapy approved for pediatric patients two months and older in the indication, with a recommended dose of 2,000,000 mesenchymal stem cells per kilogram of body weight per infusion, twice a week, for four consecutive weeks, irrespective of body weight.
Mesoblast said that about 375 US children were diagnosed with steroid refractory GvHD a year and that it cost about $US2.5 million to treat a child who died of GvHD within a year of transplant and a further $US1.8 million for those who remained alive.
The company said that "based on health economic models for lifetime ultra-rare disease and high-impact short-term therapies, including quality-of-life years gained, total benefits of patient outcomes using Ryoncil ranged from $US3.2 million to $US4.1 million, comprising long-term survival benefit, cost-offset, and cost-savings".
Mesoblast managing-director Prof Silviu Itescu said Ryoncil would be "available in the coming weeks to the children with [steroid refractory acute] GvHD in need of life-saving therapy".

IMUGENE

Imugene says it has been granted a patent in India for its CF33 oncolytic viro-therapy, a chimeric vaccinia poxvirus, as a treatment for cancer.
Imugene said the patent, titled 'Chimeric Poxvirus Compositions and Uses Thereof' would protect its intellectual property until August 9, 2037.
Imugene was up 0.2 cents or 5.6 percent to 3.8 cents with 23.4 million shares traded.

RENERVE

Renerve says the Guadalajara, Jalisco-based Imbiomex will market and sell its Nervalign nerve cuff for peripheral nerve repair in Mexico.
Renerve said Mexico's Imbiomex was a medical device distribution company "specializing in the sales and marketing of imported innovations in the biomaterials and surgical markets".
The company said that with Imbiomex it had begun the regulatory application process for market approval in Mexico and that Mexico was "a good opportunity for Renerve to expand outside the US market and into Latin America".
Renerve said its nerve cuff was "designed for the protection of repaired nerves and the regeneration of nerves during the healing process … and [was] unique as it protected the nerve during the healing process, but is naturally absorbed within six months".
Renerve fell 0.75 cents or 5.3 percent to 13.5 cents.

RESPIRI

Respiri has requested a trading halt "pending an announcement by the company to the market regarding a capital raising".
Trading will resume on March 3, 2025, or on an earlier announcement.
Respiri last traded at 4.8 cents.

CONTROL BIONICS

Phoenix Development Fund Ltd says it has increased its substantial shareholding in Control Bionics from 31,269,581 shares (18.32%) to 58,495,641 shares (19.85%).
Sydney's Phoenix said that it acquired 5,003,838 shares for $215,165, or 4.3 cents a share in a placement on May 27, 2024 and acquired a further 22,222,222 shares for $1.0 million, or 4.5 cents a share in a placement on February 26, 2025.
Last year, Control Bionics said it had "firm commitments" to raise $1.04 million at 4.3 cents a share in a placement (BD: May 15, 2024).
On Tuesday, the company said it had raised $2.0 million at 4.5 cents a share in a placement to existing shareholders Nightingale Partners Pty Ltd and Phoenix Development Fund (BD: Feb 25, 2025).
Control Bionics was up 0.4 cents or 10.3 percent to 4.3 cents.

CONTROL BIONICS

Nightingale Partners Pty Ltd says it has increased its substantial shareholding in Control Bionics from 33,480,280 shares (13.52%) to 56,292,796 shares (19.10%).
The Sydney-based Nightingale said that between December 27, 2024 and February 4, 2025 it bought 590,294 shares for $34,530, or 5.85 cents a share and on February 26, 2025 purchased 1,820,269 shares for $81,912, or 4.5 cents a share and acquired 20,401,953 shares in a placement for $918,088, or 4.5 cents a share (see above).