Biotech Daily

Monday February 24, 2025

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: DIMERIX UP 7%; ALCIDION DOWN 13%**

*** POLYNOVO RECORD H1 REVENUE UP 25% TO $60m; PROFIT UP 24% TO $3m**

*** PARADIGM PHASE III PPS KNEE OA AUSTRALIA TRIAL ETHICS OKAY**

*** NEUREN: NNZ-2591 PITT HOPKINS, ANGELMAN RARE PAEDIATRIC STATUS**

*** PERCHERON HOPES TO BUY NEUROLOGICAL DRUG PROGRAM**

*** PERENNIAL TAKES 12.9% OF MICRO-X**

*** MEMPHASYS FELIX IVF TRIAL DATA LOCK**

*** MESOBLAST APPOINTS DR GREGORY GEORGE DIRECTOR**

*** JONATHAN ADAMS REPLACES RESPIRI DIRECTOR DR TOM TAKUBO**

MARKET REPORT

The Australian stock market was up 0.14 percent on Monday February 24, 2025, with the ASX200 up 12 points to 8,308.2 points.

Ten of the Biotech Daily Top 40 companies were up, 21 fell, seven traded unchanged and two were untraded. The four Big Caps were mixed.

Dimerix was the best, up 3.5 cents or 7.3 percent to 51.5 cents, with two million shares traded. Neuren was up 4.1 percent; Curvebeam climbed 3.7 percent; Amplia and Nanosonics rose more than two percent; Avita, Genetic Signatures and Micro-X were up one percent or more; with Clarity, Cochlear, CSL and Telix up by less than one percent.

Friday's 30.95 percent best, Alcidion, led the falls, down 1.4 cents or 12.7 percent to 9.6 cents, with 10.1 million shares traded.

Actinogen lost 9.8 percent; Polynovo and Syntara were down more than eight percent; Orthocell shed 6.7 percent; Medical Developments was down 5.7 percent; 4D Medical, Cyclopharm, EBR, Nova Eye, Opthea and Proteomics fell four percent or more; SDI and Universal Biosensors were down more than three percent; Cynata, Emvision, Impedimed, Imugene and Paradigm shed two percent or more; with Clinuvel, Mesoblast, Pro Medicus and Resmed down by less than one percent.

POLYNOVO

Polynovo says record revenue for the six months to December 31, 2024 was up 24.7 percent to $59,867,000, with record net profit after tax up 23.9 percent to $3,338,000.
Polynovo said revenue was from sales of its Novosorb bio-resorbable dermal scaffold for burn wound repair and its contract with the US Biomedical Advanced Research and Development Authority (BARDA).
The company said that US sales were up 25.5 percent to $46,647,000, Australia and New Zealand revenue rose 6.0 percent to $3,633 million, revenue in the United Kingdom increased 56.5 percent to $3,491,000 and sales in the rest of the world were up 32.4 percent to $5,744,000.
Polynovo said revenue from its contract with BARDA was up 10.2 percent to $5,415,000 due to “the increase in recruitment of patients for the pivotal trial”.
Polynovo chair David Williams said that “while 28 percent growth in sales is to be applauded, we can see that the equity market wants more; and we want more”.
“It is intended that this will be captured from the base we have built by taking market share, introducing new products, and opening new markets,” Mr Williams said.
Polynovo chief executive officer Swami Raote said: “I could not be more pleased with our results and global patient impact.”
“Novosorb as a platform has a generational opportunity to transform and improve access and outcomes for plastic and reconstructive surgery,” Mr Raote said.
“With our surgeons, we are focused on building products and procedures which help provide meaningfully differentiated patient outcomes,” Mr Raote said.
The company said diluted earnings per share was up 23.1 percent to 0.48 cents.
Polynovo said that net tangible assets up 8.0 percent to 10.8 cents in the six months to December 31, 2024.
The company said that it had cash and cash equivalents of $30,462,000 at December 31, 2024 compared to $45,580,000 at December 31, 2023.
Polynovo fell 16.5 cents or 8.5 percent to $1.785 with 4.9 million shares traded.

PARADIGM BIOPHARMACEUTICALS

Paradigm says it has ethics approval for its 466-patient, phase III trial of injectable pentosan poly-sulfate sodium (PPS) for knee osteo-arthritis (OA) in Australia.
Last year, Paradigm said the US Food and Drug Administration approved its open-label, randomized, double-blind phase III trial of PPS for knee osteo-arthritis, focusing on pain reduction and functional improvement (BD: Nov 28, 2024).
Later, the company said the Australian Therapeutic Goods Administration had agreed that a phase III trial would be sufficient for full PPS registration, and that it had “firm commitments” to raise the $16 million to fund the trial (BD: Dec 9, 2024).
Today, Paradigm said the first sites would be opened in Victoria and up-to 10 total sites would be opened in Australia, with recruitment expected to begin by April and first patient dosing anticipated to begin by July, 2025.
Paradigm managing-director Paul Rennie said the “ethics submission and subsequent approval by [human research ethics committee] for the … trial represents a critical milestone in our journey to bring [injectable] PPS to patients suffering from osteo-arthritis”.
“With our Australian sites ready to activate, we remain focused on our goal of enrolling and dosing the first subject [by July 2025] and advancing this transformative therapy through phase III development,” Mr Rennie said.
Paradigm fell 1.5 cents or 2.4 percent to 60 cents with five million shares traded.

NEUREN PHARMACEUTICALS

Neuren says the US Food and Drug Administration has granted NNZ-2591 rare paediatric disease designation for Pitt Hopkins and Angelman syndromes.
Neuren said it had previously received rare paediatric disease designation from the FDA for NNZ-2591 in Phelan-McDermid syndrome.
The company said the designation made it eligible for a priority review voucher if the rare paediatric disease voucher program was “re-authorized by the US Congress and NNZ-2591 receives marketing authorization for any of these indications”.
Neuren said the designation was designed to provide an incentive for drug development for serious rare paediatric diseases.
The company said that a priority review voucher could be redeemed to receive priority review for a different product or sold to another sponsor.
Last year, the company said its North America partner Acadia Pharmaceuticals received a priority review voucher for Daybue, or Neuren’s trofenitide, for Rett syndrome, which was sold for $US150 million ($A234 million) (BD: Dec 12, 2024).
Neuren was up 54 cents or 4.1 percent to $13.81 with 753,797 shares traded.

PERCHERON THERAPEUTICS (FORMERLY ANTISENSE THERAPEUTICS)

Percheron says it has submitted a non-binding proposal to an “international pharmaceutical company” to licence a drug program for a “rare neurological disease”.
Percheron said it would licence the drug development program, which had completed the pre-clinical work, with a definitive agreement expected to take between eight-to-12 weeks to negotiate and sign.
Last year, the company said its 48-patient, phase IIb trial of avicursen for Duchenne muscular dystrophy (DMD) did not meet its primary endpoint (BD: Dec 18, 2024).
Last month, Percheron said an extraordinary general meeting on March 4, 2025, would vote on a board spill requisitioned by investors, including former Antisense chair, Robert Moses, calling for the replacement of chair Dr Charmaine Gittleson and managing-director Dr James Garner with Gregory Peters and Gennadi Koutchin (BD: Jan 24, 2025).
Earlier this month, the company said it had more than 50 leads to in-licence programs and hoped to submit initial non-binding proposals this month (BD: Feb 12, 2025).
Today, Percheron said that “given the nature of the disease the board considers that the company will be well positioned to leverage its existing capabilities and relationships”.
The company did not disclose the details of the pharmaceutical company nor the drug development program and neurological indication.
Percheron said it had begun to plan a clinical trial, expected “in early 2026” following an investigational new drug application to the US Food and Drug Administration.
Percheron was unchanged at 1.3 cents with 28.4 million shares traded.

MICRO-X

Perennial Value Management says it has increased its substantial holding in Micro-X from 60,628,240 shares (11.69%) to 86,540,365 shares (12.90%).
The Sydney-based Perennial said that it bought and sold shares between February 28, 2024 and February 18, 2025, with the single largest purchase 8,824,594 shares on April 23 for $776,564 or 8.8 cents a share.
Earlier this month, Micro-X said it had raised $3.3 million at seven cents a share in an institutional offer, with a $2.7 million retail rights offer to follow (BD: Feb 10, 2025).
Micro-X was up 0.1 cents or 1.45 percent to seven cents.

MEMPHASYS

Memphasys says it has completed the “data lock” for the trial of its Felix sperm separation system for in-vitro fertilization (IVF), with results expected in March 2025.

In 2022, Memphasys said that with the Monash IVF Group, it had enrolled and treated the first couple in the 104-couple study of its Felix device (BD: Jun 28, 2022).

Earlier this month, the company said it completed the last IVF couple visit in the trial of its the Felix electrophoresis-based system, with all required patient visits, including pregnancy outcomes completed and results expected next month (BD: Feb 11, 2025).

Today, Memphasys said the data lock was a “critical milestone in ensuring the accuracy and integrity of the trial data”, which would be used in its Conformité Européenne (CE) mark submission for marketing approval in Europe.

The company said the data lock “involved an extensive process of data clean-up, meticulous data management and rigorous source data verification, all aimed at ensuring the accuracy and integrity of the trial results”.

Memphasys managing-director Dr David Ali said the milestone ensured the company was “on track to meet our timelines for releasing preliminary trial results and advancing towards the CE mark submission”.

Memphasys was up 0.05 cents or 8.3 percent to 0.65 cents with 2.3 million shares traded.

MESOBLAST

Mesoblast says it has appointed its largest shareholder Dr Gregory George to its board of directors.

Earlier this month, the Tampa, Florida-based Dr George and G to the Fourth Investments said they increased their shareholding in Mesoblast from 206,719,319 shares (18.10%) to 243,495,998 shares (19.13%) (BD: Feb 7, 2025).

Today, the company said Dr George founded and managed Surgcenter Development, the “largest privately owned ambulatory surgical centre company in the US”.

Mesoblast said Dr George was “a medical scientist with unique operational experience having built a start-up company in the medical field and turning it into a highly-efficient multi-billion-dollar commercial organization”.

Mesoblast managing-director Prof Silviu Itescu said Dr George’s “unique operational skills and insights will provide tremendous value as Mesoblast transitions to become an efficient commercial organization”.

Dr George said he invested in Mesoblast because of his “conviction in the technology, Prof Itescu’s scientific knowledge, vision and leadership combined with the ability of mesenchymal stem cells to treat, and possibly cure, a wide array of disease processes”.

“I believe in Mesoblast’s potential to create a paradigm shift in health care by blazing a new path forward and making the impossible possible,” Dr George said.

“I have first-hand knowledge of how innovative treatments for musculo-skeletal diseases such as arthritis and back pain can transform patient outcomes and be rapidly incorporated into commercial product offerings of outpatient centres,” Dr George said.

“While our surgical centre company did not have the advantage of having a unique product with a wide patent portfolio like Mesoblast, we succeeded through operational excellence, good communications, being proactive, and trying to always beat timelines,” Dr George said.

Mesoblast fell two cents or 0.75 percent to $2.64 with 3.9 million shares traded.

RESPIRI

Respiri says it has appointed Jonathan Adams replacing non-executive director Dr Tom Takubo, effective immediately.

Respiri said the Dallas, Texas-based Mr Adams had been chair of Orb Health Inc, an accountant at Pricewaterhousecoopers (PWC) and was currently investment director at Mount Vernon Investments and a director of TTI Acquisition.

Last month, the company said it bought the Dallas, Texas-based Orb Health Inc and its chronic care management and patient services for $US9,000,000 ($A14,409,000) in scrip and raised $US700,000 ($A1,100,000) in a placement to Orb Health (BD: Jan 21, 2025).

Today, Respiri said Mr Adams held a Bachelor of Business Administration and a Master of Professional Accounting from Austin's University of Texas.

The company said it thanked "Dr Takubo for his insights and contribution to Respiri during his tenure as a director of the company".

In 2023, Respiri the company said Republican Party West Virginia State Senator Dr Takubo would replace Brad Snow as a non-executive director (BD: Dec 14, 2023).

Respiri was up 0.4 cents or 8.9 percent to 4.9 cents with 1.2 million shares traded.