Biotech Daily

Wednesday March 12, 2025

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH UP: MEDADVISOR UP 13%; IMUGENE DOWN 9%**

*** MONASH: 1st BIVACOR ARTIFICIAL HEART PATIENT DISCHARGED**

*** TELIX TO PAY UP-TO $281m FOR 'FAP' CANCER CANDIDATES**

*** FISHER & PAYKEL: AUSTRALIA, NZ NOVA NASAL SLEEP APNOEA MASK**

*** BLINKLAB TESTS 1st US AUTISM PATIENT**

*** ARGENT: DR SHLOMO SADOUN TO SELL $1.6m MALTA FACTORY**

*** NOXOPHARM APPOINTS DOHERTY FOR PHASE I SOF-SKN TRIAL**

*** NYRADA 10.8m DIRECTOR WARRANTS EGM**

*** VANGUARD TAKES 5% OF NEUREN**

*** JENCAY TAKES 6% OF MEDADVISOR**

MARKET REPORT

The Australian stock market was down 1.32 percent on Wednesday March 12, 2025, with the ASX200 down 103.9 points to 7,786.2 points.

Nineteen of the Biotech Daily Top 40 companies were up, 16 fell and five traded unchanged. All four Big Caps were down.

Medadvisor was the best, up 1.5 cents or 13.0 percent to 13 cents, with 191,754 shares traded. Medical Developments was up 6.8 percent; Cynata and Universal Biosensors climbed more than four percent; Aroa, Genetic Signatures and Starpharma were up more than three percent; Alcidion, Clinuvel, Mesoblast and Proteomics rose two percent or more; Dimerix, Micro-X, Polynovo, Syntara and Telix were up more than one percent; with Avita, EBR and Orthocell up by less than one percent.

Imugene led the falls, down 0.3 cents or 8.8 percent to 3.1 cents, with 65.3 million shares traded. Paradigm lost 6.7 percent; Atomo was down 5.3 percent; Cyclopharm, Nova Eye, Opthea, Percheron, Prescient, Resmed and Resonance fell more than four percent; Clarity and Emvision were down more than three percent; 4D Medical and Neuren shed more than two percent; Amplia, Cochlear, Nanosonics and SDI were down more than one percent with CSL and Pro Medicus down by less than one percent.

MONASH UNIVERSITY, BIVACOR

Monash University says the first Australian patient to receive Bivacor's total artificial heart has become "the first in the world to be discharged from hospital".

The University said the artificial heart implant was on November 22, 2024 at Sydney's St Vincent's Hospital and the patient had since received a donor heart transplant and was discharged from hospital on March 6, 2025, "an unmitigated clinical success".

Last year, Oneventures said the Los Angeles and Brisbane-based Bivacor had implanted its first total artificial heart for end-stage heart failure as part of a US Food and Drug Administration feasibility study (BD: Jul 26, 2024).

At that time, Oneventures said the heart was a titanium bi-ventricular rotary blood pump with a single moving part that used magnetic levitation technology.

Later, in his Millis Oration at the Ausbiotech 2024 conference, Bivacor founding chief technology officer and Bivacor inventor Dr Daniel Timms said that since July, four patients in the US had received a transplant and were able to walk again (BD: Oct 30, 2024).

At that time, Dr Timms said that with MTP Connect and the Medical Research Future Fund, Bivacor hoped to successfully complete two transplants in Australia "by the end of the year" at Sydney's St Vincent's Hospital and Melbourne's Alfred Hospital.

Today, a media release from Monash University said the patient was a New South Wales man in his forties and "became the first patient in the world to be discharged from hospital with the Bivacor total artificial heart in early February 2025".

The University said there were 105 days between the transplant of the artificial heart and the patient receiving a donor transplant, which was "the longest period in the world for a Bivacor total artificial heart patient between obtaining their implant and then receiving their donor heart transplant".

Monash University said that the surgery was part of its Artificial Heart Frontiers Program, which was funded with a $50 million grant from the Australian Government's Medical Research Future Fund and was designed as a bridge to keep patients alive until a donor heart transplant became available (BD: Feb 20, 2024).

The University said the patient was recovering well and the long-term ambition was for implant recipients to be able to live with their device without needing a heart transplant.

Monash University said that for the next three years and beyond it would continue to "accelerate this Australian-grown world leading research and development program to further develop the [total artificial heart] and related game-changing mechanical circulatory support devices".

Dr Timms said he was proud to see the technology progress in Australia.

"Being able to bring Australia along this journey and be part of the first clinical trials is immensely important to me and something that I set out to do from the very beginning," Dr Timms said. "It is incredibly rewarding to see our device deliver extended support to the first Australian patient."

"The unique design and features of the Bivacor total artificial heart translate into an unmatched safety profile, and it's exhilarating to see decades of work come to fruition," Dr Timms said. "The entire Bivacor team is deeply grateful to the patient and his family for placing their trust in our total artificial heart."

"Their bravery will pave the way for countless more patients to receive this life-saving technology," Dr Timms said.

St Vincent Hospital cardio-thoracic surgeon Dr Paul Jansz said "St Vincent's was the location for Australia's first heart transplant in 1968, the establishment of the National Heart Transplant Program by Dr Victor Chang in 1984, and the development of 'heart in a box' technology in 2014".

Bivacor is a private company.

TELIX PHARMACEUTICALS

Telix says it will pay up-to EUR162 million ($A281 million) for a fibroblast activation protein (FAP)-targeting radio-pharmaceuticals for various cancers.

In November, Telix said it would pay up-to EUR162 million for FAP-targeting radio-pharmaceutical diagnostics and therapeutics, and would initially develop TLX400 for bladder cancer (BD: Nov 19, 2024).

Today, the company said it had completed its exclusive acquisition of the suite of clinically-validated FAP-targeting radio-pharmaceutical candidates developed by the Frankfurt, Germany-based Johannes Gutenberg-Universität Mainz's Prof Frank Rösch.

Telix said it would explore TLX400's potential in multiple indications for solid tumors.

The company said FAP was a pan-cancer marker expressed in the "tumor micro-environment of epithelial cancers and on the surface of some specific cancer types, including sarcomas and mesotheliomas".

Telix said the assets acquired were "differentiated by a novel structure that drives extended tumor retention while minimizing off-target uptake, potentially overcoming the limitations seen with first-generation compounds".

The company said it had paid EUR5.3 million up-front in cash as well as a EUR700,000 signing fee, and would pay a further EUR4.0 million in the next 12 months, subject to a "potential indemnity set-off", under an agreement with Prof Rösch's SCV Gmbh and Medianezia GmbH.

Telix said it would pay a further EUR132 million on the achievement of certain clinical development and regulatory milestones related to both the diagnostic and therapeutic candidates under both agreements as well as EUR20 million payable on the achievement of "commercial milestones related to the diagnostic product".

The company said subject to approval it would pay royalties on net diagnostic sales in the low to mid-single digits and, if used, an earlier formulation of the therapeutic product.

Telix Therapeutics chief executive officer Richard Valeix said the company was "pleased to have finalized this transaction so that we can continue to leverage the FAP-targeting research pioneered by Prof Rösch and his team".

"We believe this technology holds great promise for both imaging and treating tumors, and Telix is now focused on using these compounds to build out our urology franchise and explore pan-cancer opportunities, with the goal of bringing new [diagnostic and therapeutic products] to physicians and their patients," Mr Valeix said.

Telix was up 46 cents or 1.7 percent to $27.07 with 1.4 million shares traded.

FISHER & PAYKEL HEALTHCARE

Fisher & Paykel says it has launched its Nova nasal mask for the treatment of obstructive sleep apnoea in Australia and New Zealand.

Last year, Fisher & Paykel said it released its Nova Micro "smallest and lightest" nasal pillow mask for obstructive sleep apnoea in New Zealand (BD: Apr 9, 2024).

Today, the company said the continuous positive airway pressure Nova nasal mask had achieved "positive clinical trial results" with 42 of 43 test users (97.7%), reporting it worked effectively, 39 users (90.7%) found it intuitive to use, 42 participants felt they could sleep in their preferred position and move freely without leaks, 41 users rated it as comfortable or very comfortable and all users rated the noise level "quiet or very quiet".

The company said the device included easy-to-use Swingfit headgear, Rollfit cushion with pivoting clips and a washable diffusor.

The company said the product would be launched pending regulatory clearances.

Fisher & Paykel fell $1.03 or 3.3 percent to $30.29 with 1.1 million shares traded.

BLINKLAB

Blinklab says it has tested the first patient in the US study of its Dx1 smartphone autism diagnostic aid at the Dayton, Ohio-based Primed Clinical Research.
Last month, Blinklab said it opened the first US site in its 1,000-child trial of its artificial intelligence (A.I.)-based autism diagnostic at Primed Clinical Research; and later, said Chicago's North Shore Pediatric Therapy joined the study (BD: Feb 5, 10, 2025).
Today, the company said the results from the study would be used for a 510(k) submission to the US Food and Drug Administration, expected "in 2026".
Blinklab said it expected data from the initial 100-participant study by October 2025 and then it would proceed with the main study, enrolling an additional up-to 900 patients.
Blinklab chief executive officer Dr Henk-Jan Boele said beginning the US trial was "a very special and important moment for Blinklab".
"Our mission has always been to connect fundamental neuroscience with clinical practice through accessible technology, thereby enhancing autism diagnostic evaluations and enabling early intervention for children," Dr Boele said.
"After extensive [application] and portal development, stimulus refinement, and testing in hundreds of children, we are very confident in our FDA study's potential," he said.
"Early diagnosis is life-changing, and Blinklab is dedicated to empowering families and healthcare providers with A.I.-driven tools for accurate, accessible, and timely autism assessment," Dr Boele said.
Blinklab was up two cents or 5.6 percent to 37.5 cents.

ARGENT BIOPHARMA (FORMERLY MGC PHARMACEUTICALS)

Argent says SK-Pharma chief executive officer Dr Shlomo Sadoun will "facilitate a commercial transaction" of its Malta factory for a minimum $US1 million ($A1.6 million).
Argent said the agreement aimed to "establish potential new contract manufacturing or supply and distribution partnerships outside of the company's product portfolio".
In 2018, the-then MGC said it had raised $5,000,000 in a placement at seven cents a share, to fund its new production and cultivation facility in Malta (BD: Apr 11, 2018).
In 2021, the company said it had completed construction and the implementation phase of its Cimetra production factory in Malta, following a EUR3.1 million (then about $A4.8 million) cash grant through Malta Enterprise to fund the majority of the costs of construction and equipment (BD: Nov 3, 2021).
Earlier this month, Argent said it would move manufacturing of its marijuana products Cannepil and Cognicann to the North Macedonia-based ECC Pharm for Europe and the UK (BD: Mar 5, 2025).
Today, the company said Dr Sadoun would have a three-month exclusivity period to introduce a potential investment, contract manufacturing, or supply and distribution deal.
Argent said the transaction must not negatively impact its relationship with the Malta government, with any final agreement to be approved by its corporate governance bodies and that it would retain "the ability produce its product portfolio in Malta at cost following the deal".
Last month, the company said with Trondheim, Norway's Sintef it had found "promising candidates" under its agreement to develop anti-microbial therapies and nano-formulations of ingredients as chronic wound infection treatments (BD: Feb 13, 2025).
At that time, Biotech Daily asked the company if the wound care products were marijuana-based or based on a separate technology, but did not receive a reply.
In 2023, the then MGC approved a 1,000-to-one consolidation (BD: Oct 26, 2023).
Argent was unchanged at a post-consolidation 12.5 cents with 67 shares traded.

NOXOPHARM

Noxopharm says it has appointed Melbourne's Doherty Clinical Trials for its phase I 'Heracles' trial of Sof-Skn for auto-immune diseases.
Last year, Noxopharm said it had appointed an unnamed "highly experienced Australian contract research organization" for its first human trial of Sof-Skn (BD: Aug 19, 2024).
Today, the company said the trial would be conducted by the Peter Doherty Institute for Infection and Immunity's not-for-profit organization Doherty Clinical Trials Ltd.
Noxopharm did not disclose the commercial details nor protocol for the 'Heracles' trial.
Noxopharm was up 0.4 cents or 5.6 percent to 7.6 cents.

NYRADA

Nyrada says an extraordinary general meeting will vote to issue a total of 10,800,000 warrants, or options, to its chair John Moore and four directors.
Nyrada said shareholders would vote to issue Mr Moore 3,600,000 warrants to acquire Chess depository interests (CDI) as well as 1,800,000 warrants each to directors Marcus Frampton, Dr Rüdiger Weseloh, Dr Ian Dixon and Ruediger Weseloh.
The company said the warrants would be exercisable at the higher of its share price on the issue date and 120 percent of the 10-day volume weighted average price of the CDIs on the vesting date within three years from the third anniversary of the grant date.
Nyrada said the funds raised from their exercise to be used for general working capital.
The company said the warrants were in addition to Mr Moore's $US130,000 ($A207,000) yearly fees, Dr Dixon's $US60,000 ($A95,000) annual fees, Mr Cox and Mr Frampton's $US55,000 ($A87,000) fees and Dr Weseloh's $US50,000 ($A79,500) fees.
Nyrada said investors would vote to ratify the issue of 27,416,668 CDIs and 2,500,000 broker options under its placement as well as issue CDIs to Mr Moore and Mr Frampton CDIs following their participation in the placement (BD: Oct 28, 2024).
The meeting will be held at Automic Group, Level 5, 126 Phillip Street, Sydney on April 17, 2025 at 10am (AEST).
Nyrada fell half a cent or 4.55 percent to 10.5 cents.

NEUREN PHARMACEUTICALS

The Philadelphia, Pennsylvania-based Vanguard Group says it has become a substantial shareholder in Neuren with 6,492,295 shares, or 5.023 percent of the company.
Vanguard said between November 13, 2024 and March 6, 2025 it sold shares at prices ranging from $12.14 to $14.43 a share and bought shares from $11.01 to $17.03 each.
Neuren fell 30 cents or 2.6 percent to $11.10 with one million shares traded.

MEDADVISOR

Jencay Capital Pty Ltd says it has increased its substantial shareholding in Medadvisor from 28,187,111 shares (5.11%) to 34,263,689 shares (6.21%).
Sydney's Jencay Capital said that between January 16 and March 7, 2025 it bought 6,076,578 shares for $970,896, or an average 16.0 cents a share.
Medadvisor was up 1.5 cents or 13.0 percent to 13 cents.