Biotech Daily

Monday March 24, 2025

Daily news on ASX-listed biotechnology companies

*** ASX EVEN, BIOTECH DOWN: PERCHERON UP 10%; CYCLOPHARM DOWN 11%**

*** OPTHEA PHASE III COAST TRIAL MISSES PRIMARY ENDPOINT; FINANCES**

*** US FUNDING HIT TO 7 UNIS; BIOTECH NOT CONFIRMED**

*** MEMPHASYS: 'MONASH IVF FELIX TRIAL MEETS ENDPOINT'**

*** ATOMO LICENCES BURNET SYPHILIS ASSAY**

*** IMEX TO COMMERCIALIZE AQUILA+ RADIOLOGY SOFTWARE**

*** BCAL: SYDNEY BREASTEST PLUS LAUNCH; AUSTRALIA PATENT**

*** NEURIZON AMENDS NUZ-001 'HEALEY' ALS PROTOCOL; SVC DATA**

*** CAMBIUM TO RELEASE 2.5m VOLUNTARY ESCROW SHARES**

*** BVF, MARK LAMPERT DILUTED TO 6.5% OF SYNTARA**

*** ADHERIUM: KEVEN GESSNER IN; DR WILLIAM HUNTER, DANIEL KAPLON OUT**

*** DR MARISSA LIM REPLACES PRESCIENT CMO DR TERRENCE CHEW**

*** QBIOTICS LOSES DIRECTOR HAMISH CORLETT**

MARKET REPORT

The Australian stock market edged up 0.07 percent on Monday March 24, 2025, with the ASX200 up 5.7 points to 7,936.9 points. Twelve of the Biotech Daily Top 40 companies were up, 19 fell, five traded unchanged and four were untraded.

Friday's joint worst, Percheron, was the best, up 0.1 cents or 10 percent to 1.1 cents, with 408,219 shares traded. Compumedics climbed 9.4 percent; Orthocell was up 6.1 percent; Atomo improved 5.9 percent; Curvebeam and Telix were up more than four percent; Pro Medicus and Starpharma rose two percent or more; Alcidion, Dimerix and Proteomics were up one percent or more; with Mesoblast and SDI up by less than one percent.

Cyclopharm led the falls, down 15 cents or 10.9 percent to $1.23 with 422,908 shares traded; followed by Amplia, down 0.8 cents or 10.3 percent to seven cents, with 856,747 shares traded. Clarity and Medical Developments lost more than nine percent; Immutep was down 8.1 percent; Paradigm shed 7.1 percent; Prescient was down 6.4 percent; Clinuvel and Imugene were down more than five percent; 4D Medical and Nova Eye fell four percent or more; Aroa, Emvision and Nanosonics were down three percent or more; Avita, Cochlear and Cynata shed two percent or more; Syntara was down 1.2 percent; with CSL, EBR, Neuren and Resmed down by less than one percent.

OPTHEA

Opthea says its 993-patient, phase III trial of OPT-302 with aflibercept for wet age-related macular oedema “failed to meet [its] primary endpoint” raising solvency issues.

Opthea said the trial dosed wet age-related macular oedema (AMD) patients with 2.0 milligrams of OPT-302, or sozinibercept, every four or eight weeks with aflibercept and “did not meet its primary endpoint of mean change in best corrected visual acuity (BCVA)” from baseline to week-52, when compared to aflibercept alone.

The company said that following the negative results it was “assessing its rights and obligations under its Development Funding Agreement” and could be required to pay amounts to the DFA investors that would have a material adverse impact on the solvency of the company.

In 2019, Opthea said a 366-patient, phase IIb trial of OPT-302 for wet AMD met its primary endpoints with statistical significance between the higher dose 2.0mg OPT-302 with ranibizumab at 24 weeks compared to both a 0.5mg OPT-302 with ranibizumab and ranibizumab alone ($p = 0.0107$) (BD: Aug 7, 2019).

Last year, Opthea said it had enrolled all 1,984 patients in two, phase III trials evaluating the safety and efficacy of OPT-302, with either ranibizumab (Shore) or aflibercept (Coast), compared to ranibizumab or aflibercept alone (BD: May 28, 2024).

Today, the company said at week-52, the 333-patient group dosed with combination therapy every four weeks and the 330-patient group dosed every eight weeks achieved a mean change in best corrected visual acuity (BCVA) of 13.5 eye-chart letters and 12.8 letters, respectively, compared to a change of 13.7 letters in the 330-patient aflibercept monotherapy group ($p = 0.86$ and $p = 0.42$, respectively).

Opthea said that in the 296 patients with minimally classic and occult lesions receiving OPT-302 combination therapy every four weeks and the 297 patients dosed every eight weeks achieved a mean change of 13.2 letters, compared to 13.8 letters with aflibercept alone in 299 patients ($p = 0.59$ and $p = 0.62$, respectively).

The company said there was “no numerical difference observed in the key secondary endpoints”, the combination therapy was well tolerated and that it had undertaken a review of the data to ensure its accuracy and integrity which had found “no anomalies identified that would cause the board to adopt an alternative view on the data”.

Opthea said it was “assessing its rights and obligations under its Development Funding Agreement” and could be required to pay amounts to the DFA Investors that would have a material adverse impact on the solvency of the company.

The company said that if the agreement was terminated it could be obliged to pay “up-to four multiples of the amounts paid to the company under the DFA”, with the corresponding termination trigger repayments of $US0, $US229.5 million, $US255.0 million, $US467.5 million or $US680.0 million ($A1.08 billion).

Opthea said it was in discussions with the DFA Investors to explore options and that it was possible it might reach a negotiated settlement that was “different from the parties’ existing rights under the DFA”.

The company said DFA investors had security over its assets “in the form of an ‘all assets’ lien” so that it was unable to incur further non-equity funding or dispose of its material assets without the prior consent of the DFA investors.

Opthea said it had not discussed “whether to discontinue activities for the ‘Coast’ trial or accelerate and unmask the ‘Shore’ trial”.

The company had requested to remain in a suspension pending an announcement “providing more clarity on these issues”, with trading expected to resume on March 31, 2025, or on an earlier announcement.

Opthea last traded at 60 cents.

US GOVERNMENT

Biotech Daily has confirmed seven Australian universities have had US research funding issues, but no confirmation that it impacts medical or biotechnology research.

Last week, the Australian Academy of Science president Prof Chennupati Jagadish said the Academy "urges the Australian Government to give serious and urgent attention to recent actions by American authorities" (BD: Mar 18, 2025).

The Academy referred Biotech Daily to a document from the US White House Office of Management and Budget (OMB), titled 'Outreach to implementing partners' which included 36 detailed questions over five pages.

The questions included counter-terrorism staff vetting; "patriotic values"; support for US Government policies; free speech (sic); anti-[people]-trafficking policy; not working with communist, socialist or totalitarian parties "or any party that espouses anti-American beliefs"; that the institution "has not received ANY funding from the [People's Republic of China] … Russia, Cuba or Iran" [OMB emphasis]; that there be no diversity, equality and inclusion project or elements; no climate or environmental justice element in the project; does it combat Christian prosecution; and concluded with a Paperwork Reduction Act Statement that "public reporting burden for this collection of information is estimated to average 30 minutes per response" or 18 hours in total.

Today, a Federal Government spokesperson confirmed that the universities affected were: Monash University, the Australian National University, Macquarie University, the University of New South Wales, University of Technology Sydney, the University of Western Australia and Charles Darwin University.

Monash University told Biotech Daily that "none of the funding relates to medical or biotechnology research".

The Australian National University said that it "can confirm it has received a letter from the US government indicating an intent to terminate funding related to one research project".

"We are committed to working with our affected researchers and developing appropriate remediation plans," the Australian National University said.

"We remain committed to doing distinctive research in the service of our community and our country," the ANU said.

A Macquarie University media officer told Biotech Daily that Macquarie University was "working closely with its US research partners to clarify the evolving situation facing Australian universities".

"The University does not have any other comment at this stage," the Macquarie University media officer said.

The media officer of the University of Western Australia told Biotech Daily that "the University declines to comment".

A spokesperson for Federal Education Minister Jason Clare said that "Australia and United States research institutions have a long history of cooperation that has helped develop new technologies and solutions to global challenges".

"Australian universities punch above their weight in research. Australia is only 0.3 per cent of the world's population, but we do 3.0 percent of the world's research," Mr Clare's spokesperson said.

"We are home to some of the world's most brilliant researchers and the most cutting-edge research," Mr Clare's spokesperson said.

"International partners want to work with our universities because they are the best," the spokesperson said.

"Ultimately, the US will fund whatever research it wants to fund, but we will continue to make the case to the US that collaborative research benefits both US and Australia's interests," the spokesperson said.

MEMPHASYS

Memphasys says its 104-couple trial with the Monash IVF Group of its Felix sperm separation device for use in in-vitro fertilization met its primary endpoint.
Memphasys managing-director Dr David Ali told Biotech Daily that Felix was not only not inferior to the swim-up technique it was statistically superior to density gradient centrifugation (DGC) “the most common sperm preparation technique” (p = 0.022).
In 2022, the company said that with Monash IVF Group it had enrolled and treated the first of 104 couples in the study of its Felix electrophoresis device (BD: Jun 28, 2022).
Today, the company said all couples preferred using Felix compared to density gradient centrifugation and more than half of users preferred Felix to swim-up.
Memphasys said the trial showed the Felix system was “significantly faster at isolating sperm than both [density gradient centrifugation] and swim-up methods”, with no adverse events reported relating to the Felix system.
The company said the results showed “the proficiency of the Felix system to effectively separate high-quality sperm and improve embryo utilization rates”.
Memphasys did not disclose any data or the number of couples included in the analysis.
The company said the results would be used for regulatory submissions in Europe, Australia and India and be submitted to scientific journals.
Dr Ali said the completion of the trial was “a defining moment for Memphasys”.
“The rigor of this study sets the Felix system apart from any other sperm separation technology on the market,” Dr Ali said. “Not only has the Felix system demonstrated comparable or superior performance to traditional methods, but it has also achieved the ultimate benchmark, improving embryo utilization rates.”
Memphasys was up 0.3 cents or 42.9 percent to one cent with 91.6 million shares traded.

ATOMO DIAGNOSTICS, THE BURNET INSTITUTE

Atomo says it has an exclusive licencing deal to commercialize the Burnet Institute’s rapid syphilis test assay using its Pascal blood test cassette.
Last year, Atomo said the Federal Government had provided $2.44 million for it to develop a point-of-care, blood-prick test for active cases of syphilis (BD: Oct 23, 2024).
At that time, the company said it would design a test for professional use and at-home self-testing with the Melbourne’s Burnet Institute and Sydney’s IDE Group.
Today, Atomo said the device used its Pascal cassette finger-prick blood test and a syphilis antibody assay developed by the Burnet Institute, that distinguished “active Syphilis infections from previously treated cases, and in doing so provides improved clinical specificity in rapid test settings”.
The company said it could “commence commercial activities related to arrangements to support market entry and distribution for the product in key markets including the US and Europe where Syphilis continues to be an emerging public health challenge”.
Atomo said the agreement was effective until the Burnet Institute’s patent expired in 2045 and that it would pay the Institute royalties as a percentage of revenues generated by the products, with no royalties to be paid until after regulatory approvals were secured.
Atomo managing-director John Kelly said the licence allowed the company to use its HIV test production and distribution capabilities “and reflects the natural fit between the two clinical indications and the need to often test for both in sexual health screening”.
“Being able to utilise our certified low cost South African facility for production, and established sales channels in both developed healthcare markets and into global health is invaluable in the commercialization of this very promising product,” Mr Kelly said.
Atomo was up 0.1 cents or 5.9 percent to 1.8 cents.

IMEX HEALTH SERVICES

Imex says it has “largely” completed the development of its Aquilia+ radiology management software, with the product currently installed in eight sites.
In 2022, Imex said that it had sold its first Aquila internet cloud-based picture archiving and communication system (PACS) for radiology management in Thailand (BD: Jan 20, 2022).
Today, the company said it had begun developing its “new value proposition”, Aquila+ at the beginning of last year and had started beta testing the product before July 2024.
Imex said Aquila+ was the successor to its ‘Aquila v3.6’ and that the two platforms would co-exist for about 12 months.
The company said Aquila+ added “a much wider capability of the entire platform and embedded menu of tools”.
Imex said the product improved the productivity of radiologists and made radiology workflow more efficient through artificial intelligence (A.I.)-based worklist allocation.
The company said the product reduced its engineering operations costs and storage and computing costs.
Imex said Aquilia+ provided “the highest security standards for medical data in the sector” and had received International Organization of Standardization 27001 certification.
The company said the Bogota, Colombia-based compensation fund Compensar had tested Aquila+ against competitors and had selected and installed the product “in the first of its 22 hospitals”.
Imex said it expected to commercialize Aquila+ in Latin America “in April 2025”.
Imex was untraded at 36 cents.

BCAL DIAGNOSTICS

Bcal says its Breastest Plus breast cancer blood test will be sold at Sydney Breast Clinic from March 27, 2025 and the test has been granted an Australian patent.
Bcal said that a planned roll-out of Breastest Plus at additional clinical sites, initially in Melbourne and Sydney, would follow.
The company said that it was “focused on ensuring a systematic national roll-out, working closely with our clinical partners, to ensure Australian women will have access to Breastest Plus”.
The company said commercialization of the test had been achieved within the previously announced target timeframe of having the test commercially available in Australia by [April 2025]”.
Bcal said Intellectual Property Australia had granted its first self-developed patent covering the key methods and lipid markers for the Breastest Plus device.
The company said the patent, titled ‘Diagnostic Signature’ would protect its intellectual property until May 10, 2043.
Bcal chief executive officer Shane Ryan said the commercial launch of Breastest Plus was “an incredible milestone for Bcal and for the future of breast cancer screening”.
“This innovative blood test has the potential has the potential to significantly improve the early detection pathway of breast cancer, and places Bcal at the forefront of blood-based tests for the detection of breast cancer,” Mr Ryan said.
Bcal was up 1.7 cents or 17.35 percent to 11.5 cents with 2.4 million shares traded.

NEURIZON THERAPEUTICS (FORMERLY PHARMAUST)

Neurizon says it has extended the dosing period in its 'Healey' ALS platform trial of NUZ-001 trial from 24-to-36 weeks and lowered symptom onset from 36-to-24 months.

Neurizon said data from an analysis of its previous Mend trial showed that NUZ-001 "slows the decline reduced slow vital capacity (SVC), a key respiratory function and survival metric in amyotrophic lateral sclerosis (ALS)" and SVC would be a secondary endpoint in the 'Healey' trial.

Last year, the then Pharmaust said Massachusetts General Hospital had accepted the then monepantel, now NUZ-001, into its phase II/III 'Healey' amyotrophic lateral sclerosis (ALS), or motor neuron disease (MND) platform trial (BD: Jul 15, 2024).

Later, the company said it filed an investigational new drug application to the US Food and Drug Administration to conduct a phase II/III trial of NUZ-001 for ALS "within the 'Healey' ALS platform trial framework" (BD: Dec 18, 2024).

Earlier this year, Neurizon said the FDA put its investigational new drug application for NUZ-001 on a "clinical hold", due to "certain concerns about the sufficiency of information to assess the application and any risks to human subjects of the trial and with the proposed dosing regime" (BD: Jan 19, 2025).

Last month, the company said the FDA requested "additional animal exposure data to assess the adequacy of systemic exposure to NUZ-001" (BD: Feb 17, 2025).

Last week, Neurizon said it had requested advice on two "short-term, low-cost" studies with the FDA to lift the clinical hold on NUZ-001 (BD: Mar 17, 2025).

Today, the company said it had extended the treatment period to allow for "longer evaluation of treatment effects and increase the power to detect positive treatment outcomes".

Neurizon said the reduced time since symptom onset inclusion criteria was to "enrich the study population for fast progressors", with peripheral blood mononuclear cells collection added to aid future research and therapy development.

The company said it would use slow vital capacity, a measure of respiratory function, as a secondary endpoint for the trial following positive data analysis from last year's phase I trial of the then monepantel.

Neurizon said it could finalize its regimen specific appendix under the master protocol for submission to the FDA once the clinical hold was lifted.

Neurizon managing-director Dr Michael Thurn said that the company was "excited to learn about the strong correlation between reducing the respiratory function decline rate in patients treated with NUZ-001 and overall functional decline".

"Having supporting positive secondary endpoints greatly increases the likelihood of receiving accelerated approval," Dr Thurn said.

Neurizon fell half a cent or 4.55 percent to 10.5 cents.

CAMBIUM BIO (FORMERLY REGENEUS)

Cambium says it will release 2,468,094 shares from voluntary escrow on April 5, 2025, and according to its most recent filing has 18,282,666 shares on issue.

Cambium said the shares related to its merger as the then Regeneus with the Atlanta, Georgia-based Cambium Medical Technologies (BD: Apr 5, 2024).

Last year, the company said it had completed a 100-to-one stock consolidation and had 11,931,006 post-consolidation shares on issue (BD: Jul 12, 2024).

Cambium was unchanged at 35 cents.

SYNTARA

San Francisco's BVF Partners and Mark Lampert say their 104,789,174 share-holding in Syntara has been diluted from 8.80 percent to 6.46 percent due to a share issue.
Last year, Syntara said it had commitments to raise $15.0 million at six cents a share (BD: Dec 12, 2024).
Syntara fell 0.1 cents or 1.2 percent to 8.1 cents with 3.6 million shares traded.

ADHERIUM

Adherium says Keven Gessner will replace non-executive director Dr William Hunter, with chief financial officer Daniel Kaplon to resign, effective from May 31, 2025.
Adherium said Mr Gessner had more than 25 years' experience in pharmaceutical and digital health sectors and had worked for Pfizer, Teva, Astrazeneca and Glaxosmithkline.
According to his Linkedin page, Mr Gessner held a Bachelor of Accounting from the Philadelphia, Pennsylvania-based Drexel University and a Master of Business Administration from the University of North Carolina at Chapel Hill.
The company said Dr Hunter was appointed a director on December 17, 2015 and would step down once Mr Gessner had been appointed, pending regulatory requirements.
Adherium said it had begun the search for a replacement chief financial officer.
Adherium chair Lou Panaccio said on behalf Adherium "I would like to extend our sincere gratitude to Dr Hunter for his extraordinary contributions over the past nine years".
Adherium acting chief executive officer Jeremy Curnock Cook thanked Mr Kaplon "on behalf of Adherium and our entire team for his professionalism and contribution".
Adherium was untraded at 1.1 cents.

PRESCIENT THERAPEUTICS

Prescient says Dr Marissa Lim will replace chief medical officer Dr Terrence Chew effective from today, with Dr Chew to remain "in an advisory capacity".
Prescient said Dr Lim had more than 20 years' experience in pharmaceuticals and biotechnology and would oversee the company's clinical development pipeline, including PTX-100 and its upcoming phase II trial for cutaneous T-cell lymphoma, as well as its cell therapy platforms Omnicar and Cellpyrme.
The company said Dr Lim had worked for CSL Vifor, Telix and Ipsen and had been clinical and medical advisor and chief medical officer at "several biotechnology companies".
According to her Linkedin page, Dr Lim held a Bachelor of Medicine and Bachelor of Surgery from Melbourne's Monash University.
Prescient fell 0.3 cents or 6.4 percent to 4.4 cents, with 1.2 million shares traded.

QBIOTICS GROUP

Qbiotics says non-executive director Hamish Corlett has resigned, effective from today.
Qbiotics said Mr Corlett had been a non-executive director since April 9, 2021.
Qbiotics chair Mark Fladrich said the board had "greatly benefitted from Mr Corlett's skills, experience and strategic insights during his time as a non-executive director".
Qbiotics is a public unlisted company.