Biotech Daily

Tuesday March 4, 2025

Daily news on ASX-listed biotechnology companies

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*** HYPERION BELOW 5% OF FISHER & PAYKEL**

*** PHARMA NUTRIA TAKES 5.2% OF FIREBRICK FOR $1m**

*** THORNEY, TIGA TAKE 7% OF NEXT SCIENCE**

*** DARREN KEAMY REPLACES IMUGENE CO-SEC, CFO MIKE TONROE**

MARKET REPORT

The Australian stock market was down 0.58 percent on Tuesday March 4, 2025, with the ASX200 down 47.6 points to 8,198.1 points. Seven of the Biotech Daily Top 40 stocks were up, 26 fell and seven traded unchanged.

Percheron was the best, up 0.1 cents or 11.1 percent to one cent, with 9.2 million shares traded. Nova Eye climbed 4.8 percent; Compumedics rose two percent; CSL and Emvision were up one percent or more; with Aroa, Clinuvel, Resmed and SDI up by less than one percent.

Actinogen led the falls, down 0.8 cents or 20 percent to 3.2 cents, with 38.2 million shares traded. Opthea lost 9.9 percent; Mesoblast and Starpharma fell more than eight percent; Medadvisor, Neuren and Orthocell shed more than six percent; Clarity and Paradigm lost more than five percent; Prescient and Universal Biosensors fell four percent or more; Alcidion, Avita, Immutep, Medical Developments, Nanosonics, Polynovo and Telix were down more than three percent; Amplia, Cyclopharm, Impedimed and Proteomics shed more than two percent; 4D Medical, EBR and Syntara were down more than one percent; with Genetic Signatures and Pro Medicus down by less than one percent.

PRESIDENT DONALD TRUMP FDA EDITORIAL

Trump FDA staffing ‘fiasco’ puts sector in choppy, unchartered waters

By Tim Boreham

Last week’s sackings and re-hirings at the US Food and Drug Administration suggest limits to the Trump administration’s efficiency drive.

While ASX-listed companies with approval applications in train appear to be okay, it’s nervous times for the rest, and optimists believe the overly-bureaucratic FDA processes may be streamlined for the better.

In a dramatic week for the FDA, the agency was forced to fire hundreds of employees as part of US President Donald Trump’s zealous efficiency drive. A couple of days later, they were reportedly back at their desks.

We say ‘reportedly’ because the agency - which has thousands of staff overall - has not confirmed the quantum of any comings and goings.

The de-hirings reportedly were within the Center for Devices and Radiological Health, which has sprawling responsibilities. Other reports suggest the artificial intelligence team was in the (literal) firing line, because it consisted of newer employees who were let go as part of a ‘last on, first out’ policy.

“There is no question that this has all the makings of a fiasco,” says Prof Andrew Wilks, who co-developed the FDA-approved, Australian-developed myelofibrosis drug Ojjaara.

Adding to the anxiety, a meeting by a panel of science advisors to choose influenza strains to include in a vaccine was abruptly cancelled, raising concerns that health czar and anti-vaxxer Robert F Kennedy Jnr may be influencing US vaccination policy, already.

Threats and opportunities

Most advanced-stage ASX device or drug makers are likely to front the FDA’s imposing portals at some stage - and indeed a conga line of hopefuls has done so already.

No company will admit to being affected individually or, more likely, they just don’t know at this stage. But there’s rampant speculation about approval timelines being delayed or marketing applications knocked back altogether.

Some pundits fear approval dossiers will be shunted from staffer to staffer, resulting in rampant inefficiencies as the new person gets up to speed.

Before the cuts were reversed, Biden-era FDA commissioner Dr Robert Califf dubbed the cuts as “anti-efficiency”. He said many recent hires had been recruited to fill knowledge gaps (including in artificial intelligence and food-chemical safety).

On the flipside, it's hoped that tortuously bureaucratic processes will become more streamlined. One chief executive officer with an approved product recalls 27 FDA representatives being on the line at a key consultation meeting.

"You only need one person to flag an objection and that can cause delays," he said.

Dog day for DOGE

A US-based CEO of an ASX-listed biotech says the faux sackings show the level of opposition that will be encountered by the Department of Government Efficiency (DOGE).

(Earlier, hundreds of National Nuclear Security Administration employees were swiftly re-hired when the razor gang realized they weren't just pen pushers, but responsible for assembling the country's warheads.)

"There is great appetite in the US for eliminating waste and fraud in government spending, but not for reducing important functions of government," the CEO says. "There was almost universal pushback against the firing of FDA staffers".

But the re-hirings certainly don't imply that it's business as usual. Certain functions are likely to be emphasised or de-escalated, according to the whims of Mr Kennedy Junior and the new FDA chief Martin "Marty" Makary.

Expect delays …

Companies with current FDA applications include heart device companies Artrya and EBR Systems, nerve-regeneration play Orthocell, radio-pharmacy giant Telix Pharmaceuticals and wound healer Polynovo.

Echo IQ is seeking a pre-submission meeting with the FDA about its AI-enabled heart failure support tool, Echosolv HF. Last August, the FDA approved the company's aortic stenosis device, Echo Solv.

"The short version is that it is too early to tell," says Echo IQ chief commercial officer Deon Strydom. "The longer version is that we believe pharma/device companies should anticipate delays in scheduled reviews, extended review timelines, and reduced access and collaboration with lead reviewers for deficiency resolution."

He adds that none of this should impact Echo IQ. The company is also heartened that contrary to the artificial intelligence (A.I.) sackings-that-weren't, the agency intends to prioritize A.I. products. "This obviously puts us in a favorable position," Mr Strydom said.

… and efficiencies?

Polynovo has multiple approval applications with the FDA, to extend the use of its wound-healing product to more applications.

Polynovo chair David Williams says it is “uncertain” how it will affect the company, and the sackings may have been overstated.

“I think there is a chance that efficiency and speed might pick-up and be in our favor,” Mr Williams says. “I am told unless they have been in the job for less than 12 months it is not possible to sack Federal workers, so I expect a lot of FDA sacked workers will come back.” And that appears to have transpired.

“A little more chaotic”

Cyclopharm managing-director James McBrayer is relieved that the agency has already approved its lung-imaging technology Technegas (a combination of a drug and a device) for “as broad an indication you could possibly get” in respiratory conditions, rather than just for the initial indication of pulmonary embolisms.

“That’s a rare and unusual position to be in and I’m relieved the process is done and dusted.”

For other applicants, he says there’s a danger that the agency might struggle to meet its statutory requirement of deciding on approvals within a set time.

“The person handling your application has to be intimately aware of the inputs, so if that person walks away someone else has to start again.”

The Drug User Fee Amendment (PDUFA) deadline – the FDA’s statutory approval timeline – can be delayed if the agency ‘stops the clock’ by requesting further information.

Mr McBrayer adds: “Things are happening so quickly that it will become a little bit more chaotic before we find some rhythm in terms of what the new normal is going to look like.”

Hold on to your hats

In the meantime, speculation about the new-look FDA is likely to result in more share volatility in the sector.

“Investors hate uncertainty,” says Bianca Ogden, the portfolio manager for Platinum Asset Management’s global health sciences fund. “When corporate restructurings happen, uncertainty prevails and [this] draws out project timelines,” she says. “There may be a more stringent approach to accelerated approvals, or when looking at biomarkers [to approve] neurodegenerative diseases.”

Industry figures collectively hope the new regimen won’t result in less scientific rigour, resulting in flawed therapies coming on to the market.

“The FDA is a beacon,” says Prof Wilks. “An imperfect one, of course, but the best we have.”

This article first appeared on the Stockhead website.

PROTAGONIST THERAPEUTICS INC

Protagonist says its 293-patient, phase III trial of rusfertide for polycythemia vera blood cancer met its primary endpoint ($p < 0.0001$) and all four secondary endpoints.

In 2020, the Brisbane-based Protagonist said early data from its 50-patient, phase II trial of rusfertide, or PTG-300, an injectible peptide for the blood cancer polycythemia vera, showed a “robust clinical response” and dose-related effects (BD: Jun 1, 2020).

Today, the company said that under a licence and collaboration with Takeda it would earn a $US25 million ($40.3 million) milestone payment following the positive results, payable upon completion of the clinical study report.

Protagonist said the study met its primary endpoint of a significantly higher proportion of clinical responders among rusfertide-treated patients compared to placebo, with 226 treated-patients (77%) achieving a response compared to 97 patients (33.1%) for placebo ($p < 0.0001$).

The company said a clinical response was the absence of patient eligibility for a phlebotomy during weeks 20 to 32.

Protagonist said the trial met its first secondary endpoint of a mean of 0.5 phlebotomies for each patient in the rusfertide arm of the trial compared to a mean of 1.8 phlebotomies for each patient in the placebo arm up until week 32 of the trial (p- < 0.0001).

The company said that many patients with polycythemia vera required regular phlebotomy, which was “a process of removing blood to manage elevated haematocrit levels caused by an excess of red blood cells, as well as treatment with cyto-reductive therapies”.

Protagonist said the phlebotomy process could be “burdensome and exacerbate symptoms” including fatigue, visual disturbances and iron deficiency.

The company said current treatment guidelines recommended reducing haematocrit below 45 percent as a primary treatment goal for patients with polycythemia vera.

Protagonist said the study met its three other secondary endpoints with statistical significance, including haematocrit control and patient self-reported outcomes using two questionnaires.

The company said that rusfertide was “generally well tolerated” with safety in-line with previous studies and no additional safety findings observed.

Protagonist said most adverse events were grade one-to-two injection site reactions and all serious adverse events reported were deemed “not drug-related”, with no evidence of an “increased risk of cancer in rusfertide-treated patients compared to placebo”.

Protagonist chief medical officer Dr Arturo Molina said that the positive results from the phase III study, across the primary and all key secondary endpoints, provided “compelling evidence of the potential for rusfertide as a first-in-class erythrocytosis-specific agent to address unmet medical needs in patients with [polycythemia vera] who are unable to achieve adequate hematocrit control despite standard-of-care treatments”.

Protagonist chief executive officer Dr Dinesh Patel said “the totality of impressive clinical data to date shows that rusfertide has the potential for meaningful positive impact on the lives of patients with [polycythemia vera]”.

“We look forward to working with our partner, Takeda, to submit our findings to the regulatory agencies,” Dr Patel said.

“Today’s study results also mark a critical inflection point in Protagonist’s decade long journey in the hepcidin program and further validates our platform and expertise in innovating highly differentiated peptide-based medicines to fulfil unmet medical needs,” Dr Patel said.

On the Nasdaq, Protagonist was up 0.91 US cents ($A1.47) or 2.42 percent to $US38.50 ($A62.10) with 2,395,985 shares traded.

PERCHERON THERAPEUTICS (ANTISENSE THERAPEUTICS)

Percheron says its extraordinary general meeting voted up to 56.55 percent against the removal of directors Dr Charmaine Gittleson and managing-director Dr James Garner.
Last year, Percheron fell as much as 91.5 percent after its phase IIb trial of avicursen for Duchenne muscular dystrophy did not meet its primary endpoint (BD: Dec 18, 2024).
In January, the company said investors had called to replace chair Dr Charmaine Gittleson and Dr Garner with Gregory Peters and Gennadi Koutchin (BD: Jan 19, 2025).
Last week, Percheron said it had a separate notice from Powerhouse Ventures Ltd calling for a general meeting to vote on the replacement its board of directors (BD: Feb 25, 2025).
Today, Percheron said Dr Gittleson's removal was lost with 358,803,995 votes (56.55%) against and 275,740,203 votes (43.45%) in favor, with the removal of Dr Garner blocked by 352,071,969 votes (55.52%) against and supported by 282,073,969 votes (44.48%).
Percheron said the appointments of Mr Peters and Mr Koutchin were opposed by 80.91 percent and 81.41 percent of the meeting, respectively.
According to its most recent filing, Percheron had 1,087,437,633 shares on offer, meaning that the largest vote in favor of the board spill, 282,073,969 votes, amounted to 25.9 percent of the company, sufficient to force a remuneration report strike or requisition extraordinary general meetings.
Percheron was up 0.1 cents or 11.1 percent to one cent with 9.2 million shares traded.

CHIMERIC THERAPEUTICS

Chimeric says it hopes to raise about $3.2 million at 0.5 cents a share in a pro-rata, non-renounceable, two-for-five entitlement offer, with one attaching option per share.
Chimeric said the share price was a 28.6 percent discount to the five-day volume weighted average price and a 23.1 percent discount to the last closing price.
The company said the attaching options were subject to shareholder approval; and would be exercisable at 0.8 cents each, by December 19, 2025.
Chimeric said the funds raised were for its CDH17 chimeric antigen receptor T-cells (CAR-T) program, including a phase I/II trial in neuro-endocrine tumors, colorectal cancer and gastric cancer, as well as to support phase Ib trials of its natural killer cell program in advanced colorectal and blood cancers and a phase Ib trial of its CHM1101 chlorotoxin CAR-T cells in glioblastoma multiforme, and general working capital.
Chimeric said PAC Partners and Taylor Collison were lead managers of the raise.
Chimeric fell 0.05 cents or 7.7 percent to 0.6 cents with 4.6 million shares traded.

INVION

Invion says it has raised $2.0 million at 14 cents, a 2.5 percent premium to the 30-day volume weighted average price, in a placement to support its phase I/II trials.
Invion said investors would receive one option for every share purchased, exercisable at 28 cents each within three years, subject to shareholder approval.
The company said the funds would recruit a second site for its phase I/II skin cancer trial, open a phase I/II ano-genital cancer trial with the Peter MacCallum Cancer Centre.
Invion said it hoped to use safety data from its phase I/II non-melanoma skin cancer trial to "accelerate a pathway to the ano-genital trial as both trials are using the same topical formulation of INV043", with ano-genital cancers including penile, vulva and anal cancers.
Invion said Blue Ocean Equities was lead manager and would receive a six percent capital raising fee and $80,000 worth of options.
Invion fell half a cent or 3.6 percent to 13.5 cents.

DIMERIX

Dimerix says Osaka's Fuso Pharmaceuticals has paid it the JPY300 million ($A3.2 million) upfront fee as part of its licencing deal of DMX-200 in Japan.

Earlier this year, Dimerix said it would receive up-to $107 million to licence DMX-200 for focal segmental glomerulosclerosis (FSGS) in Japan to Fuso, including an up-front payment, $104.1 million in development and sales milestones, with $4.1 million expected by April 2025, and 15-to 20 percent in sales royalties (BD: Jan 19, 2025).

Today, the company said it expected a further $4.1 million from Fuso on the first development milestone being achieved, meaning the opening of the first clinical site in Japan "in the next six-to-12 weeks".

Dimerix said it continued to focus on licencing DMX-200 in territories not already covered, including the US and China.

Dimerix was unchanged at 44 cents with 1.8 million shares traded.

UNIVERSITY OF QUEENSLAND

The University of Queensland says with Molecule to Medicine it has invested an initial $1 million in Curlew Bio a start-up developing anti-inflammatory disease medicines.

The University of Queensland said that in partnership with the Queensland Emory and Drug Discovery Initiative the Brisbane-based Curlew Bio would use research developed by its Prof Katharina Ronacher, who had discovered an immunological pathway that could be drug targeted to reduce inflammation.

The University said the partnership was an opportunity to translate laboratory-based research into therapeutics that would be impactful in real-world healthcare settings.

The University of Queensland said its commercialization arm Uniquest had invested $1 million in the start-up, which was the second company to be formed with Oxford UK and Melbourne-based Molecule to Medicine's (MTM) since its expansion in Australia.

Last year, the University said with Molecule to Medicine it had invested an initial $1 million in Lucia Bio, a Brisbane biotechnology start-up developing an anti-inflammatory treatment for neuro-degenerative diseases (BD: Nov 8, 2024).

The University said MTM's co-founder Dr Tom McCarthy was chief executive officer of its start-up Spinifex Pharmaceuticals when the company was acquired by Novartis for $US200 million ($A321.5 million) in 2015.

Uniquest chief executive officer Dr Dean Moss said Curlew Bio built on the University's "relationship with MTM and our joint focus of combining world-leading science with the right people and funding to establish new [biotechnology] companies to meet unmet health challenges".

"This is another example of Uniquest backing the science of [the University of Queensland] to create new business and commercial opportunities, with investment from the Uniquest extension fund," Dr Moss said.

MTM chief executive officer Kirsty McCarthy said MTM had "forged strong links with the exceptional drug discovery team at [Queensland Emory and Drug Discovery Initiative] and it's an honor to be working with Prof Ronacher, a pioneer in the inflammatory field".

"We'll be using MTM's deep experience in company formation and drug development to support and accelerate the delivery of a novel anti-inflammatory modality," Ms McCarthy said.

Curlew Bio is a private company.

BIOTRON

Biotron has told the ASX its announcement of a $500,000 share plan or its voluntary administration was market sensitive but was lodged incorrectly due to “human error”.
In an aware query, the ASX asked Biotron whether it believed the information announced to the ASX on February 21, 2025, titled ‘Share purchase plan’ was material.
The ASX noted the company’s share price fell 27.3 percent from 1.1 cents to a low of 0.8 cents following the release of the announcement, but did not note an increase in the volume of shares traded.
Biotron said it considered the announcement market sensitive and that “during lodgement of the announcement, the wrong box, market sensitive [versus] non-market sensitive, was pressed. This was a human error”.
The company said details on the participation of its directors in the share plan was “no longer relevant” as it had withdrawn the share plan in place of a $2.7 million one-for-one rights issue at 0.3 cents a share (BD: Feb 28, 2025).
Biotron was unchanged at 0.4 cents with 10.5 million shares traded.

FISHER & PAYKEL HEALTHCARE

Hyperion Asset Management says it has reduced its holding and been diluted in Fisher & Paykel below the substantial five percent threshold.
Hyperion said that it bought, sold and transferred shares between October 13, 2023 and February 27, 2025, with the single largest sale on February 27, 2025 of 1,545,649 shares for $53,083,723, or $34.34 a share.
Hyperion said it retained 28,698,823 shares, or 4.8962 percent of Fisher & Paykel.
Fisher & Paykel fell 38 cents or 1.2 percent to $30.28 with 583,786 shares traded.

FIREBRICK PHARMA

Firebrick says the Manila, Philippines-based Pharma Nutria NA Inc will become a substantial shareholder having bought 11,578,947 shares (5.2%) for $1.1 million.
Firebrick said Pharma Nutria NA Inc was part of the SV More Group and acquired the shares at 9.5 cents a share, a 13 percent premium to the 15-day volume weighted average price at February 27, 2025.
The company said the shares would be issued with its existing placement capacity, would support marketing its Nasodine nasal spray in Singapore, as well as product development and working capital, with the shares to be held in voluntary escrow for 12 months.
Firebrick chair Dr Peter Molloy said the investment was a “welcome top-up of our funding capacity to support our plans in 2025 … [and] a measure of the importance and strength of our partnership in the Philippines and a strong endorsement by a commercial partner of Nasodine’s market potential”.
Firebrick was up 0.2 cents or 2.2 percent to 9.2 cents with 1.6 million shares traded.

NEXT SCIENCE

Melbourne’s Thorney Investment Group and Tiga Trading say they have increased their holding in Next Science from 13,964,280 shares (5.74%) to 21,385,466 shares (7.32%).
Thorney Investment Group Australia (Tiga) said that with Alex Waislitz and Jasforce Pty Ltd it bought shares on-market and in a share plan between October 25, 2023 and March 3, 2025, with the largest purchase 1,653,319 shares for $173,599, or 10.5 cents a share.
Next Science fell half a cent or 4.8 percent to 10 cents.

IMUGENE

Imugene says former Clinuvel chief financial officer Darren Keamy will replace chief financial officer and company secretary Mike Tonroe, effective immediately.

Imugene said Mr Keamy had worked in finance for the bio-pharmaceutical industry for more than 25 years, including as chief financial officer and company secretary at Clinuvel from 2005 to 2024, as well as financial roles with Amcor, Salamon Smith Barney and Superdrug Stores.

The company said Mr Keamy's experience included "corporate governance, risk management, financial reporting, and international expansion, having established legal and operational frameworks in multiple jurisdictions including the US, Switzerland, Singapore, Ireland, Monaco, and the UK".

Imugene said Mr Keamy held a Bachelor of Commerce from La Trobe University.

Imugene managing-director Leslie Chong said Mr Keamy's "outstanding experience in financial management, capital markets, and corporate governance within the life sciences sector makes him a valuable addition to Imugene".

"His proven ability to drive financial performance and strategic growth will support the company as we continue advancing our immuno-oncology pipeline," Ms Chong said.

Imugene thanked "Mr Tonroe for his service and contributions to the company and wish him all the best for his future endeavors".

Imugene was unchanged at 3.6 cents with 25.1 million shares traded.