



# Biotech Daily

Tuesday March 11, 2025

*Daily news on ASX-listed biotechnology companies*

- \* **ASX, BIOTECH DOWN: ATOMO UP 6%; PRO MEDICUS DOWN 10.5%**
- \* **PROTAGONIST ICOTROKINRA MEETS BOWEL DISEASE ENDPOINTS**
- \* **4D MEDICAL, CLEVELAND CLINIC 3-YEAR LUNG IMAGING EXTENSION**
- \* **RENERVE THAI NERVALIGN APPROVAL, 1st HONG KONG ORDER**
- \* **AUDEARA, GEORGE & MATILDA EYECARE HEARING BUDS DEAL**
- \* **POLYNOVO LOSES CEO SWAMI RAOTE, DR ROBYN ELLIOT ACTING CEO**
- \* **DR JAMES CAMPBELL TO REPLACE PRESCIENT CHAIR STEVEN ENGLE**

## MARKET REPORT

The Australian stock market was down 0.91 percent on Tuesday March 11, 2025, with the ASX200 down 72.2 points to 7,890.1 points.

Six of the Biotech Daily Top 40 companies were up, 28 fell and six traded unchanged.

Atomo was the best of the six, up 0.1 cents or 5.6 percent to 1.9 cents, with 1.1 million shares traded.

Nova Eye climbed 4.8 percent; Avita and Resmed were up three percent or more; SDI rose 2.9 percent; Genetic Signatures was up one percent; with Medical Developments up by 0.85 percent.

Pro Medicus led the falls, down \$26.74 or 10.45 percent to \$229.19, with 605,207 shares traded.

Alcidion and Polynovo lost eight percent or more; Dimerix, EBR and Starpharma were down more than seven percent; Actinogen, Cynata and Neuren shed six percent or more; Immutep and Paradigm were down more than five percent; Amplia, Clinuvel, Curvebeam, Emvision, Impedimed, Medadvisor and Prescient fell four percent or more; 4D Medical, Aroa, Micro-X, Opthea, Orthocell and Telix were down more than three percent; Clarity, Cyclopharm, Imugene and Mesoblast shed more than two percent; with Cochlear, CSL and Nanosonics down by more than one percent.

## PROTAGONIST THERAPEUTICS

Protagonist says its 252-patient, phase IIb trial of icotrokinra for ulcerative colitis met its primary endpoint, with a 63.5 percent clinical response rate and 30.2 remission rate. Last year, the Brisbane-based Protagonist said two phase III studies showed oral icotrokinra, or JNJ-2113, licenced from Johnson & Johnson, led to “significant skin clearance versus placebo in ... plaque psoriasis” (BD: Nov 20, 2024).

At that time, the company said JNJ-2113, formerly PN-235, was a targeted oral peptide that blocked the interleukin-23 (IL-23) inhibitor, which underpinned the inflammatory response in plaque psoriasis and other IL-23-mediated diseases such as ulcerative colitis. Last week, Protagonist said 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 (BD: Mar 4, 2025).

Today, the company said the study of icotrokinra for ulcerative colitis was conducted by its collaboration partner Johnson & Johnson and met its primary endpoint at 12 weeks with a 63.5 percent response rate in patients treated with the highest dose compared to a 27.0 percent response rate for placebo ( $p < 0.001$ ).

Protagonist said that in 2017 it had signed a licence and collaboration agreement with Janssen Biotech, a Johnson & Johnson company which “enabled the companies to work together to discover and develop next-generation compounds that ultimately led to icotrokinra” (BD: May 31, 2017; Mar 27, 2018).

The company said clinical response was a decrease from baseline in the ‘modified Mayo score’ by more than or equal to 30 percent, with either a decrease from baseline in the rectal bleeding sub-score or a rectal bleeding sub-score of zero or one.

Protagonist said 30.2 percent of the highest dose-treated patients showed clinical remission at week 12 compared to 11.1 percent for the placebo group ( $p < 0.001$ ).

The company said clinical remission was a ‘Mayo stool frequency’ sub-score of zero or one with no increase from baseline, a ‘Mayo rectal bleeding’ sub-score of zero and a ‘Mayo endoscopy’ sub-score of zero or one, with no friability present on the endoscopy.

Protagonist said clinical remission continued to improve at week 28.

The company said the study showed clinically meaningful differences compared to placebo in secondary endpoints of clinical remission, symptomatic remission and endoscopic improvement at week 12.

Protagonist said patients were dosed with icotrokinra daily and the drug “was well-tolerated, with the proportions of participants reporting one or more adverse events being similar between the icotrokinra dose groups and the placebo group”.

The company said full results from the study were “being prepared for presentation at upcoming medical congresses by our partner”.

Protagonist chief executive officer Dr Dinesh Patel said the company was thrilled “with the impressive results of once daily oral icotrokinra in the ‘Anthem’ phase II ulcerative colitis study, broadening the potential utility of this first-in-class and only-in-class oral IL-23 receptor antagonist from psoriasis to inflammatory bowel diseases”.

“This is another example of Protagonist’s oral peptide platform delivering transformative, paradigm shifting outcomes in the hands of a world-leading development partner,” Dr Patel said. “Icotrokinra has the potential to transform the treatment landscape in [ulcerative colitis] through its distinctive profile of efficacy, safety, tolerability, and convenience of a once-daily oral treatment.”

“We eagerly await icotrokinra’s further progression into more advanced clinical studies in ulcerative colitis and Crohn’s disease,” Dr Patel said.

On the Nasdaq, Protagonist was up \$US17.60 (\$A28.05) or 45.9 percent to \$US55.95 (\$A89.18) with 5,227,810 shares traded.

## 4D MEDICAL

4D Medical says it has extended its lung imaging analysis software contract with Ohio's Cleveland Clinic for three years at a minimum of \$227,000 a year.

4D Medical said the main campus of the Cleveland Clinic was "a 1,000-bed, multi-specialty clinical and research facility that spans 170 acres".

4D Medical managing-director Prof Andreas Fouras told Biotech Daily that the x-ray velocimetry (XV) technology and the computed tomography lung ventilation analysis software (CT-LVAS) imaging products were included in the software-as-a-service agreement.

4D Medical said the extension ensured "the Cleveland Clinic can continue leveraging 4D Medical's innovative technology to advance respiratory health".

Prof Fouras said the company had "numerous opportunities to expand our existing presence at the Cleveland Clinic, with considerable interest shown at recent congresses in our current and future portfolio, including [computed tomography ventilation-perfusion".

4D Medical fell 1.5 cents or 3.85 percent to 37.5 cents with 1.7 million shares traded.

## RENERVE

Renerve says it has marketing approval for its Nervalign nerve cuff for nerve repair and regeneration in Thailand and has received its first purchase order in Hong Kong.

Renerve said it would work with its partners to commercialize Nervalign in Thailand, which had a population of more than 70 million people "and is popular for medical tourism".

The company said it had an initial stocking order in Hong Kong for Nervalign, the first purchase from a hospital in the region.

Renerve managing-director Dr Julian Chick said Thai approval was a step forward for its Asian operations, plans to expand beyond the US and the Hong Kong order was "a significant milestone".

Renerve fell half a cent or four percent to 12 cents.

## AUDEARA

Audeara says the Sydney-based George & Matilda Eyecare will sell its audio products, beginning with its recently launched Audera Buds hearing aids.

Audeara said George & Matilda was established in 2016 and had more than 115 practices in Australia, increasing Audeara's sales outlets to more than 1,500 clinics.

The company said it expected first sales from George & Matilda stores "in the coming weeks" with an aim to broaden to its full suite of audiology products for patients who may not yet require hearing aids.

Audeara said "additional revenue generating agreements [were] expected near term".

The company did not disclose commercial terms of the deal.

Audeara managing-director Dr James Fielding said the company was "excited to have executed this agreement with George & Matilda Eyecare, which is one of the most trusted names in the Australian eye health and optical retail segment".

"Their reputation, Australian market footprint and our innovative audio technology has the potential to reach a broad customer base, who are expected to considerably benefit from the company's solutions," Dr Fielding said.

"Importantly, this agreement will unlock another sales channel in the Australian market for the company's hardware products and build on our established footprint of 1,500 clinics," Dr Fielding said.

Audeara was untraded at 3.9 cents.

## POLYNOVO

Polynovo says Swami Raote will step down as chief executive officer, effective immediately, with director Dr Robyn Elliott appointed acting chief executive officer. Polynovo said Dr Elliott had agreed to fill the role of acting chief executive officer pending the appointment of a permanent replacement and would remain on the board.

The company said it had “failed to reach an agreement with Mr Raote following the conclusion of confidential discussions”.

Polynovo said that Mr Raote would cease his employment on June 10, 2025, “but step down as chief executive officer effective immediately”.

Last week, Polynovo said that following media speculation, it was proposed that chief executive officer Mr Raote cease his employment from June 2025 and Dr Elliott would be acting chief executive officer, but that no agreement reached (BD: Mar 7, 2025).

Yesterday, the company said “some issues were raised” about interactions between chair David Williams and some executives and said it had ensured “a positive, safe and inclusive workplace” (BD: Mar 10, 2025).

Today, Polynovo said “after careful consideration the board has come to the conclusion that a change in [its] chief executive officer is in the best interests of [Polynovo] at this time and that new leadership is required to continue the company’s growth”.

The company said Mr Raote had been requested to be available to assist the acting chief executive officer with the transition as required by her until the cessation date.

Polynovo said that Mr Raote would be paid his usual salary and benefits up-to June 10, 2025, with unvested options at that date to lapse, and that 64,022 escrowed shares would become freely available to him on, or about, September 30, 2025.

The company said that it “thanks Mr Raote for his service to the company over the past nearly three years, and the contributions he has made to the business over that time”.

“These include overseeing a period of growth of the company’s operations globally and the transformation and expansion of the company’s manufacturing and research and development capability,” Polynovo said.

The company said Dr Elliott had retired as CSL’s head of portfolio management and was previously the managing-director of IDT Australia.

Polynovo fell 10 cents or eight percent to \$1.155 with 8.5 million shares traded.

## PRESCIENT THERAPEUTICS

Prescient says it has promoted its director and Patrys managing-director Dr James Campbell to chair following Steven Engle’s retirement, effective from March 30, 2025.

Prescient said Mr Engle had been its chair for more than 10 years and that it was searching “for a new non-executive director who can replace Dr Campbell as chair of the audit and risk committee when he assumes the role of board chair”.

Mr Engle said he was “honored to have played a role in guiding Prescient to the company it is today [...] a dynamic management team with a phase II stage clinical product targeting T-cell lymphoma, a life-threatening disease, and with a next generation immunotherapy, Omnicar in development”.

Prescient fell 0.2 cents or 4.65 percent to 4.1 cents with 1.2 million shares traded.