



# Biotech Daily

Wednesday March 26, 2025

*Daily news on ASX-listed biotechnology companies*

- \* **ASX UP, BIOTECH DOWN: GENETIC SIGNATURES UP 8%; 4D DOWN 10%**
- \* **FEDERAL BUDGET 2025; COMMENT & RESPONSE:**  
**ATSE, TCA, AUSBIOTECH, MTP CONNECT, RSM AUSTRALIA**
- \* **LTR: 'ROXUS' VARDENAFIL SPRAY; FDA SPONTAN PRE-IND MEETING**
- \* **ORTHOCELL 1st GERMANY, AUSTRIA, SWITZERLAND STRIATE+ SALE**
- \* **CLINUVEL: 'PRENUMBRA FUNCTIONAL IMPROVEMENT FOR STROKE'**
- \* **PRESCIENT OPENS 1st PHASE IIb PTX-100 SITE**
- \* **ECP, POHL BELOW 5% OF NANOSONICS**
- \* **ISLAND CO-FOUNDER DR BILL GARNER INCREASES, DILUTED TO 16%**
- \* **ISLAND M-D DR DAVID FOSTER BELOW 5%**
- \* **CONTROL BIONICS FOUNDER PETER FORD OUT; STEPHANIE PHILLIPS IN**
- \* **4D MEDICAL \$6.5m COST, STAFF CUTS; CFO, CO-SEC OUT**

## MARKET REPORT

The Australian stock market was up 0.71 percent on Wednesday March 26, 2025, with the ASX200 up 56.5 points to 7,999.0 points. Twelve of the Biotech Daily Top 40 companies were up, 17 fell, 10 traded unchanged and one was untraded. The four Big Caps were mixed.

Genetic Signatures was the best, up four cents or 7.6 percent to 56.5 cents, with 16,119 shares traded. Orthocell climbed 4.7 percent; Immutep was up 3.45 percent; Clinuvel, EBR and Resonance rose two percent or more; Amplia, Micro-X, Proteomics, Starpharma and Telix were up one percent or more; with Cochlear, Medical Developments and Resmed up by less than one percent.

4D Medical led the falls (see below), down 3.5 cents or 9.9 percent to 32 cents, with 3.6 million shares traded. Impedimed lost 6.5 percent; Neuren and Nova Eye were down more than five percent; Dimerix fell 4.2 percent; Clarity was down 3.7 percent; Cynata, Imugene, Nanosonics, Polynovo, Prescient and Syntara shed more than two percent; Avita, CSL, Cyclopharm, Mesoblast and SDI were down more than one percent; with Emvision and Pro Medicus down by less than one percent.

## FEDERAL BUDGET 2025

Federal Treasurer Dr Jim Chalmers did not cite biotechnology in his fourth Budget speech, but the Budget papers say that spending on general research and the Federal Research and Development Tax Incentive will fall.

Dr Chalmers told the Parliament that the five main priorities were cost of living, strengthening Medicare, housing, education and building a stronger economy.

Dr Chalmers said there would be two new tax cuts along with increased energy relief, including \$150 a year for households and small business. He said the Government would cut university student debt by \$19 billion for more than three million Australians.

Dr Chalmers said there would be \$8.5 billion more for Medicare to encourage greater bulk-billing. He said that the cost of Pharmaceutical Benefits Scheme (PBS) medicines would fall from \$31.60 to \$25.00 while pensioners and Health Care Card holders would pay \$7.70 per prescription. Dr Chalmers said that Labor initiatives like the PBS would not be daunted by “foreign multinationals”.

He said the Government would allocate \$793 million for women’s health including endometriosis, contraception and “new menopausal hormone therapies”.

Dr Chalmers reaffirmed the Government’s commitment to fee-free Technical and Further Education as well as ending “non-compete clauses” for three million Australians, saying that people shouldn’t need a lawyer to change jobs.

The Budget papers said the Government “will provide \$158.6 million over five years from 2024–’25 to support research and translate medical research to clinical practice, including: \$150.3 million over five years from 2024–’25 to extend and expand the Zero Childhood Cancer Precision Oncology Medicine Program (Zero), and to extend the Precision Oncology Screening Platform Enabling Clinical Trials (Prospect) program and the Australian Rare Cancers Portal (ARC Portal)”.

The Budget papers said that there would be “funding to support an intergovernmental agreement for the cooperative governance and development of the National One Stop Shop for Clinical Trials and Human Research”.

The Budget said that the Government would provide \$55.0 million over four years from 2025–’26 “to maintain the research capability of the Commonwealth Scientific and Industrial Research Organisation”.

The Budget papers said that payments related to the Research and Development Tax Incentive program were expected to increase by \$55.8 million in 2025–’26 and decrease by \$640.6 million over five years to 2028–’29, “largely reflecting lower-than-expected numbers of claims”.

The Budget papers said that general research funding would fall from \$4,776 million in 2024–’25 to \$4,527 million in 2025–’26 and to \$4,425 million in 2028–’29, including science services and innovation fund, discovery research and training, linkage partnerships science and commercialization.

## AUSTRALIAN ACADEMY OF TECHNOLOGICAL SCIENCES AND ENGINEERING

The Australian Academy of Technological Sciences and Engineering says the Budget “picks a welcome winner in green metals” with tax cuts, energy bill credits and the beer excise freeze, providing cost of living relief.

“These are not, however, the policies that will power long-term economic growth,” the Academy said.

“Bold initiatives that will shape a resilient economy of the future – such as a commitment to re-thinking Australian [research and development] investment through the Strategic Examination of Research and Development; the Universities Accord; and the Diversity in STEM reviews – were ignored in tonight’s budget,” ATSE said.

“ATSE continues to call for significant, bipartisan, sector-wide investments in science, technology and innovation to safeguard Australia’s economy,” the organization said.

ATSE chief executive officer Kylie Walker said that “investments in future Australian innovators and innovations are a must to help the nation become a key global player in research and development”.

“Bold initiatives that will shape the resilient economy of the future need ample resourcing,” Ms Walker said.

“Australia’s future economic resilience will be narrow if it is not built on investments in innovation and STEM skills as drivers of economic prosperity,” Ms Walker said.

Ms Walker welcomed the announcement of investments in key science and technology infrastructure and workforce, providing crucial ongoing support for the national research and development agency Commonwealth Scientific and Industrial Research Organisation, and in the areas of nuclear medicine, biosecurity and the National Measurement Institute.

“ATSE also welcomes the new investment in public schooling, including in science and engineering education,” Ms Walker said.

The organization said it hoped “to see further commitments across education and innovation to enable Australia to play a global role in developing and profiting from the technologies of the future”.

## THE TECH COUNCIL OF AUSTRALIA

The Tech Council of Australia said it supported “a range of initiatives announced in the Budget to grow skills, and to support the development of energy technology to advance Australia’s economic growth”.

The TCA said it was “disappointed that no explicit [technology] sector investment was included in the package of budget measures”.

“This is a missed opportunity to build our national competitiveness – at a time of domestic productivity decline, and of critical global trade volatility,” the Council said.

“The TCA will continue to engage with the Government to ensure that technology investment sits front-and-centre of its 2025 election platform,” the organization said.

“Technology investment complements the Government’s Future Made in Australia, training and education programs, which reflect a welcome focus on building sovereign industry capability,” the organization said.

“We encourage the Government and the Opposition to formalize their support of our Tech Investment Target: to expand both [research and development] investment and technology adoption to comprise 4.6 percent of Australia’s share of GDP within the next decade,” the Tech Council said.

“There are several Budget measures, including training and business cost-relief, that contribute to this goal,” the TCA said.

“We welcome the Government’s commitment to drive innovation in the renewable energy transition, which includes a \$2 billion investment through the Clean Energy Finance Corporation,” the Council said.

“This aligns with the mission of our Consumer Energy Tech Alliance which is to expand Australian-grown technology solutions for grid orchestration, empowering consumers to optimize energy use through behind-the-meter solutions and reduce energy bills,” the TCA said.

“We look forward to working with the Government as we await details on announced changes to non-compete clauses and how these may impact tech businesses,” the TCA said.

### [AUSBIOTECH](#)

Ausbiotech said that while no new significant commitments were made for Australia’s life sciences sector in the 2025-’26 Federal Budget, the organization “remains steadfast in its advocacy to unlock the full potential of this critical industry for Australia’s health, economic future and security”.

Ausbiotech said that Dr Chalmers “outlined a commitment to making Australia’s economy stronger, more productive and more resilient ... [including] investing in our competitive advantage, fostering resilient supply chains and building a Future Made in Australia.”

The industry organizations said that Australia’s life sciences sector was “central to these priorities, providing essential contributions to health security, sovereign capability in medical manufacturing and economic diversification, backed by considerable competitive advantages”.

Ausbiotech said it welcomed “the continued investment in key industry programs, including the Industry Growth Program, National Reconstruction Fund, Cooperative Research Centres and the Research and Development Tax Incentive”.

“Additional funding of \$10 million over four years has been allocated to CSIRO for gene technology research, and the first stage of a refit for the Australian Centre for Disease Preparedness has been approved,” Ausbiotech said.

“Support remains for the Medical Research Future Fund and the National Health and Medical Research Council, however, it's also clear that [research and development] funding is not keeping pace with the need here in Australia,” Ausbiotech said.

Ausbiotech chief executive officer Rebekah Cassidy said that Australia was “a global leader in scientific research, ranking in the top 10 on the Global Innovation Index, [but] we have fallen to thirtieth for research outputs”.

“Now more than ever, Australia’s life sciences sector requires unified, coordinated, and collaborative representation between industry and government,” Ms Cassidy said.

Ausbiotech said it called on the Government to: develop Australia’s first whole-of-government National Life Sciences Strategy to set policy priorities, eliminate gaps and overlaps; establish an Australian Life Sciences Council in partnership with industry and government to drive this strategy, address sector challenges and ensure value for investment; recognize life sciences as the next priority sector under the Future Made in Australia Act; and invest in data collection to drive innovation and improve policy and decision making.

### [MTP CONNECT](#)

MTP Connect chief executive officer Stuart Dignam said that the Federal Budget was “a bit of a surprise - the most ‘pre’ of pre-election budgets”.

“With more than \$1 billion set aside in the budget for ‘new programs’ - decisions taken but not yet announced - we’re now looking to the next six weeks of election campaigning for commitments to the sort of targeted, strategic initiatives that will directly support our life science start-ups, [small and medium-sized enterprises] and entrepreneurs,” he said.

“Things like action on anti-microbial resistance to save lives, making life sciences a priority under the Future Made in Australia plan, and the establishment of a whole-of-government life sciences council,” Mr Dignam said.

“The commitment to women’s health services is particularly welcome; even better would be supporting Australian innovators to bring their home-grown medical devices and drugs to market to be included in those services to improve health and wellbeing for Australians,” Mr Dignam said.

“And additional funding to support the largest cancer genomics initiative in Australia, the Prospect program, is a positive step towards matching patients to trials and new therapies,” Mr Dignam said.

“And while changes to non-compete clauses will help with mobility within an existing workforce, in areas like complex therapeutics manufacturing where our sector has been investing in infrastructure, there’s an urgent need to skill-up and grow the actual size of this specialized workforce,” Mr Dignam said.

“We need thousands of new and skilled workers over the next few years and if we can’t address that shortage now, we’ll just have a bidding war for the scarce few with the necessary skills, and we’ll cruel prospects for future growth of this critical, sovereign advanced manufacturing capability,” Mr Dignam said.

#### [RSM \(ROBSON RHODES, SALUSTRO REYDEL, MCGLADREY\) AUSTRALIA](#)

The Perth-based accountancy firm RSM Australia said that “no changes were announced to the [Federal Research and Development] Tax Incentive program, but noted that the Strategic Review into research and development was underway, with submissions due by April 11, 2025.

RSM Australia partner Jessica Olivier said that expenditure on the RDTI program was “likely to increase over the period from 2025-’26 to 2028-’29, due to the expected rise in the number of R&D claims by eligible companies and the increased quantum of those claims made”.

“A second Federal Budget 2025-’26 is likely to be handed down later in the year, possibly October once a new government has been installed after the expected May Federal election”, Ms Olivier said.

“A post-election Budget would be expected be more policy-heavy at the start of the Parliamentary cycle,” Ms Olivier said.

Ms Olivier said that the Budget papers confirmed that the Government would provide \$158.6 million over five years from 2024-’25 to support research and translate medical research to clinical practice.

RSM Australia said that investment in artificial intelligence (A.I.) training and implementation “has been very much front of mind for the technology sector on the back of lower productivity and concerns around Australia’s competitiveness on the global A.I. stage”.

RSM national technology leader Mathavan Parameswaran said the firm was “disappointed to see no further announcements in relation to investment into [artificial intelligence]”.

“While the development of the National A.I. Capability Plan back in December was a positive first step, the lack of continued investment in this year’s Federal Budget will make it even tougher to achieve success and for Australia to be competitive globally,” Mr Parameswaran said.

“More broadly, technology will be critical in overcoming Australia’s productivity woes and investment into digital literacy nationwide is critical in driving further technology adoption and investment would have been welcomed by the sector had it been provided,” Mr Parameswaran said.

“We do welcome the announcement of \$2 billion being recapitalized into the [Clean Energy Finance Corporation] to allow for further investment in renewable energy, energy efficiency and low emissions technologies,” Mr Parameswaran said.



## LTR PHARMA

LTR says it is developing a second vardenafil-based nasal spray, called 'Roxus', and the US Food and Drug Administration "broadly endorsed" its Spontan development plans. LTR said it was developing Roxus, a nasal spray based on vardenafil, marketed by Bayer as Levitra, for erectile dysfunction with a "pharmaceutical partner in Australia".

The company said Roxus would be submitted for US approval via the 503(a)-compounding pharmacy pathway, allowing "early market entry while Spontan progresses through FDA approval", with testing expected to be completed in the coming six months. LTR executive chair Lee Rodne told Biotech Daily he was not at liberty to describe the technical differences between Roxus and Spontan but said Roxus had been developed specifically for the US market and hoped to launch the product for erectile dysfunction in early to mid-2026.

The company said it had discussed Spontan's development in a pre-investigational new drug application meeting with the FDA, which included a non-clinical toxicology component and a chemistry, manufacturing and controls component.

LTR said the FDA had agreed on a clinical development path that included "one pivotal safety and efficacy trial and a multi-dose pharmaco-kinetic study" that would reinforce Spontan's labelling and commercial positioning, with a clear guideline for US approval.

The company said it would work with Aptar Pharma and other clinical research organizations to complete the required studies ahead of a new drug application.

LTR said it would investigate using the additional data needed for US clearance in other regulatory submissions, with a pre-submission meeting with the Australian Therapeutics Good Administration expected by July 2025.

Last year, the company said the first patients had been prescribed Spontan under an Australian TGA special access scheme (BD: Aug 5, 8, 16, 2024).

Mr Rodne said the company's positive FDA pre-investigational new drug meeting had "provided regulatory clarity while unlocking immediate and mid-term commercial opportunities in the US".

"As Spontan moves through the formal FDA process, Roxus offers a fast-track pathway to serve patients through personalized care channels," Mr Rodne said.

LTR fell 4.5 cents or 9.4 percent to 43.5 cents with 4.1 million shares traded.

## ORTHOCELL

Orthocell says it has completed the first sale of its Striate+ dental guided bone and tissue regeneration device in the Germany, Austria and Switzerland region.

Orthocell said exclusive distribution partner Biohorizon's subsidiary, Biohorizons Camlog, was responsible for the marketing and distribution of Striate+ in Europe and the UK and had completed "its targeted pre-launch activities, placed first orders and is now actively selling Striate+ in the [Germany, Austria and Switzerland] region".

In 2022, the company said it received \$21,420,144 from Birmingham, Alabama's Biohorizons to licence its Striate+ for bone repair (BD: Jun 28, Jul 21, 2022).

Today, Orthocell said its Striate+ sterile, resorbable collagen membrane was approved for use in the US, Australia, New Zealand, Europe, the UK, Canada and Singapore, with the expansion into Germany, Austria and Switzerland to "significantly increase the revenue opportunity for the company".

The company did not disclose the commercial terms of the sale.

Orthocell said it expected approval for Striate+ in Brazil "within the next here months, with further regulatory applications under review".

Orthocell was up seven cents or 4.7 percent to \$1.57 with 1.8 million shares traded.

## CLINUVEL PHARMACEUTICALS

Clinuvel says early results show eight of nine patients in its phase IIa trial of Prénumbra Instant, or afamelanotide, for stroke had functional improvement at day 42.

In 2023, Clinuvel said it dosed the first of 12-patients in its 42-day, phase II trial evaluating the safety and efficacy of Prénumbra Instant in arterial ischaemic stroke patients ineligible for standard-of-care treatment, which included three mild-to-moderate stroke, three moderate-to-severe stroke and three severe stroke patients (BD: Mar 20, May 9, 2023).

At the time, the company said its hormone analogue, brain tissue protecting, anti-oxidant and anti-swelling drug afamelanotide was well-tolerated in all three mild-to-moderate stroke patients, with functional improvement observed after dosing.

Today, Clinuvel said the study showed Prénumbra was well-tolerated in all nine patients, with all treatment-related adverse events mild, transient and consistent with the drug's established safety profile.

The company said eight of nine patients (88.9%) showed an "improvement in initial stroke symptoms and neurological disability following treatment with afamelanotide" as measured by reduced National Institutes of Health Stroke Scale and functional disability scores.

Clinuvel said magnetic resonance imaging (MRI) showed that the infarct size, or dead brain tissue volume due to stroke, had decreased or stabilized in six of nine patients.

The company said two of the three moderate-to-severe stroke patients died "due to complications unrelated to afamelanotide treatment", one of whom died two months after study completion.

Clinuvel chair Prof Jeffrey Rosenfeld said while progress had "been made in treating stroke with approved therapies, a large number of patients remain ineligible for existing therapies".

"Afamelanotide represents an innovative approach, taking a drug with a long-standing safety profile and evaluating whether a known mechanism of action may provide a therapeutic option for these previously untreated patients," Prof Rosenfeld said.

"While the stroke program is not an immediate focus for the business, I expect our teams will be able to use these data to support future decision making that may result in positive outcomes for patients," Prof Rosenfeld said

Last year, Clinuvel said it had "temporarily suspended" its stroke, Parkinson's disease and xeroderma pigmentosum (XP) clinical programs "streamlining the current operations" (BD: Nov 18, 2024).

Clinuvel was up 34 cents or 2.9 percent to \$12.04 with 214,211 shares traded.

## PRESCIENT THERAPEUTICS

Prescient says it has completed the first site initiation visit for its about 40-patient, phase IIa trial of PTX-100 for relapsed and refractory cutaneous T-cell lymphoma.

Last year, Prescient said it had US Food and Drug Administration investigational new drug approval for a phase II trial of PTX-100 for T-cell lymphoma cancer (BD: Dec 19, 2025).

Today, the company said the open-label study would be conducted at multiple sites in Australia, the US and Europe to evaluate two dosage levels of PTX-100, with a primary endpoint of efficacy and secondary endpoints including safety.

Prescient chief executive officer James McDonnell said the completion of the first site initiation visit was "a key milestone in our development of PTX-100 as a potential [cutaneous T-cell lymphoma] treatment".

"We look forward to continuing our progress with more study site initiations and achieving the next milestone of first patient in and dosed in the coming weeks," Mr McDonnell said.

Prescient fell 0.1 cents or 2.3 percent to 4.3 cents.



### NANOSONICS

ECP Asset Management Pty Ltd says with Emmanuel Pohl, EC Pohl, BNP Paribas, Citicorp and JP Morgan it has ceased its substantial shareholding in Nanosonics.

The Sydney-based ECP said it bought and sold shares on market between February 21 and March 21, 2025, with the single largest sale of 1,337,888 shares on March 20 for \$6,516,185, or \$4.87 a share.

Nanosonics fell 12 cents or 2.6 percent to \$4.57 with 1.4 million shares traded.

### ISLAND PHARMACEUTICALS

Island co-founder Dr Bill Garner says he increased and been diluted in the company from 28,386,852 shares (18.42%) to 33,198,166 shares (15.79%).

The Puerto Rico-based Dr Garner said that he acquired 4,811,314 shares in a placement on December 4, 2024 for \$336,792, or seven cents a share and was diluted on March 19, 2025.

Last week, the company said that it had raised \$1,941,586 through the exercise of options issued in a March 2024 rights issue, in addition to a previous \$779,413, for a total \$2,720,999 (BD: Mar 19, 2024; Mar 19, 2025).

Island was up 1.5 cents or 8.6 percent to 19 cents.

### ISLAND PHARMACEUTICALS

Island managing-director Dr David Foster says he has increased his substantial shareholding in the company and has been diluted through the exercise of options.

The Dallas, Texas-based Dr Foster said that on February 12 and March 5, 2025 he exercised 20,588 options and 500,000 options for \$1,235 and \$30,000, respectively, or 6.0 cents each, and was diluted on March 19, 2025 (see above).

### CONTROL BIONICS

Control Bionics says it has appointed Dr Stephanie Phillips as a director, effective today, with founder Peter Ford to resign, effective from March 31, 2025.

Control Bionics said Dr Phillips was a consultant anaesthetist and clinical professor at Canberra's Australian National University and had been deputy head of school and academic lead for education at the University of Sydney and Sydney Adventist Hospital Clinical School as well as managing-director of Northern Specialist Anaesthetics.

According to her LinkedIn profile, Dr Phillips held a Bachelor of Medicine from New South Wales' University of Newcastle.

The company said Mr Ford's "vision and passion were the driving force behind the creation of Control Bionics ... [and that his] insight in 1999, that damaged muscles still emit usable electrical signals, led to the development of the Neuronode and the founding of the company".

Control Bionics said Mr Ford remained "a significant shareholder" of the company.

Control Bionics chair Dr Samuel Straface said "on behalf of the entire board, I would like to sincerely thank Mr Ford for his extraordinary contribution to Control Bionics over the past 25 years".

"His innovation, leadership and unwavering belief in the power of technology to change lives has left an indelible mark on the company," Dr Straface said.

Control Bionics was up 0.2 cents or 5.7 percent to 3.7 cents.

#### 4D MEDICAL

4D Medical says it has taken “decisive steps to optimize operational efficiency” including staff cuts to save an initial \$6.5 million a year.

4D Medical said it had been able to “reduce the total number of employees, and retain key talent in our Australian employee base, in a cost-effective manner”, partly due to Australian staff-related costs being offset by the Federal Government’s Research and Development Tax Incentive program.

The company said chief financial officer Simon Glover and company secretary Naomi Lawrie had “both left the company”, with the positions to be “covered by a combination of existing resources within the company and usage-based outsourced services”.

4D Medical said it had appointed financial controller Chris Cox as interim chief financial officer and Bio101 director Hamish George as company secretary.

The company said that as it matured, the organizational structure and operational activities required had changed, including its functional and structural lung imaging products requiring less research and development capacity.

4D Medical said it had material cost efficiencies in its clinical trial program due to its increased focus on computed tomography (CT)-based analysis, such as its CT ventilation perfusion (VQ) product compared to XV lung ventilation analysis software (Lvas), “resulting in more clinical evidence at a lower cost”.

The company said the cost-saving initiatives were expected to have “no impact” on its ability to deliver on its revenue targets or upcoming milestones.

4D Medical managing-director Prof Andreas Fouras said peak operating costs were “well behind us, while revenue continues to grow strongly”.

“Nevertheless, in the current macro-economic environment, it is prudent to expand and accelerate cost reduction measures,” Prof Fouras said.

“In combination with previously realized savings and our just-completed capital raise, these measures protect core activities,” Prof Fouras said.

4D Medical fell 3.5 cents or 9.9 percent to 32 cents with 3.6 million shares traded.