Biotech Daily

Friday September 26, 2025

Daily news on ASX-listed biotechnology companies

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MARKET REPORT

The Australian stock market edged up 0.09 percent on Friday September 26, 2025, with the ASX200 up 7.5 points to 8,780.5 points. Eighteen of the Biotech Daily Top 40 companies were up, 17 fell, four traded unchanged and one was untraded.

Orthocell was the best, up 14.5 cents or 12.55 percent to $1.30, with 2.15 million shares traded. Paradigm climbed 11.1 percent; Proteomics rose 9.4 percent; Cynata was up 7.3 percent; 4D Medical, Actinogen and Botanix were up more than three percent; Aroa, Emvision, Impedimed, Nanosonics and Resonance rose more than two percent; Genetic Signatures and Medical Developments were up more than one percent; with Avita, Clarity, Clinuvel, Micro-X and Resmed up by less than one percent.

Amplia led the falls, down one cent or 6.25 percent to 15 cents, with 6.2 million shares traded. Compumedics and Polynovo lost more than five percent; Starpharma fell 4.35 percent; Atomo, Imricor, Mesoblast and Telix were down more than three percent; Cyclopharm, EBR, Medadvisor and Pro Medicus shed more than two percent; with Cochlear, CSL, Dimerix, Imugene, Neuren, Optiscan, Prescient and SDI down by more than one percent.

DR BOREHAM'S CRUCIBLE: 4D MEDICAL

By TIM BOREHAM

ASX code: 4DX

Share price: $1.81

Shares on issue: 500,021,335 (this figure will change as options are exercised)

Market cap: $905.0 million

Chief executive officer: Prof Andreas Fouras

Board: Lilian Bianchi (chair), Prof Fouras, Dr Robert Figlin, John Livingston, Julian Sutton and Dr Geraldine McGinty

Financials (Year to June 30, 2025): operating revenue $5.85 million (up 56%), research and development concession/government grants $10.6 million (down 3%), cash of $6.87million (down 77%)

Identifiable major shareholders: Prof Andreas and Helen Fouras 13.1%, Paul Tomlin 0.62%, Chandler Bridge 0.5% Alex and Christine Petrou 0.5%, Dr Sam Hupert 0.4%.

You make your own luck - and 4D Medical has enjoyed that commodity in shovel-loads over the last month.

It all started in August when the lung scanning innovator inked a deal with the giant ASX-listed Pro Medicus, involving a $10 million loan and the hint of other liaisons to come.

On September 1, 4D Medical ushered in Spring with the Big One: US Food & Drug Administration (FDA) assent for its ventilation perfusion device, CT VQ.

4D founder and CEO Prof Fouras describes the news as a "transformational milestone".

"We couldn't be more excited," Prof Fouras said. "This is great news for patients, great news for doctors and great news for our shareholders."

Investors agreed, with 4D shares soaring up to 40 percent on the day - and that was only the entrée. Two days later, the company said the US Centers of Medicare and Medicaid Services had granted public reimbursement for the device, at $US650.50 a scan.

Securing payment is almost as important as the FDA approval itself.

What's all the fuss about?

In short, CT VQ is the "the world's first and only non-contrast, [computed tomography]-based ventilation-perfusion imaging technology".

A VQ scan is a specialized nuclear medicine procedure that evaluates both airflow (ventilation) and blood flow (perfusion) in the lungs.

The test creates images showing how well air and blood flow are distributed throughout the bellows, helping doctors identify areas of imbalance.

VQ scans are primarily used to diagnose pulmonary embolism (blood clots in the lungs), a potentially life-threatening condition. CT VQ can also evaluate other conditions, such as asthma and chronic obstructive pulmonary disorder (COPD).

“We got a pretty rare win, in that the FDA did only one round of seeking additional information,” Prof Fouras says. “There were zero questions about our clinical trials.”

Prof Fouras says CT VQ appeals on the grounds of ease of use, cost and patient benefits.

As software, CT VQ piggybacks off - but does not replace - an extensive base of 14,500 US CT scanners.

Unlike the standard-of-care, the scans don’t involve the patient inhaling radioactive ‘dust’ and the use of potentially hazardous contrast agents.

“The hospital either needs to make the dust on site, or have it delivered within a short time frame,” Prof Fouras says. “Nuclear medicine is an expensive procedure with relatively poor resolution.”

CT VQ scans suit rural and smaller healthcare facilities lacking nuclear medicine infrastructure.

LVAS is still in the building …

Amid the excitement about CT VQ, it’s easy to overlook that 4D already has two home-grown approved products in the US.

These are the lung ventilation analysis software (XV LVAS), which interfaces with current imaging techniques, uploading the images to produce a “rich high-resolution picture of the lungs”.

The technology ‘sees’ what the lung is doing and can detect conditions including emphysema, COPD, lung cancer, asthma and occupational diseases such as silicosis.

In May 2020, the FDA approved XV LVAS for imaging any lung indication, with Australia’s Therapeutic Goods Administration (TGA) following in September 2020.

In late 2023 the FDA also ticked off CT LVAS. Unlike CT VQ, LVAS involves altering clinical workflows.

“We see really big opportunities for [LVAS], but it’s a process of educating the market and doctors so they see the value proposition,” Prof Fouras says.

… but CT VQ steals the limelight

In the US, about $US5 billion of perfusion imaging takes place each year and of that, nuclear imaging accounts for about $US1.1 billion - 4D's starting point for CT VQ.

"Over time, we expect to own that whole sector," Prof Fouras says.

Prof Fouras says CT VQ can be substituted for nuclear scans with at least as good a result, but with more convenience and at a lower price (with higher reimbursement).

"It's an easier sell than teaching someone about the benefits of doing something new."

While the US is the home of nuclear medicine, about 60 percent of lung imaging is done with antiquated planar (2-dimensional) techniques.

The modern method is three-dimensional, single-photon emission computed tomography (Spect) imaging. All the more reason to switch to CT VQ!

Veterans' contract is a slow burn

Until recently, 4D's commentary focused on the unaddressed need to scan US veterans with lung diseases.

Most notably, these ailments result from exposure to 'burn pits' - bulldozed holes in war zones, in which items and substances are combusted indiscriminately. The result is plumes of acrid, black smoke.

Specific Biden-era legislation supports spending on veterans' respiratory illnesses. About 5.5 million US veterans deployed to Middle East conflicts have developed hard-to-diagnose diseases - such as constrictive bronchiolitis - that current methods can't detect.

4D is vying for a lung imaging contract with the sprawling Department of Veterans Affairs (DVA), which spans 176 hospitals, thousands of clinics and 400,000 employees. However military decision-making is notoriously slow and the political turmoil engulfing the US has not helped.

"We under-estimated the organizational turbulence and distraction and the impact on day-to-day business," Prof Fouras says.

However, the company did anticipate - correctly - that the Republicans would boost veterans' health spending.

4D's entreaties to the DVA are in league with Philips. The $US30 billion medical technologies giant provides imaging equipment to almost half of US veterans' lung screening clinics.

"DVA is still an opportunity, but we have stopped putting it on the front foot with investors," Prof Fouras says. "The DVA are not fast, but they can 'do big'".

How it all started

Going back in the Tardis, Prof Fouras' inspiration for 4D was a case of blowing in the wind - literally.

A Melbourne-based mechanical engineer, he frequented Monash University's wind tunnel laboratories and realized there was a better way to measure air movement through the lungs.

He founded 4D in 2012, having ploughed all of his own money into the venture.

The company listed on the ASX on August 7, 2020 at 73 cents a share, after an over-subscribed initial public offer.

In 2023, the company then signed a memorandum of understanding with the aforementioned Philips, which was upgraded to a reseller contract this year.

In December 2023, 4D bought Imbio, a private US outfit specializing in artificial intelligence-based lung and heart analysis.

4D paid $US25 million of upfront cash and up to $US20 million of earn outs.

Imbio had five FDA-approved products, covering functions such as screening chronic obstructive pulmonary disease (COPD) patients for suitability for valve treatment.

What about Australian lungs?

Proudly Australian, 4D is not ignoring its home turf where about 80 hospitals and clinics are using LVAS.

The company expects the FDA assent for CT VQ to translate to TGA assent.

This month, the company said it had signed agreements with the Royal Melbourne Hospital (RMH) and Spectrum Medical Imaging to deploy LVAS.

RMH will assess 4D's full portfolio and will be the first public hospital to do so.

The pilot program includes imaging for the recently initiated National Lung Cancer Screening Program.

Other 4D users are Integral Diagnostics, the country's second biggest radiology imaging chain, Jones Radiology, Q Scan, and Perth Radiological Clinic.

But the economic reality is that in the US the company can make three times as much per scan than here, with a patient population 15 times larger.

"So, you can make 45 times more money selling healthcare in the US than you can in Australia."

Finances and performance

Prof Fouras says that in carrying out an equity raising last February and March, thanks to now in-the-money options, the company inadvertently did its next one as well.

4D raised $13.9 million by way of a $5.5 million placement at 42.5 cents and $8.4 million in an oversubscribed share purchase plan, at 36 cents apiece.

Holders received one option for each share, exercisable at 55 cents, expiring nex t Wednesday, October 1.

If all of these 41.2 million options are converted, $22.7 million will flow into 4D's coffers (some holders will forget to exercise them).

On exercise, holders receive one share and one attached 'piggyback' option, exercisable at 75 cents by September 1, 2027. This would raise up to a further $30.9 million.

Separately, 4D has 22.1 million listed options exercisable at $1.365 by December this year. If fully exercised, these would raise $30.2 million.

So, there's an almost certain $52.9 million by the end of 2025, plus any 'piggyback' conversions.

Including other options exercisable at various amounts and various times, 4D could raise up to $83.9 million over the next few years.

Merely a month ago, the options weren't in the money and most holders wouldn't have bothered to exercise them.

4D reported operating revenue of $5.9 million for the year to June 30, 2025, up 56 percent.

Of that, software-as-a-service income accounted for $5.7 million, up 89 percent. The remainder was leasing and maintenance income.

Of the revenue, 98 percent derived from the US.

4D's net loss contracted to $30 million, from just under $36 million previously.

During the June quarter, the company's software undertook 74,000 "structural and functional" scans, up 35 percent year-on-year.

As of June 30, the company held cash of $6.87 million, down 77 percent. But that was before Pro Medicus's $10 million, a $6 million Federal Research and Development Tax Incentive and "the oppies".

Over the last 12 months 4D Medical shares have traded between 24 cents on July 31, 2025 (an historic low) and $2.31 on September 1 (pushing 4D's market cap beyond $1.1 billion).

4D shares actually peaked at $2.38 on October 9 2020, but there were fewer shares on issue then.

Bizarrely, earlier this month, 4D Medical was demoted from the S&P All Ordinaries index.

The index guardians evidently decided on this before 4D's September share romp, which also greatly boosted daily turnover.

"No doubt the next time around they will be putting us back in," Prof Fouras says.

Dr Boreham's diagnosis:

4D now faces the hard graft of taking CT VQ to market. But given the clinical and monetary benefits, this shouldn't be too hard a sell.

Naturally, 4D will tackle the biggest clinics with the highest scan volumes.

These include University of California San Diego (for pulmonary embolism) and Cleveland Clinic for COPD.

"We will use every lever and channel we have to get this product to market," Prof Fouras says.

"The sales teams will be beating the doors down to the hospitals."

Amid the euphoria, investors should remember 4D's revenue and earnings ramp-up won't happen overnight.

Broker Bell Potter forecasts revenue of $11.5 million and a $20.8 million reported loss for the year to June 2026.

This improves gradually to revenue of $40 million and a $13 million deficit in the year to June 2028.

Prof Fouras hopes 4D can achieve profitability in less than three years.

4D's fortuitous run is an antidote to this year's drug trial and approval setbacks for the ASX-listed drug development sector.

Left to their own 'devices', the medtechs (medical technologies) are doing well, with EBR, Orthocell, Artrya and Nanosonics this year winning FDA approvals.

"We feel it is a non-brainer," Prof Fouras says of CT VQ take-up. "We don't see why anyone over the long term would stick to the old tech."

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. If left to his own devices, he promises not to tool around.

INOVIQ

Inoviq says it will pay up-to $360,000 to licence exosomal biomarkers for ovarian cancer from Uniquest, the University of Queensland's commercialization company.

In 2022, Inoviq said it would expand its exosome-based ovarian cancer screening test development program with the University of Queensland, which would further evaluate its Exo-Net isolation technology to develop an ovarian cancer test, and later said a University of Queensland study of 97 plasma samples showed its Exo-Net more than 90 percent accurate for the detection of early-state ovarian cancer (BD: Apr 1, Dec 13, 2022).

In June, the company said a 532-sample study showed its EXO-OC exosome-based ovarian cancer blood test had 77 percent sensitivity and 99.6 percent specificity for all stages of disease (BD: Jun 2, 2025).

Today, Inoviq said it would pay Uniquest a $25,000 upfront fee, with up-to $360,000 in milestone payments and tiered royalties of up-to 2.5 percent of net sales, excluding its own Exo-Net component, for an exclusive licence to develop and commercialize products using the University's intellectual property, for the "longer of 10 years from first commercial sale or expiry of licenced patents".

Inoviq chief executive officer Dr Leearne Hinch said the "rights to these biomarkers is a pivotal milestone for Inoviq".

"Incorporating [the University of Queensland's] novel exosomal biomarker [intellectual property] into our EXO-OC test enables development of [a] potential best-in-class exosome-based test for the early-detection of ovarian cancer," Dr Hinch said.

"Our strategy is to commercialize EXO-OC as a laboratory developed test in the US, then expand globally following in-vitro diagnostic registrations," Dr Hinch said.

"With unmatched performance to date, our EXO-OC test has the potential to change the paradigm in ovarian cancer detection and drive significant value creation for shareholders," Dr Hinch said.

Uniquest chief executive officer Dr Dean Moss said there was "a critical unmet need for the earlier detection of ovarian cancer".

"We are excited to partner with Inoviq to advance this exosome-based ovarian cancer screening test towards commercialization and clinically meaningful impact," Dr Moss said.

"Delivering an ovarian cancer screening test that has the potential to save women's lives by enabling earlier diagnosis and intervention is a successful translational outcome from the long-standing collaboration between [the University of Queensland], Uniquest and Inoviq," Dr Moss said.

Inoviq was up 3.5 cents or nine percent to 42.5 cents.

IMEX HEALTH SERVICES

Imex says has a contract to supply radiology services to the Bogotá, Colombia-based Oncolife hospital and its other sites for about $1.4 million in annual recurring revenue.

Imex said Oncolife operated in north Bogotá, with additional centres in Villavicencio and Zipaquirá, with the sites treating cancer patients and requiring high-complexity diagnostic procedures, including advanced radiology services.

The company said the contract had an initial term of one year, beginning immediately, and was expected to contribute about $1.4 million in annual recurring revenue, including both radiology and software revenue.

Imex chief executive officer Dr German Arango said "this agreement underscores the strength of our radiology services offering in high-complexity care, supported by our integrated software solutions and [artificial intelligence] modules".

Imex was up half a cent or 2.1 percent to 24 cents.

MONASH UNIVERSITY

Monash University says it has a memorandum of understanding with the Songdo, South Korea's K-Bio Lab Hub to support up-to 30 biotechnology startups by 2027.

Monash University said K-Bio Lab Hub was backed by the South Korea government and designed to accelerate biotechnology innovation by supporting "high-potential startups" and connecting them to international partners, with a research and development and incubation complex under construction in Songdo.

The University said K-Bio Lab Hub would begin its first Australian projects within Monash's technology precinct, with its Melbourne base to support therapeutics ventures nearing clinical trial, as well as early-stage drug discovery companies, allowing for close collaboration with Monash's research strengths, particularly in pharmacology, drug discovery, clinical research and commercialization.

Monash University said the initiative was being supported by Invest Victoria, the Consulate of the Republic of Korea in Melbourne and "other local eco-system partners" to strengthen ties between Australian and Korean biotechnology communities.

Monash University research vice chancellor Prof Mike Ryan said the deal with K-Bio "reflects Monash's globally recognized excellence in research, and we're looking forward to linking our strengths in biotech with Korea's thriving ecosystem to accelerate discovery and impact".

QUEENSLAND UNIVERSITY OF TECHNOLOGY

Queensland University of Technology (QUT) says its Pioneer Bio-pilot facility will develop and manufacture "new types of food" and dietary alternatives.

The University said it would turn its Mackay, Queensland-based facility into "Australia's leading pilot-scale fermentation food-grade facility", with an $18 million expansion funding from the Federal Government and the Queensland State Government, that would allow companies to work with its researchers to "create new types of food and other bioproducts offering dietary alternatives and sustainable solutions to agricultural challenges".

The University said that the Pioneer Bio-pilot, formerly the Mackay Renewable Bio-commodities Pilot Plant, had played a "crucial role for industry for the past 15 years in the real-world translation of research, converting biomass such as sugarcane bio-gases into bio-fuels, green chemicals and bioproducts".

The University said its researchers, using the Bio-pilot, would partner with Brisbane's Eclipse Ingredients and others in a $5.5 million project to commercialize human lactoferrin, a protein in breastmilk and immune cells, with "immune-boosting, iron-enhancing, anti-inflammatory properties".

Queensland University of Technology deputy dean of engineering Prof Ian O'Hara said a "key feature of the … facility was its fermentation bio-reactors, which allowed companies to fast-track product development in the food and beverage sector".

"This facility will enable innovative companies to take their ideas beyond the lab and into commercial reality, building Queensland's reputation as a regional leader in biomanufacturing," Prof O'Hara said.

"The feedstocks we are developing for this process are diverse, but the sugar-cane industry is the key driver for much of this work," Prof O'Hara said.

"Precision fermentation is a technology that allows us to convert sugars into a range of other food ingredients and products in brewery-style fermentation tanks," Prof O'Hara said. "The advantages of precision fermentation are that it can lead to new food products and ingredients that supplement production through traditional methods, providing sustainability benefits and increasing consumer choice."

AUSBIOTECH

Ausbiotech says it is aware of the US President's announcement to impose a 100 per cent tariff on branded and patented pharmaceutical products.
Ausbiotech said that the tariffs were due to take effect on October 1, 2025, unless “a company [was] building their pharmaceutical manufacturing plant in America”.
In July, Biotech Daily reported that “prospective 200 percent tariffs on Australian pharmaceutical exports to be levied by US President Donald Trump are not expected to have a significant impact” (BD: Jul 9, 2025).
CSL, LTR, Neuren and Telix said in July, that they manufactured in the US; Mesoblast said it was exempted from any drug tariffs; and there was doubt over the legality of the tariffs.
Today, Ausbiotech said it was “actively engaging with the Australian Government and members as we await further details from the US administration”.
“We are also aware of the proposed Section 232 National Security Investigation of Imports of Personal Protective Equipment, Medical Consumables, and Medical Equipment, Including Devices, by the US Department of Commerce,” the industry organization said.
Ausbiotech said that the proposed Section 232 Notice was available at: https://public-inspection.federalregister.gov/2025-18729.pdf.

AUSBIOTECH

Ausbiotech says applications for session submissions for its Ausmedtech conference in Perth from May 19 to 21, 2026 are open until November 21, 2025.
Ausbiotech said it was calling for session submissions from medical technology leaders, researchers, clinicians, investors and policymakers “actively shaping the future of the medtech sector”.
For session submissions, go here: https://www.ausmedtech.com.au/session-proposal.

VITASORA HEALTH (FORMERLY RESPIRI)

Vitasora says will release 6,200,000 shares from voluntary escrow on October 3, 2025.
According to its most recent notice, Vitasora had 1,594,527,197 shares on issue.
Vitasora was unchanged at 2.7 cents.

QBIOTICS GROUP

Qbiotics says it has promoted David Phillips to deputy chair, having been a non-executive director since May 20, 2024.
Qbiotics is a public unlisted company.