



Biotech Daily

Friday September 25, 2026

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH DOWN: MICRO-X UP 10%; BOTANIX, IMMUTEP DOWN 5%**
- * **DR BOREHAM'S CRUCIBLE: CYCLOPHARM**
- * **NEXSEN, FLASHDX SHENZHEN J-V FOR GBS TEST**
- * **IDENTIFAI \$10m IPO FOR WINDROSE PRE-NATAL GENETIC TEST**
- * **MEMPHASYS PIVOTS TO US FDA 510(k) ROUTE**
- * **ACADIA 'NARROWLY' MISSES ACP-204 PSYCHOSIS ENDPOINT**
- * **GRIFFITH UNI: 'BREATH BEATS CT FOR FINDING LUNG CANCER'**
- * **MICROBA APPOINTS GEOFF COCKERILL INTERIM CEO, ON \$2.1k/DAY**

MARKET REPORT

The Australian stock market was up 0.3 percent on Friday September 25, 2026, with the ASX200 up 25.9 points to 8757.8 points.

Twelve of the Biotech Daily Top 40 companies were up, 20 fell, seven traded unchanged and one was untraded. All four Big Caps were down.

Micro-X was the best for the fourth day this week, up 0.4 cents or 9.8 percent to 4.5 cents, with 1.2 million shares traded.

Avita climbed 8.1 percent; Optiscan was up 7.7 percent; Saluda improved 5.1 percent; Racura and Starpharma were up more than three percent; Alcidion rose 2.4 percent; Clarity, Nova Eye, Prescient and Telix were up by one percent or more; with Emvision up by 0.6 percent

Botanix and Immutep led the falls, both down 5.26 percent to 1.8 cents and 3.6 cents, respectively, with 2.3 million shares traded and 24.0 million shares traded, respectively.

Orthocell fell 5.1 percent; Artrya, Curvebeam, Dimerix, Imricor, Proteomics and Syntara lost four percent or more; 4D Medical, Aroa, Atomo, Clinuvel, Cyclopharm, EBR and Polynovo shed two percent or more; CSL, Medical Developments, Mesoblast, Nanosonics, Neuren and Pro Medicus were down more than one percent; with Cochlear and Resmed down by less than one percent.

DR BOREHAM'S CRUCIBLE: CYCLOPHARM

By TIM BOREHAM

ASX code: CYC

Share price: 45 cents

Shares on issue: 125,734,145

Market cap: \$56.6 million

Chief executive officer: James McBrayer

Board: Douglas Cubbin (chair), Mr McBrayer, Dianne Argus, Prof Gregory King

Financials (half year to June 30, 2026): revenue \$17.5 million (up 14%), net loss of \$8.8 million (\$7.7 million deficit previously), cash balance \$12.3 million (down 1.3%)

Identifiable major shareholders: Anglo Australian Christian and Charitable Fund 12.2%, Regal Funds Management 9.87% Chemical Overseas Ltd 8.49%, CVC Ltd 6.1%, Investors Mutual 5.86%

Just as top breeders recommend(ed) Pal and more than 80 percent of dentists advocate Colgate toothpaste, Cyclopharm has been elevated into a recognition league of its own with its Technegas lung imaging tool.

In late July, the company crowed that Technegas had been named as the preferred US lung ventilation imaging agent in guidelines decreed by four nuclear medicine societies, in the US, Europe, Australia and New Zealand.

But unlike dog aficionados and dentists pushing pooch nourishment and peg cleaner, the guidelines are more than marketing fluff.

The document establishes international pulmonary scintigraphy guidelines.

Also known as a gamma scan, scintigraphy is a nuclear medicine test that uses small amounts of radioactive material to create images of the bodily insides.

Updated for the first time in 14 years, the guidelines – a.k.a. ‘The Bible’ - establish Technegas as the standard-of-care in the US and “generally preferred when available”.

Cyclopharm notes that such guidelines usually are carefully “brand neutral”: merely describing classes of agent or listing generic names.

“The new guidelines break that convention”.

The guidelines define Technegas in a dedicated section, “while competing agents appear under their general headings”.

Cyclopharm CEO James McBrayer dubs the recognition as an “incredible event in any company's history”.

The revised ‘Bible’ comes as Cyclopharm starts to roll out Technegas in the US, for detecting pulmonary embolisms (blood clots).

What’s all the fuss about?

Technegas is based on a structured, ultra-fine dispersion of radioactive labelled carbon.

This agent is produced at the bedside by using dried Technetium-99m in a carbon crucible, heated to around 2,700 °C. (Dang! We forgot to patent the term.) The crucible is cremated in the process.

The resultant gas-like substance is inhaled by the patient (lung ventilation) via tubing.

Only three to four breaths are required. The gas works as an imaging agent, allowing three-dimensional viewing with a gamma or single photon emission computed tomography (CT) camera.

The nanoparticles have a six-hour radioactive life, after which they are dispersed through breathing.

The US Food and Drug Administration ascribed Technegas with the wide indication of “visualisation of pulmonary ventilation” – not just a pulmonary embolism (PE) – for kids and adults.

Under its Beyond PE drive, the company is angling to use Technegas for broader applications. These include chronic obstructive pulmonary disease (COPD), asthma, pulmonary hypertension, and ‘interventional’ applications such as lung cancer surgeries.

Cyclopharm makes the Technegas generators at its facility at Kingsgrove in inner Sydney. The consumables include carbon billets, single-use tubing and the crucibles.

A case study in patience

Cyclopharm waited three decades for the FDA to approve Technegas, despite it being used in 64 other countries (including neighbor and putative 51st state, Canada).

The agency finally did so in October 2023, after the company responded to the requirements of an FDA ‘complete response letter’ in June 2021.

Technegas has 'made in Australia' writ all over it, having been invented in the 1980s by Australian National University bio-medical engineer Prof Bill Burch.

He partnered with industrialist Ian Tetley to form Tetley Medical (nothing to do with teabags).

Technegas was commercialized after being approved in Europe in 1988. Cyclopharm was incorporated in 2005 and listed in January 2007, after raising \$11 million at 30 cents apiece. Technegas was approved in Australia in 1986 and then in Europe in the early 1990s.

A pharmacist, Mr McBrayer joined in June 2008. Mr McBrayer took over from John Sharman who went on to head up Medical Developments and Universal Biosensors.

Mr McBrayer headed the nuclear medicine mob Syncor Australia, as well as Lipa Pharmaceuticals.

Technegas has been used in more than five million patient procedures worldwide and is supported by more than 230 published papers and more than 2,400 "scholarly citations".

What's the problem?

Currently, about 85 percent of patients are imaged with computed tomography pulmonary angiography, or CTPA, with nuclear imaging confined to patients unsuited for this imaging (they may be pregnant, have poor renal function or are allergic to the imaging agents).

Cyclopharm's remit is to replace older two-dimensional nuclear techniques.

"A CT scan shows what a lung looks like. Technegas shows how it is working," the company says.

'The Bible' notes the Technegas particles spread evenly into the smallest airways, thus providing an accurate picture of breathing in every lung 'region'.

Crucially, a Technegas-based lung scan delivers a breast radiation dose around 70 times lower than a single CTPA.

To date, PEs commonly were diagnosed with the help of isotope called Xenon-133, via a method that requires a negatively pressured room and a method to trap gases expelled by the patient.

Then there's another Technetium-99 based liquid aerosol agent called – and let's take a breath first – diethylene-triamine-penta-acetate (DTPA).

DTPA is indicated for renal (kidney) imaging but has been deployed off-label for PEs.

DTPA is based on the same isotope as Technegas but is dispensed from a nebulizer as a wet aerosol. This creates a pooling effect in the lungs that hampers the imaging.

To date, computed tomography pulmonary angiography, or CTPA, has been more effective than the nuclear imaging options.

But Cyclopharm claims Technegas surpasses all of them in terms of avoiding both false positives and false negatives.

In its established geographies, Technegas has achieved 85 percent market share (and 100 percent penetration in Canada).

Isn't there an algo for that?

Then there's the spectacular rise and rise of the ASX-listed 4D Medical with its FDA-approved, US-reimbursed PE imaging tool, computed tomography, ventilation perfusion (CT VQ).

CT VQ is an algorithmic software tool that enhances lung images data from CT.

4D Medical dubs CT VQ as the "the world's first and only non-contrast, CT-based ventilation-perfusion imaging technology".

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

Opining on which tool is better is well beyond your columnist's pay grade.

Speaking generally – and not about 4D Medical – Mr McBrayer notes a "rapidly growing landscape of software companies".

The software draws the data from the CT scans and packages them up in different and enhanced formats. Thus, such methods need a CT scan to start with.

"Technegas [provides] an abundant amount of validated data and clinical information, showing all the measurements clinicians could possibly want," he says.

"The sensitivity, specificity and negative and positive predictive values have been established".

While 4D Medical is in the early stages of a US entry, Mr McBrayer says the companies largely will not compete with each other.

Cyclopharm's \$65 million market cap compares with the largely pre-revenues 4D Medical's \$2.15 billion.

Why the disparity? Refer to the reference above about pay grades. All we're willing to say is that time will tell as to whether investors are right.

A legal action from 4D Medical against Cyclopharm is ongoing.

Finances and performance:

Cyclopharm reported revenue of \$17.5 million for the six months to June 2026, up 14.3 percent and the fifth consecutive record half year.

The company lost \$8.79 million, compared to a \$7.68 million deficit previously, with June-30, 2026 at \$12.2 million, 1.3 percent lower than at June 30, 2025.

US Technegas sales contributed \$2.1 million of the revenue, up 74 percent and third-party distribution accounted for \$8.1 million, up four percent (see below).

Mr McBrayer says the company has been careful with cash burn during the US rollout.

“Typically, companies hire a huge sales force and burn cash; we were very deliberate and targeted.”

The company has signed up ‘famous name’ US hospitals including the Mayo Clinic, Brigham Massachusetts General, Stanford and Emery.

“Once you get into their first site, it grows from there,” Mr McBrayer says, noting that just over half of the company’s installed base derives from expanded use from existing customers.

At Cyclopharm’s May AGM, 50 US installations had installed Technegas. By the end of June, the tally had grown to 70 and, at last count, 83.

Of a total of 5,200 US lung sites doing nuclear medicine, the company cites an “engaged pipeline” of 1,684 sites.

“We think about 2,000 will give us the vast majority (of revenue),” Mr McBrayer says.

On the company’s reckoning, these 2,000 sites equate to a total addressable market of \$US180 million. The current Technegas coverage covers 22 states and 240 million Americans.

“We should have another 10 states by the end of the year,” Mr McBrayer says.

Over the last 12 months, Cyclopharm shares have cycled between a low of 46 cents in early July last year and a high of \$1.23 in late January this year. They traded at a record \$3.00 in January 2021 and trawled an all-time low of 12 cents in March 2013.

Coming to the (third) party

Cyclopharm has its own sales force in 17 of its 67 countries, including Canada, the UK, Australia and New Zealand and several Scandinavian countries.

So why not leverage the sales force and other sunk costs to distribute third party products? Why not indeed!

The third-party business relates to radio-pharmaceutical products, mainly in Europe. Examples are cardiac imaging agents and 'hot cell' manufacturing.

Mr McBrayer says some of the companies are much bigger than Cyclopharm.

"They don't have to put their flag up, we can fly it for them," he says.

"We have people on the ground who have direct [relationships] with nuclear medicine departments and we have service engineers to support the products."

Mr McBrayer says the third-party business is "profitable, but not as profitable as Technegas". Consumables margins are 90 percent or more.

While the company expects to continue to grow its third-party revenues, Technegas US sales will grow at a faster clip.

Dr Boreham's diagnosis:

Cyclopharm is a story of endurance amid adversities, including a few wrong turns along the way.

These included assuming the FDA would accept 'real world' evidence, rather than requiring a formal clinical trial.

Mr McBrayer says CT has been around for decades, with millions of patient studies.

"[Changing] clinical practice is not a speedboat," he says. "It's a freighter which takes a long time. You need to add value to what's already being done."

In that sense, the endorsement of 'The Bible' amounts to words of gold.

Mr McBrayer acknowledges Technegas has been around "for a very long time", which implies that investors should have had more bang for their buck, by now.

But he says while the customer hotlines are ringing, the company is yet to benefit in earnest from the new guidelines.

"We are only getting started."

Then there's the much bigger sectors beyond PE.

For instance, the COPD diagnosis market is thought to be 30 times bigger than detecting PEs.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. But is only getting started.

NEXSEN

Nexsen says it has an agreement to form a 50-50 joint venture with China's Flashdx Shenzhen to develop and commercialize a group B Streptococcus (GBS) test.

Yesterday, Nexsen said it suspended enrolment in its trial of its Strepsure test for Group B streptococcus for women in labour at Melbourne's Northern Health in Epping "to refine the program before committing to a larger US regulatory study" (BD: Sep 24, 2026).

Today, the company said the proposed joint venture would use Flashdx's Conformité Européenne (CE) marked molecular GBS diagnostic as the technical and regulatory foundation for "an enhanced ... product, incorporating further agreed product development, including a Nexsen-contributed sample-preparation enhancement designed to improve detection at low bacterial levels".

Nexsen said that it would progress its own planned US and European regulatory pathways, providing the joint venture "with access to established molecular technology, manufacturing capability and regulatory know-how without having to develop a molecular system from the ground up".

The company said that Flashdx would provide the molecular technology and manufacturing capability, and it would "fund and lead the agreed regulatory program".

Nexsen said that the enhanced product would "sit alongside, rather than replace, Nexsen's Strepsure program".

The company said the two products were designed to address different healthcare settings, workflows and price points, broadening its GBS market opportunity rather than competing for the same use case.

Nexsen said that the joint venture product was "intended for hospital and intrapartum testing through a molecular diagnostic pathway, while Strepsure remains a separate rapid lateral-flow program for antenatal screening and decentralized care".

Nexsen managing-director Mark Muzzin said "the proposed joint venture with Flashdx has the potential to materially accelerate Nexsen's commercial strategy".

"We have built strong hospital, clinical and commercial relationships across Asia-Pacific, and Flashdx gives us the opportunity to combine that network with an established molecular technology that already underpins a CE-marked GBS diagnostic," Mr Muzzin said.

Nexsen said that Flashdx's existing GBS test detects group B Streptococcus from vaginal swab samples using an enclosed, sample-to-answer molecular testing system, with results available in under one hour, detecting two separate genetic markers of the bacteria and including a built-in quality control, "placing it in a category the US regulator has previously cleared".

The company said this provided "a shorter pathway to regulatory expansion and commercialization while broadening [its] position in GBS diagnostics".

Nexsen said it would contribute "a sample-preparation enhancement designed to release more GBS material from each sample before testing, making low levels of the bacteria easier for the molecular test to detect".

The company said that it and FlashDx would "participate equally in the profits generated by the joint venture".

Nexsen said that the joint venture would bring forward commercial market entry across the Asia-Pacific region.

The company said that Flashdx's existing GBS diagnostic provided "an advanced starting point for near-term market entry in priority markets including Hong Kong and India, leveraging Nexsen's existing clinical and large commercial network".

Nexsen fell 2.5 cents or 15.15 percent to 14 cents with 1.4 million shares traded.

IDENTIFAI GENETICS

Identifai hopes to raise up to \$10 million at 20 cents a share in an initial public offer to list on the ASX to develop its Windrose pre-natal genetic testing.

Identifai said that it hoped to list under the ASX code ID1 on October 13, 2026, with an indicative market capitalization of \$38.4 million.

The company said it was at the intersection of artificial intelligence (A.I.), genomics and preventative health “three of the most-watched investment themes of 2026”.

Identifai said one blood sample, would test “hundreds of genetic anomalies ... on the foetus with results delivered earlier than the current genetic testing pathway”.

The company said that current screening “can take 20 plus weeks and multiple invasive follow-ups before a parent gets an answer”, with “three to six percent of all newborns worldwide are affected by a serious congenital or genetic disorder”.

Identifai said that during pregnancy, the maternal bloodstream contained cell-free DNA (cfDNA) which was a mixture of maternal and foetal cfDNA.

The company said that it was “able to leverage small differences between maternal and foetal cfDNA to detect disease-causing mutations across the entire foetal genome”.

Identifai said it had been granted patents in the US, China and Israel,

The company said that its chief executive officer was the Tel Aviv, Israel-based Eyal Miller, who had more than 28 years in healthcare including at Stratasys, Nucleix and Ivory Graft and the chief scientific officer Prof Noam Shomron was Tel Aviv University Medical School’s head of functional genomics.

Identifai said offer opened on September 10 and would close on September 29, with the lead manager Sydney’s Aesir Corporate Pty Ltd.

The prospectus was at: <https://identifai-genetics.com/prospectus/>.

MEMPHASYS

Memphasys says it will pursue the US Food and Drug Administration 510(k) pathway for its Felix sperm separator rather than the de-novo route.

Memphasys said that a “board reassessment of the US regulatory strategy has identified a potential expedited pathway for Felix to seek FDA clearance, replacing the more complex de-novo pathway previously contemplated.

The company said it had “identified a medical device it believes may provide an appropriate predicate, potentially enabling Felix to pursue the FDA’s more established 510(k) clearance pathway, but did not disclose the name of the predicate device.

Memphasys said it would have a pre-submission engagement with the FDA to seek feedback on the proposed pathway, predicate and supporting evidence before moving to a formal submission “before committing to a formal regulatory submission” by April 2027.

The company said that it previously expected Felix would need to progress through the de-novo classification pathway because a suitable predicate device had not been identified, but the “legally marketed device” meant that it had the potential for Felix to pursue the FDA’s established 510(k) pathway, based on demonstrating substantial equivalence, rather than the de-novo pathway previously contemplated.

Memphasys executive chairman David Tasker said the “reassessment of our US regulatory strategy has identified a potentially faster and more direct pathway for Felix into a \$US5.9 billion [in-vitro fertilization] market representing around 20 percent of the global market”.

Mr Tasker said the company would maintain its focus on driving Felix adoption and revenue in Europe, Australia, New Zealand, Asia and the Middle East and North Africa.

Memphasys was unchanged at 0.5 cents with 10.8 million shares traded.

ACADIA PHARMACEUTICALS, NEUREN PHARMACEUTICALS

Acadia says its phase II trial of ACP-204 for Alzheimer's disease psychosis "narrowly missed [the] primary endpoint ($p = 0.0603$) but met secondary endpoints.

In 2023, Neuren said the US Food and Drug Administration approved partner Acadia Pharmaceuticals Daybue (trofinetide) for Rett syndrome for adults and children two years and older (BD: Mar 13, 2023).

Last month, Neuren said the San Diego, California-based Acadia had European Union approval for Daybu, or trofinetide, for Rett syndrome, triggering milestones up-to \$US205 million (\$A287 million).

Overnight, Acadia did not state the number of patients in the phase II trial of ACP-204, or remlifanserin, for Alzheimer's disease psychosis, but clinicaltrials.gov said that 1,074 patients were expected to be enrolled in three sub-studies of which the first was the phase II trial evaluating "efficacy and dose response of ACP-204 30mg and 60mg versus placebo".

The clinicaltrials.gov website said that sub-studies 2A and 2B were both phase III trials which would be "confirmatory studies of either both doses (ACP-204 30mg and 60mg, respectively) or a single dose from part 1 versus placebo".

The website said that sub-studies 2A and 2B would be performed independently of each other and would begin after enrollment of part 1; and all three sub-studies would "be analyzed independently of each other".

Acadia said that "meaningful and consistent efficacy trends across endpoints support continuing with phase III development of 60mg once daily remlifanserin in [Alzheimer's disease psychosis], with demonstrated evidence of dose effect".

The company said that the ongoing 'Radiant' trial program was evaluating remlifanserin for the treatment of hallucinations and delusions associated with Alzheimer's disease psychosis (ADP).

Acadia said that for the primary endpoint of change from baseline in the scale for the assessment of positive symptoms-hallucinations and delusions subscales (SAPS-H+D), once daily 60mg remlifanserin showed a change of -12.6 versus a -10.4 change for placebo at week 6, yielding a standardized effect size of 0.26 ($p = 0.0603$).

The company said that "for the key secondary endpoint, clinical global impression – severity (CGI-S-ADP), the 60mg dose achieved a change from baseline of -1.3 versus a change of -0.9 for placebo at week-6, a standardized effect size of 0.37 ($p = 0.0077$)".

Acadia said that "on both efficacy measures, the difference in the 60mg dose versus placebo increased through the 6-week treatment period ... [while] the 30mg dose showed minimal improvement across endpoints compared to placebo".

The company said that remlifanserin had "a favorable safety profile, with rates of adverse events, serious adverse events, and discontinuations due to adverse events, similar to placebo".

Acadia said that "there was no signal of [cardiac] QT prolongation versus placebo ... [and] no negative impact on motor symptoms or cognition.

The company said it would continue enrolling its two phase III studies evaluating remlifanserin in ADP "while implementing amendments to the phase III program, including removing the 30mg dosage arm".

Acadia chief executive officer Catherine Owen Adams said that the results "provide valuable information regarding the efficacy, safety and tolerability of once daily remlifanserin in Alzheimer's disease psychosis".

Overnight on the Nasdaq, Acadia fell \$US3.25 (\$A4.63) or 1.93 percent to \$US22.18 (\$A31.63) with 6.6 million shares traded.

On the ASX, Neuren fell 38 cents or 1.8 percent to \$20.22 with 975,638 shares traded.

GRIFFITH UNIVERSITY

The Queensland Gold Coast-based Griffith University says “human breath could help identify cancerous lung nodules, negating the need for invasive testing”.

Griffith University said it analyzed exhaled breath to help doctors distinguish between cancerous and non-cancerous lung nodules, supporting earlier lung cancer diagnosis.

The University said that the research was funded by Sydney’s Tour de Cure,

Griffith University said that about 2.5 million new cases of lung cancer were diagnosed each year.

The research, titled ‘Complementary Breath Profiling Using eNose and Gas Chromatography-Mass Spectrometry for Noninvasive Triage of Indeterminate Pulmonary Nodules’, was published by Wiley Medcom Open Access and the full article is available at: <https://onlinelibrary.wiley.com/doi/10.1002/mco2.71012>.

Griffith’s Institute for Biomedicine and Glycomics Prof Chamindie Punyadeera said the study evaluated two complementary technologies, with both showing promise.

“We studied an electronic nose, or eNose, which identifies patterns in breath chemicals,” Prof Punyadeera said.

“The second technology was gas chromatography-mass spectrometry which identified specific volatile organic compounds in breath,” Prof Punyadeera said.

“Both breath-based approaches showed substantially better discrimination between malignant and benign nodules than models using standard clinical information alone,” Prof Punyadeera said.

Griffith University said the research could replace the need for invasive testing which currently entailed a computed tomography (CT)-guided lung biopsy to obtain tissue for a diagnosis.

The University said that other invasive techniques encompassed a bronchoscopy to sample suspicious nodules, or in some cases, surgery to remove or investigate nodules that may be cancerous.

Griffith University said that “sometimes patients underwent invasive techniques to later find out 95 percent of pulmonary nodules identified on low-dose CT scans were ultimately found to be non-cancerous”.

MICROBA LIFE SCIENCES

Microba says it has appointed Geoffrey Cockerill as interim chief executive officer, from September 29 as chief executive officer Dr Luke Reid is on medical leave.

Microba said that Mr Cockerill would be paid \$2,100 a day for a five-day week including superannuation.

The company said that Mr Cockerill had more than 30 years’ experience including as an executive at Diageo Australia, Lion, Subway Systems and most recently as chief executive officer of Vitura Health.

The company said that Mr Cockerill was based in Brisbane and held a Bachelor of Commerce from Griffith University.

Microba was up 0.1 cents or two percent to 5.1 cents with 1.5 million shares traded.