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Daily news on ASX-listed biotechnology companies

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.

June-end cash stood 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.

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 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.