PITT STREET RESEARCH

Cyclopharm Ltd.

Clock's ticking

Share Price: A$2.05

ASX: CYC

Sector: Healthcare Equipment & Services

27 April 2023

At the end of March 2023, Cyclopharm (ASX:CYC) informed shareholders that it submitted the formal reply to the US Food and Drug Administration (FDA) Complete Response Letter (CRL) for its proprietary functional lung ventilation imaging agent Technegas. This kicks off a six-month review process and the company's hope is that once the process is over, the FDA will grant its core radiopharmaceutical product, Technegas approval. This will unlock an initial US$180m market for the diagnosis of Pulmonary Embolism (PE) in the USA.

For real this time?

The recent rally in the company's share price indicates that investors are optimistic that approval will be granted. And the company is too. We were recently invited by the company to a Site Visit where we observed first hand some of the preparations the company has made for US market entry – which we will outline in this report. The company has shared much of this information previously to investors in general terms.

A solid ex-US business with future growth potential beyond PE

Technegas is already being sold in over 60 countries and has been growing strongly. Technegas offers a safer and more effective alternative radioactive compound. Its sensitivity, specificity and accuracy are equivalent to alternative imaging technologies while diagnosing PE even at sub-segmental levels. Moreover, Technegas involves a minimal radiation dosage and can be administered to patients without any exclusion criteria.

The bigger opportunity in the long term will be applications of Technegas beyond PE. CYC is targeting new applications through clinical studies that are focussing on diagnosis of Chronic Obstructive Pulmonary Disease (COPD), asthma and other respiratory diseases, like Long-Covid. For now, we will not consider these indications in our valuation for conservatism's sake but may in the future.

Valuation range of A$3.09–4.37 per share

In light of the company's solid FY22 result, we update our valuation to A$3.09 per share in our base case and A$4.37 per share in our bull case, assuming US approval and a roll out from early CY24. Our valuation ex-US is $2.56 per share in our base case and $3.51 in our bull case. It goes without saying that the key share price catalyst will be US FDA approval if and when received. Please see page 9 for key assumptions & other details on our valuation and page 12 for the key risks.

Market cap. (A$ m)	157.0
# shares outstanding (m)	76.6
# shares fully diluted (m)	76.6
Market cap full. dil. (A$ m)	157.0
Free float	31.8%
52-week high/low (A$)	2.95 / 1.43
Avg. 12M daily volume ('1000)	36.7
Website	www.cyclopharm.com

Source: Company, Pitt Street Research

Share price (A$, l.h.s.) and avg. daily volume (k, r.h.s.)

Source: Refinitiv Eikon, Pitt Street Research

Valuation metrics	
Fair valuation range (A$)	3.09–4.37
WACC	11.6%
Assumed terminal growth rate	2.0%

Source: Pitt Street Research

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Disclosure: Pitt Street Research / Stocks Down Under directors own shares in CYC.

Please refer to page 12 for key investment risks.

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The evolution of Cyclopharm/Technegas

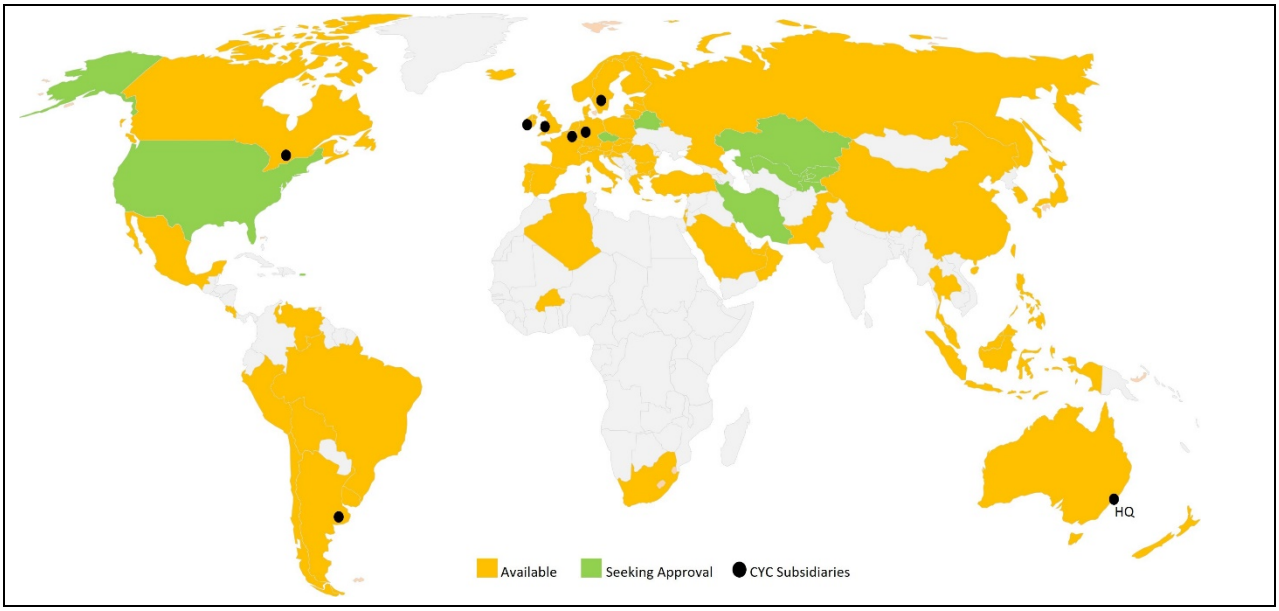
For investors new to the story, we will recap the history and development of Technegas, CYC as a company as well as how Technegas works and how it is superior to competing technologies. Investors interested in further detail beyond the scope of this report should read our March 2022 initiation report.

Technegas was discovered in the mid-80s and was registered as a drug in Europe in 1996. 2001 marked the commencement of the Phase III study for Technegas' submission to FDA. During 2003–2005, Technegas achieved a major breakthrough by entering the Canadian market and securing an agreement with the Australian National University to continue research into liquid Technegas. As a market, Canada is the largest individual nation for Technegas by sales and the company has captured virtually all of the market.

Since listing, the company has expanded Technegas' presence to over 60 countries, but the USA has not been one of them.

Cyclopharm was incorporated in 2005 as an unlisted public company and it completed the acquisition of the Technegas System business from Vita Life in May 2006 via a share exchange. Subsequently, Cyclopharm went public in 2007 and started trading on the ASX. Since listing, the company has expended its presence to over 60 countries (Figure 1), but the USA has not been one of them. Cyclopharm is now aiming to enter the US market and replicate its success in the Canadian market. It is in the final stages of the FDA approval process for Technegas and is all set for commercialisation once it secures the approval.

Figure 1: Cyclopharm's global presence



Source: Company

Technegas – Cyclopharm's flagship product

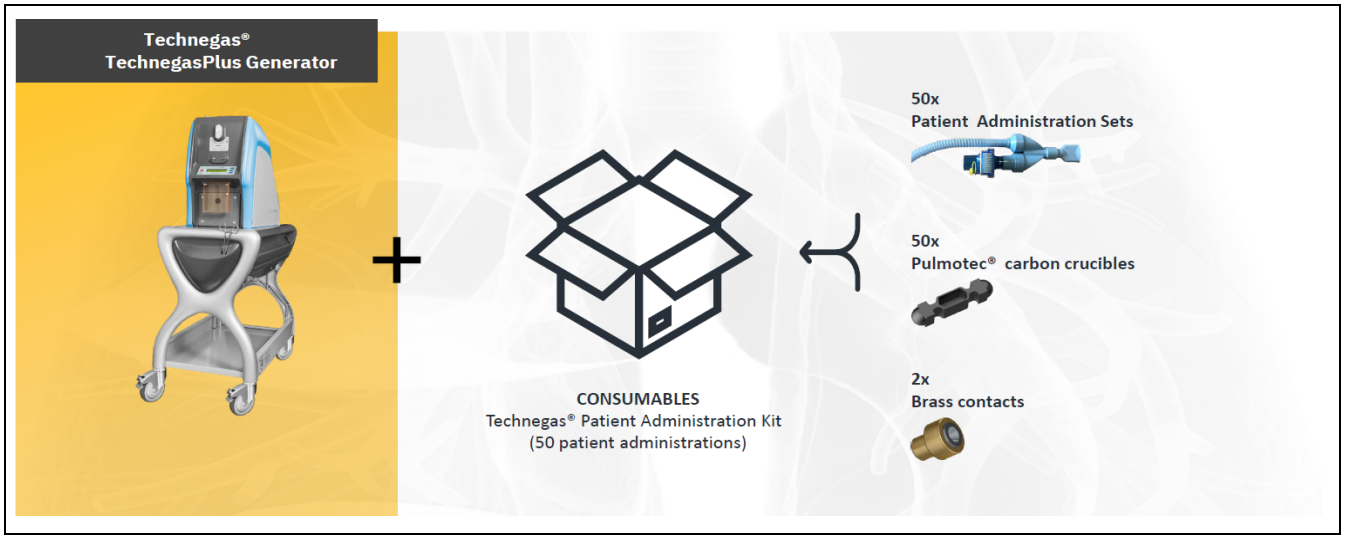
What is it and how does it work?

The Technegas technology entails a structured, ultra-fine dispersion of radioactive labelled carbon, produced by using dried Technetium-99m (Tc-99m) in a carbon crucible, micro furnaced for a few seconds at around 2,700^0 C. The resultant gas-like substance is inhaled by the patient (lung ventilation) via a breathing apparatus, which then allows multiple views and tomography imaging under a gamma or single photon emission computed tomography (SPECT) (As per Figure 4 on page 6). Technegas is typically used in the context of a Ventilation-Perfusion (VQ) scan, a nuclear medicine scan of the lungs. In particular, it is used with V/Q SPECT, the latest generation of 3D nuclear medicine imaging.

To produce Technegas, an electrically powered medical device called TechnegasPlus Technegas Generator is used (Figure 2 and 3). This device produces hydrophobic Tc-99m-labelled carbon particles, which is dispersed as an aerosol. Tc-99m is an isotope commonly used in a number of medical diagnostic imaging scans. It is also used as a radioactive tracer in nuclear medicine.

The company has multiple revenue streams being not only a supplier of the generator and consumables, but a provider after-sales services of the devices. If and when FDA approval is obtained, CYC's USA business model will be to retain ownership of individual generators and charge a US$5,000 installation fee and a US$3,500 ongoing maintenance fee per annum.

Figure 2: The Technegas solution includes generators along with consumables

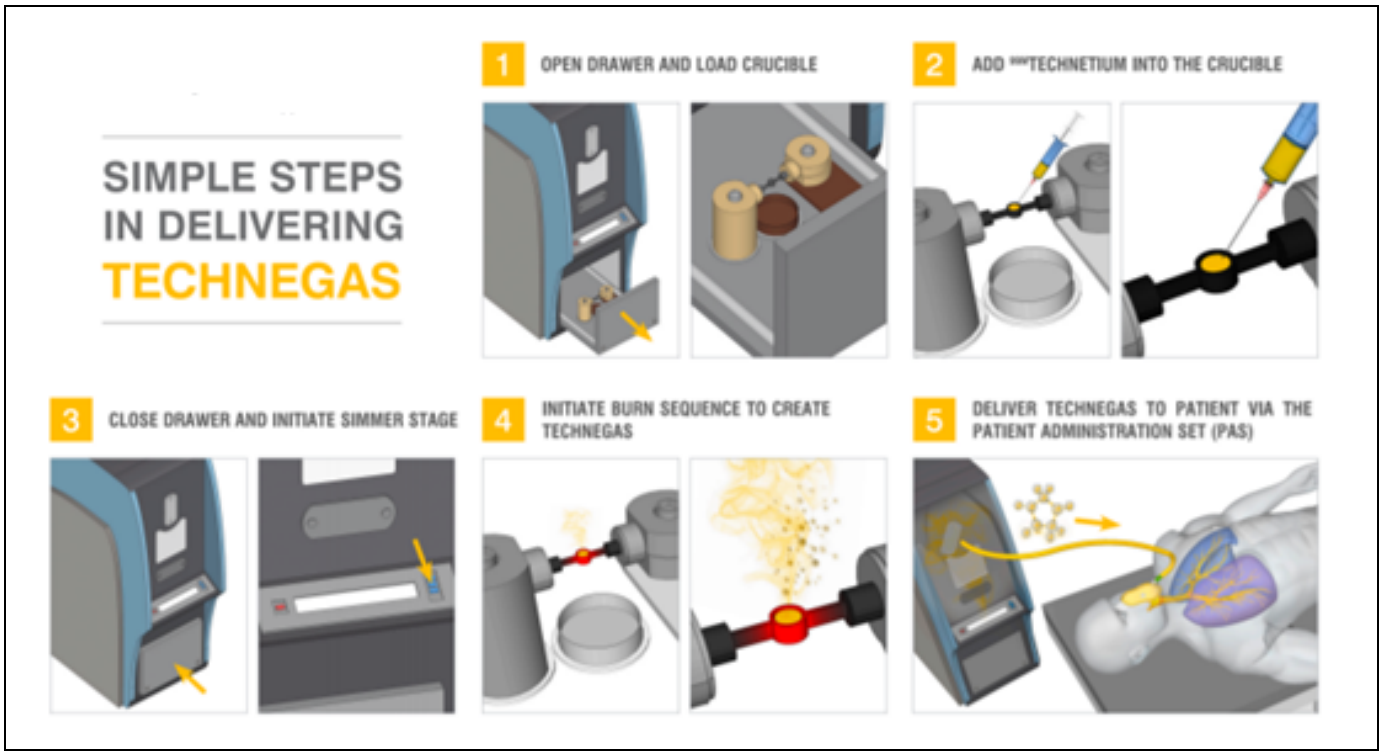


Source: Company

Figure 3: A Technegas Generator in real life

Source: Nicholas Sundich - Pitt Street Research

Figure 4: Technegas generation and delivery process



Source: Company

Technegas, offered as part of a V/Q SPECT imaging procedure, offers not only a less damaging but also more effective radioactive compound.

Why Technegas is superior

Technegas, offered as part of a V/Q SPECT imaging procedure, offers not only a less damaging but also a more effective alternative radioactive compound. The key benefits of this technology are described below:

- **Diagnostic accuracy:** Sensitivity, specificity and accuracy are equivalent to computed tomography pulmonary angiogram (CTPAs), while diagnosing PE even at sub-segmental levels.
- **3D images:** The gas-like behaviour of Technegas along with the ideal energy of Tc-99m allows excellent penetration to peripheral areas of the lungs. As a result, images can be captured in multiple projections facilitating image interpretation.
- **Low radiation burden:** V/Q SPECT with Technegas has a 27 to 36 times lower radiation dosage being administered to a patient compared with CTPA.
- **Quick and simple:** Rapid and easy administration of Technegas (3–4 breaths by patients) enables accurate and immediate decision-making even in case of lung obstructive disease. Only a few breaths of Technegas particles are required.
- **Minimal exclusion criteria:** Technegas can be administered to almost all patients, including ones with renal impairment, iodinated contrast allergy and chronic lung obstruction disease. It can also be administered to pregnant women.
- **Non-invasive:** Technegas is easy to inhale and hence aids in patients' comfort and compliance. Also, it uses SPECT technology, which is a well-established, non-invasive technique, for quantitative assessment of

regional lung ventilation and perfusion distribution in both children and adults.

The US awaits

The company hopes to obtain the FDA green light by the end of September 2023.

Despite the company's success in other markets, the US market has eluded CYC but the company hopes to obtain the FDA green light by the end of September 2023. This is the maximum 6 months allowed for the FDA to review a company response to a Complete Response Letter (CRL), given it submitted at the end of March. It could be before September's end, although realistically not for at least another few weeks.

How this point was reached

CYC's efforts to be FDA approved have taken several years. The company concluded its successful Phase III trials in September 2020 and applied to the FDA shortly thereafter. Shareholders were confident based on the success of the trial and that the FDA conducted a pre-approval audit of the company's facility in March 2021 – spending 2 weeks in Australian hotel quarantine to make the trip.

In June 2021, the FDA issued CYC with a Complete Response Letter (CRL). It determined it was unable to approve it in its present form and provided it with a definitive list of items and recommendations to be addressed. This was not an outright rejection (which would be a distinct response from this) but investors have arguably treated it as such.

It is important to note that the regulation did not have an issue with the technology's effectiveness, nor with the clinical trial. Instead, they related to better defining and validating the unique characteristics, production and delivery of the Technegas particle as well as specific aspects of crucible manufacturing and dosimetry in adults and children. It is also important to note that none of these issues have been raised in other jurisdictions where Technegas is delivered.

It was nonetheless a setback considering the company aspired to enter the US market in 2H21. The company's CRL response has taken longer than indicated. CYC initially indicated 9 months (which would have been March 2022) but has only submitted it in March 2023. This has set off the 6-month deadline. It is possible the FDA could ask further questions of CYC during the process and they might even conduct another site visit. Whether or not the company can or will provide a running commentary on these matters is anyone's guess.

A major opportunity

The US market is a major opportunity for CYC, not just because it is the world's largest healthcare market generally. It is also a market where Pulmonary Embolism (PE) is a major burden. The American Lung Association estimates that PE impacts around 900,000 people annually and that it 10-30% of individuals die within one month of diagnosis[1]. Pulmonary Embolism occurs when an artery in the lungs gets blocked by a blood clot. In many cases, this blocks the flow of blood to the lung and this makes it life threatening.

[1]

In the US, about four million diagnostic procedures are conducted each year on PE patients. Out of all these diagnostics tests being conducted, 15% are based on nuclear medicine imaging and 85% of them are CTPA. These 600,000 nuclear medicine ventilation procedures being conducted every year represent a market opportunity of ~US$90m. However, CYC believes it can double the number of scans sent to nuclear medicine imaging, thereby increasing the PE market to US$180m.

CYC is well positioned

In our view, Cyclopharm is well placed to obtain FDA approval and ultimately leverage the growth opportunities in the US driven by its superior technology, real-world evidence from 60 countries and significant support of Key Opinion Leaders. Ultimately, the decision is in the hands of the FDA, but we feel the company has done as much as it can. At our site visit, the Company noted among the steps they have taken include hiring ex-FDA consultants to look at the company's response to the CRL. It has also raised some of these issues with other regulators that had previously approved Technegas and they did not see those issues. Finally, we note that it has significant support in the US medical community.

We also feel the company is ready to roll out Technegas in the USA once the green light is given. The company rationalised its supply chain pre-COVID so shouldn't be impacted, at least in the immediate term. The company has ~200 generators ready to be shipped as soon as FDA approval is granted. In the medium term, the company hopes to build a 2nd manufacturing site in the US. The CEO has indicated it would likely be in Atlanta, Georgia given it is such a major aviation hub and is in an ideal position in the country, with 80% of the population just one flight away. It has received over 400 expressions of interest from US hospital about Technegas. Management has ensured that Technegas will be reimbursable by health insurers from day one making its adoption easier by patients and hospitals.

CYC has indicated that Key Opinion Leaders (KOLs) that have supported Technegas will be first in line, particularly those that have written to the FDA requesting to expedite approval of Technegas for the use in the US market. The physicians are in support of the observation that Technegas has a superior safety profile in relation to COVID-19 when compared to its alternatives.

CYC's experience in Canada is a good case study

CYC has consistently told its shareholders, and us too at our site visit, that Canada is a case study for how it could perform in the USA. Canada is Technegas' largest individual country market by patient numbers and shares many similarities with the US market.

Technegas was first approved in 2004 and recorded 14 years of consecutive growth in patient volumes per annum from then onwards. By now, it has captured almost all of the market opportunity. Ironically, it was the smaller hospitals that were the last 'hold outs' for adopting the technology. In 2022, Technegas was used on over 45,000 patients and there were over 160 active generators. Sales in 2022 totaled $2.96m, up 21% from the year before and totalling 13% of the company's revenue. Although this figure is outshone by the $7.5m generated from Europe as a whole, it is more than the $2.88m recorded in the entire APAC region.

Valuing Cyclopharm

We update our model on CYC to account for the company's growth in FY22. Our key assumptions & adjustments to them from previous iterations are as follows:

- **Revenue streams and growth**: The key revenue streams assumed in our model include sale of generators and consumables as well as service revenue. We have modelled US revenue and non-US revenue separately. We assumed 25% revenue growth in FY23 with 20% growth in FY24-FY26 in our base case. We believe these are conservative assumptions considering the company increased its sales by 31%.
- **US entry and growth**: We have modelled our US assumptions as a function of hospital adoptions, fees paid and PAS kits supplied. We are assuming entry into the lucrative US market in early H1 2024, and growth to accelerate thereafter over the next 4-5 years. We forecast $2.2m in CY24, based off 100 hospitals adopting Technegas (just 25% of the expressions of interest). We then assume $3.7m in CY25 (based of 100 continuing and 100 new hospitals) and $5.9m in CY26 (based off 320 total hospitals). PAS kit revenues are calculated by assuming individual hospital screening numbers from the entire number of PE cases in the population) By CY32, we assume $16.7m in revenues and in no year does our US sales exceed more than 11.48% of total company sales. Our bull case assumes faster growth, reaching $25m in revenues by CY32 but in no year do US sales account for over 13.29% of sales. See Figure _ for a breakdown.
- **Expenses**: All expenses but depreciation and amortisation are calculated as a percentage of revenues. We start by assuming the same percentages of sales as in CY23 and these percentages slowly decline over time allowing for growth in revenues. Our NPAT margins fluctuate over the life of our model but average 25% and peak at 32% in CY32.
- **Discount rate**: We have applied a discount rate of 11.6%, using a 3.6% risk free rate of return, a 1.4 beta and a 6% equity premium. We assume a 2.5% weight of debt and a 4.2% post-tax cost of debt. The latter figure may appear too optimistic given higher interest rates but would note 3 points. First, this is post-tax, the pre-tax figure is 6%. Second, the company's pre-tax cost of debt was only 4.4% in CY22 by our estimates. Third, these figures do not have a major impact on the valuation considering the weight of debt is just 2.5% - we experimented with a 12% rate and the effect is only a couple of cents.
- **Capital structure**: Our case including the USA assumed that the company will raise $20m in CY24 for a new manufacturing facility and general working capital and that it raises capital at $2 per share – our ex-US case does note. We note that the company does not have plans for a capital raising at this stage and may be able to build this facility with its own cash reserves.
- **Terminal growth rate**: We have assumed this as 2.0% keeping in mind the US growth plans and the uniqueness of the company's technology.

Entry into US should drive the company's valuation.

Our model now yields a value of A$3.09–4.37 per share (Figure 5). We believe this is a conservative estimate as we have not factored in any benefits from the potential growth in the addressable market for PE diagnosis beyond 5 years as well as the 'Beyond PE' initiatives of Cyclopharm. Figure 6 depicts the estimates in our model.

Figure 5: Valuation of CYC

(A$ m)	Base Case	Bull Case
Enterprise Value^ (A$ m)	**239.1**	**337.5**
Net (debt) cash	2.8	2.8
Equity value (A$ m)	**236.3**	**334.7**
Shares on Issue (m)	76.6	76.6
Implied price (A$)	3.09	4.37
Current price (A$)	2.05	2.05
Upside (%)	50.7%	113.3%

Figure 6: Key financial data (including USA)

Year to December (AUD)	2021A	2022A	2023F	2024F	2025F	2026F	2027F
Group Revenue (m)	20.1	25.0	30.3	39.0	48.5	60.4	74.5
YoY growth		23.9%	21.3%	28.7%	24.5%	24.6%	23.4%
EBITDA (m) Adjusted	2.0	2.6	9.3	12.7	16.7	22.0	28.6
Net Profit (m) Adjusted	0.2	1.2	5.8	8.1	8.6	12.7	17.6
EBITDA Margin (%)	9.7%	0.1	30.6%	32.6%	34.5%	36.5%	38.4%
RoA (%)	0.7%	0.0	0.2	0.2	0.1	0.2	0.2
Net Gearing (%)	-33.3%	16.5%	7.1%	-16.4%	-25.2%	-32.7%	-39.3%
EPS before extr. & amort.	0.3	1.6	7.5	6.9	7.4	10.9	15.1
EPS (cents)	0.3	1.6	7.5	6.9	7.4	10.9	15.1
DPS	NA	NA	NA	NA	NA	NA	NA
Price		1.46	2.18	2.18	2.18	2.18	2.18
M-Cap (m)		111.8	167.0	254.2	254.2	254.2	254.2
Net Debt (cash) (m)		2.8	1.6	(8.2)	(14.7)	(23.3)	(34.9)
Non-controlling interest (m)	na	NA	NA	NA	NA	NA	NA
Provisions (m)	na	NA	NA	NA	NA	NA	NA
EV (m)	0.00	114.7	168.6	246.0	239.4	230.9	219.3
EV/Sales		4.6x	5.6x	6.3x	4.9x	3.8x	2.9x
EV/EBITDA		44.9x	18.2x	19.4x	14.3x	10.5x	7.7x
P/E		0.9x	0.3x	0.3x	0.3x	0.2x	0.1x

Estimates: Pitt Street Research

What if CYC doesn't obtain FDA approval

We have also modelled an alternative scenario excluding USA sales but keeping everything else equal. Then we obtain a value of $2.56 per share base case and $3.51 per share bull case (Figures 7 and 8). We note that our valuation has not specifically taken account of any use cases beyond PE and it is possible that the company could create further revenues down the track. Such revenues would be a while away, however.

Figure 7: Valuation of CYC (assuming no USA approval)

(A$ m)	Base Case	Bull Case
Enterprise Value^ (A$ m)	**198.8**	**272.1**
Net (debt) cash	2.8	2.8
Equity value (A$ m)	**196.0**	**269.3**
Shares on Issue (m)	76.6	76.6
Implied price (A$)	2.56	3.52
Current price (A$)	2.05	2.05
Upside (%)	24.7%	71.5%

Figure 8: Key financial data (excluding USA)

Year to December (AUD)	2021A	2022A	2023F	2024F	2025F	2026F	2027F
Group Revenue (m)	20.1	25.0	30.3	36.8	44.8	54.6	66.6
YoY growth		23.9%	21.3%	21.5%	21.7%	21.9%	22.0%
EBITDA (m) Adjusted	2.0	2.6	9.3	11.8	15.0	19.2	24.4
Net Profit (m) Adjusted	0.2	1.2	5.8	7.5	9.6	12.4	15.9
EBITDA Margin (%)	9.7%	0.1	30.6%	32.1%	33.6%	35.1%	36.6%
RoA (%)	0.7%	0.0	0.2	0.2	0.2	0.2	0.2
Net Gearing (%)	-33.3%	16.5%	7.1%	-7.4%	-18.8%	-27.7%	-34.9%
EPS before extr. & amort.	0.3	1.6	7.5	6.4	8.3	10.6	13.7
EPS (cents)	0.3	1.6	7.5	6.4	8.3	10.6	13.7
DPS	NA	NA	NA	NA	NA	NA	NA
Price		1.46	2.13	2.13	2.13	2.13	2.13
M-Cap (m)		111.8	163.1	248.3	248.3	248.3	248.3
Net Debt (cash) (m)		2.8	1.6	(2.3)	(7.5)	(14.5)	(23.8)
Non-controlling interest (m)	na	NA	NA	NA	NA	NA	NA
Provisions (m)	na	NA	NA	NA	NA	NA	NA
EV (m)	0.00	114.7	164.8	246.1	240.8	233.8	224.5
EV/Sales		4.6x	5.4x	6.7x	5.4x	4.3x	3.4x
EV/EBITDA		44.9x	17.8x	20.8x	16.0x	12.2x	9.2x
P/E		0.9x	0.3x	0.3x	0.3x	0.2x	0.2x

Estimates: Pitt Street Research

Key investment risks

The main risk that we see to our investment thesis is the company not obtaining approval in the USA. As we have shown above, this is a significant driver of the company's value. Any further interruption or delay in receiving the FDA approval will delay commercial progress and consequently jeopardise investor sentiment.

Other risks include:

- **Competition:** As the global diagnostic imaging market expands, the larger (both regional and global) service providers will also try to increase their presence in niche segments. Cyclopharm will have to counter their financial and technological prowess to retain its market leadership.
- **Reputational:** The performance of Technegas is critical to its reputation and ability to achieve market acceptance. Any product or personnel failure could have an adverse affect on the company's reputation, especially since the company has had an unblemished record since the commencement of sales.
- **Reliance on key operations:** The company could be impacted by the loss of large customers, a change in the terms of business with a large customer, or by such customers not adequately or fully complying with their contractual obligations.
- **Regulatory:** As the company's struggle with the FDA has depicted, the company entering new markets - not to mention retaining its right to sell products in existing markets – is contingent on obtaining and maintaining regulatory approval. If for any reason product registrations are withdraw, cancelled or not renewed, this would inevitably impact sales.

Appendix I – Analysts' Qualifications

Nick Sundich, lead analyst on this report, is an equities research analyst at Pitt Street Research.

- Nick obtained a Bachelor of Commerce/Bachelor of Arts from the University of Sydney in 2018. He has also completed the CFA Investment Foundations program
- He joined Pitt Street Research in January 2022. Previously he worked for over three years as a financial journalist at Stockhead.
- While at university, he worked for a handful of corporate advisory firms.

Stuart Roberts has been an equities analyst since 2002.

- Stuart obtained a Master of Applied Finance and Investment from the Securities Institute of Australia in 2002. Previously, from the Securities Institute of Australia, he obtained a Certificate of Financial Markets (1994) and a Graduate Diploma in Finance and Investment (1999).
- Stuart joined Southern Cross Equities as an equities analyst in April 2001. From February 2002 to July 2013, his research speciality at Southern Cross Equities and its acquirer, Bell Potter Securities, was Healthcare and Biotechnology. During this time, he covered a variety of established healthcare companies, such as CSL, Cochlear and Resmed, as well as numerous emerging companies. Stuart was a Healthcare and Biotechnology analyst at Baillieu Holst from October 2013 to January 2015.
- After 15 months over 2015–2016 doing Investor Relations for two ASX-listed cancer drug developers, Stuart founded NDF Research in May 2016 to provide issuer-sponsored equity research on ASX-listed Life Sciences companies.
- In July 2016, with Marc Kennis, Stuart co-founded Pitt Street Research Pty Ltd, which provides issuer-sponsored research on ASX-listed companies across the entire market, including Life Sciences companies.
- Since 2018, Stuart has led Pitt Street Research's Resources Sector franchise, spearheading research on both mining and energy companies.

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