PITT STREET RESEARCH

Cyclopharm Ltd.

Set for a good year, even with FDA approval taking a bit longer

Share Price: A$0.96

ASX: CYC

Sector: Healthcare Equipment & Services

24 June 2022

Cyclopharm (ASX:CYC) has been trying to get its core radiopharmaceutical product, Technegas, to be approved by the US Food and Drug Administration (FDA). In March, shareholders received the disappointing news that it would not receive approval until at least early 2023.

We cannot blame shareholders for being disappointed, but we think the wait will be worth it. The FDA has not outright reject the technology or order the company back to the drawing board to do another clinical trial. The company has proven Technegas is not only clinically superior to competing technologies but is safer and easier to use.

We are also excited about further clinical applications including Chronic Obstructive Pulmonary Disease (COPD), Asthma and Long-Covid. COPD represents an addressable market that is substantially larger than what Technegas is used for today.

Shareholders can expect more from the company

Despite the US market eluding the company for now, Technegas is already being sold in over 63 countries and generated $13.2m in Technegas revenue in CY2021 (up 7% from the prior year) and $20.1m in total company revenue (up 14%). With these revenues and a net cash position of $29.3m, Cyclopharm is fully funded for the foreseeable future. We think CYC can achieve $23.7m in group revenue in FY22, which would represent 17.7% growth from FY21, and $29.9m in FY23 (up 26.1%).

Valuation range of A$1.88–2.27 per share

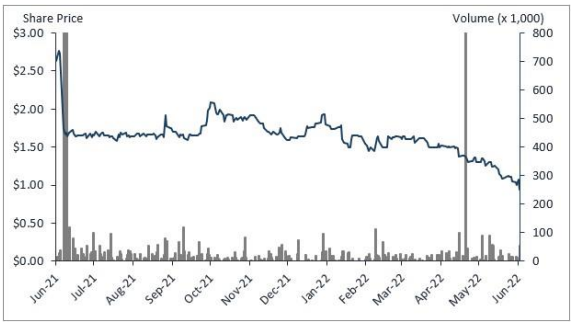
We initiated coverage $2.74 per share base case and $3.33 per share bull case, as outlined in our initiation report published on 1 March 2022. We have cut our valuation to $1.88 per share base case and $2.27 bull case. This is a result of increasing the Risk-free Rate of Return from 1.7% to 4.1% considering the rise in the 10-year Australian government bond, which we use for our Risk-free Rate of Return at Pitt Street Research. Our WAAC consequently rises to 12.5%. The key share price catalyst will be US FDA approval if and when received.

If we exclude our forecasted US sales from our model, our base case becomes $1.67 per share. This depicts that there is value left in the business even if it cannot enter the US market. But our US forecasts are very conservative (with only a 7% penetration in our base case), so CYC could be missing out on further value that we have not modelled for.

Market cap. (A$ m)	84.2
# shares outstanding (m)	89.6
# shares fully diluted (m)	89.6
Market cap full. dil. (A$ m)	84.2
Free float	31.8%
52-week high/low (A$)	2.95 / 0.94
Avg. 12M daily volume ('1000)	37.7
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$)	1.88–2.27
WACC	12.5%
Assumed terminal growth rate	3.0%

Source: Pitt Street Research

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

Please refer to page 7 for key investment risks.

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Cyclopharm still focused on FDA approval

The key focus for Cyclopharm and its shareholders has been obtaining FDA approval

The key focus for Cyclopharm and its shareholders has been obtaining FDA approval for Technegas. This would grant it access to the world's largest healthcare market generally as well as the world's largest nuclear medicine ventilation imaging market. The latter of these for PE (Pulmonary Embolism) alone (Technegas' primary use) is around ~US$180m annually. In Europe France is the single largest market.

Cyclopharm submitted a New Drug Application (NDA) for Technegas with the US FDA in 2020 and management is expecting to receive FDA approval in 1HY23 at the latest. On 26 June 2021, the FDA handed it a Complete Response Letter (CRL), which required further manufacturing and product characterisation information before final approval can be granted.

While the company has faced a setback in not being able to achieve its previous goal of receiving FDA approval by mid-2021, it is important for investors to understand that the FDA has not asked for any additional clinical trials and there is a finite list of issues/queries that management now needs to respond to. The company has also met with the FDA earlier this year to discuss its progress to date and its proposals to address the remaining elements outlined in the CRL.

Furthermore, the company has been receiving tremendous support from Key Opinion Leaders in the US, which reinforces our belief that it will be a matter of time before Technegas will receive FDA approval. In fact, the 16,000-member Society of Nuclear Medicine and Molecular Imaging has requested the FDA fast track approval. It is hardly the case that the FDA did nothing but give Cyclopharm's submission a quick glance and discard it. The US regulator came out to Australia last year to conduct on-site inspections of Cyclopharm's Sydney facility, which took place over a 7 day period. The FDA deemed the pre-approval inspection as 'Mission Critical'. At its AGM in May, Cyclopharm told shareholders it will supply the required information in the second half of this year. This will set off a 6-month period for the FDA to review the submission and a response is expected in the first half of 2023.

Ready to go when approved

Once it receives FDA approval, Cyclopharm is well positioned to expand rapidly in the US

Once FDA approval is secured, Cyclopharm will hit the ground running having made preparations in its inventory, sales capabilities and infrastructure. It hopes it can achieve a 50% share in the US PE market over its first 2-3 years, rising to an 80% share over a 5-7 year period.

In the US market, Technegas will be reimbursable by health insurers from day one making its adoption easier for hospitals. Moreover, the company plans to supply Technegas generators to US hospitals through a service model rather than an upfront sale of generators. This revenue model should help the company build a recurring revenue base in the US very quickly.

Other, more significant opportunities await

The Total addressable market for Technegas will expand considerably if it can be successfully applied to other respiratory diseases

Currently, the primary use case for Technegas is PE, but the company has already commenced investing in trials and supporting clinicians to expand the use of Technegas beyond PE, into Chronic Obstructive Pulmonary Disease (COPD), asthma and other respiratory disease states. COPD has been the most exciting of these because the company estimates the global COPD market to be about 30 times of the size of the PE market!

Long COVID is another opportunity and in May the company received a major boost in its ambitions. Results of an independent peer reviewed study by McMaster University in Ontario found that Technegas, used with the imaging

method VQ-SPECT-CT, found the technique had the potential to be 'a valuable tool for clinicians in the management of patients who are being evaluated after COVID-19 as it permits objective evaluation of functional lung impairment that may underly and help explain post-COVID-19 symptoms'.

It also endorsed Technegas' utility in stating 'Technegas is a widely available and guideline supported nuclear medicine ventilation imaging agent that behaves in a gas-like manner because of its small particle size permitting peripheral penetration and alveolar deposition'.

Cyclopharm set to have a good year in FY22, even without the US market

With the company's persistence and focus on obtaining FDA approval, you might be forgiven for forgetting that Technegas is already commercialised and sold in 60 countries globally and has been used in over 4.4 million patients.

The company is increasing its sales every year, generating $17.7m in FY21 (the 12 months to 31 December 2021), which was up 20.6% over the prior year. Europe and the UK are particularly important markets for the company and it has taken steps to strengthen and protect its market position including renewing its CE Marketing Authorisation and establishing direct sales and distribution offices in Belgium and the UK.

In FY22, we have forecasted that CYC will achieve $23.7m in revenue, up 18% from the prior year, and positive EBITDA of $0.2m.

In FY22, the company expects to record another successful year reporting a strong performance in the year to date (without providing formal guidance). In our model, we have forecasted that it will achieve $23.7m in revenue, up 18% from the prior year, and positive EBITDA of $0.2m. We have forecasted a NPAT of -$1.0m. This year, Europe will be CYC's most important market with $13.8m in revenue.

In FY23, we have forecasted $29.9m in revenue (up 26%), $2.7m in EBITDA and an inaugural positive NPAT of $1.2m. This is assuming inaugural sales in the US, but for conservatism's sake, we have only assumed modest revenues of $1.9m. Europe will continue to remain the most important market with $16.6m in forecasted revenues in FY23.

Valuing Cyclopharm

Our new valuation is $1.88 per share base case and $2.37 per share bull case as a result of a substantial increase of the Risk-free rate of Return.

We valued Cyclopharm in our initiation report dated 1 March 2022. To briefly recap: We used a DCF approach based on its sales of generators and consumables as well as service revenue. We assumed US market entry in 1HY23 and accelerated growth over the 5 years thereafter. We applied a discount rate of 10.1% and a terminal growth rate of 3% considering the US growth plans and uniqueness of the company's technology. We have also assumed a 10% growth rate for its sales for Technegas and its third-party products, both equipment & consumables and after sales services.

The key difference between the base and bull cases was the CAGR growth rate over the first five years in the US market, i.e. 21.9% in the base case and 24.2% in the bull case. CYC's US growth was modelled to be organic (without acquisitions), although reliant on equity funding. We assumed the US remains a modest proportion of its revenues, our base case assumes 7.4% by FY26, while our bull case assumes 12.2%.

New base case of $1.88 per share

Our valuation in our initiation report was $2.74 per share base case and $3.33 per share bull case. However, the change in market conditions has forced us to adjust our model. The Risk-free rate of Return rises from 1.7% to 4.1% in line with the rise in the 10-year Australian Government bond. Our WAAC, consequently rises to 12.4% and our base case valuation falls to $1.88 per share, while our bull case is $2.27 per share. However, we have otherwise left our model unchanged.

Figure 1: Estimates of CYC's key financial data

Year to December (AUD)	2018	2019	2020	2021	2022F	2023F	2024F	2025F	2026F
Group Revenue (m)	15.6	17.0	17.7	20.1	23.7	29.9	36.6	44.8	54.2
YoY growth		9.0%	3.8%	13.9%	17.7%	26.1%	22.4%	22.3%	21.1%
EBITDA (m) Adjusted	0.7	(1.1)	(4.7)	(3.5)	0.2	2.7	6.2	10.9	15.0
Net Profit (m) Adjusted	(0.0)	(2.9)	(6.0)	(5.0)	(1.0)	1.2	3.6	6.8	9.7
EBITDA Margin (%)	4.2%	NM	NM	NM	0.9%	8.9%	16.9%	24.3%	27.8%
RoA (%)	NM	NM	NM	NM	NM	2.1%	6.1%	10.4%	13.0%
Net Gearing (%)	-33.7%	-33.3%	16.5%	-57.4%	-48.7%	-43.0%	-40.0%	-39.5%	-40.6%
EPS before extr. & amort.	(0.1)	(4.3)	(7.9)	(5.6)	(1.1)	1.3	4.0	7.6	10.8
EPS (cents)	(0.1)	(4.3)	(7.9)	(5.6)	(1.1)	1.3	4.0	7.6	10.8
DPS	NA	NA	NA	NA	NA	NA	NA	NA	NA
Price			2.50	1.64	0.96	0.96	0.96	0.96	0.96
M-Cap (m)			191.5	146.9	86.0	86.0	86.0	86.0	86.0
Net Debt (cash) (m)			2.8	(24.7)	(20.5)	(18.6)	(18.7)	(21.2)	(25.7)
Non-controlling interest (m)		na	NA	NA	NA	NA	NA	NA	NA
Provisions (m)		na	NA	NA	NA	NA	NA	NA	NA
EV (m)		0.00	194.3	122.2	65.5	67.4	67.3	64.8	60.3
EV/Sales			11.0x	6.1x	2.8x	2.3x	1.8x	1.4x	1.1x
EV/EBITDA			NM	NM	306.9x	25.3x	10.9x	6.0x	4.0x
P/E			NM	NM	NM	0.7x	0.2x	0.1x	0.1x

Estimates: Pitt Street Research

What if Cyclopharm cannot obtain US approval?

If we exclude the US, our base case becomes $1.67 per share.

We have also modelled an alternative scenario in which the company is unsuccessful in obtaining FDA approval and opts to give up on obtaining approval. In that case, our base case scenario would drop to $1.67 per share – which is 12% lower.

However, we reiterate that we were conservative in our US forecasts. Our base case assumed the US only accounted for 7.4% by FY26, while our bull case assumed 12.2%. Therefore, it could be missing out on further revenues than we have forecasted. Nonetheless, we believe this shows there is value left in the business based on sales in its existing markets. We have not modelled an alternative bull case because our growth forecasts in our original model for markets ex. USA were the same.

Figure 2: Estimates of CYC's key financial data (ex-USA)

Year to December (AUD)	2018	2019	2020	2021	2022F	2023F	2024F	2025F	2026F
Group Revenue (m)	15.6	17.0	17.7	20.1	23.7	28.0	33.2	39.4	46.8
YoY growth		9.0%	3.8%	13.9%	17.7%	18.1%	18.4%	18.7%	19.0%
EBITDA (m) Adjusted	0.7	(1.1)	(4.7)	(3.5)	0.2	2.5	5.6	9.5	13.0
Net Profit (m) Adjusted	(0.0)	(2.9)	(6.0)	(5.0)	(1.0)	1.0	3.2	5.9	8.3
EBITDA Margin (%)	4.2%	NM	NM	NM	0.9%	8.9%	16.9%	24.3%	27.8%
RoA (%)	NM	NM	NM	NM	NM	1.9%	5.5%	9.4%	11.7%
Net Gearing (%)	-33.7%	-33.3%	16.5%	-57.4%	-48.7%	-45.0%	-43.1%	-43.2%	-44.3%
EPS before extr. & amort.	(0.1)	(4.3)	(7.9)	(5.6)	(1.1)	1.2	3.6	6.6	9.3
EPS (cents)	(0.1)	(4.3)	(7.9)	(5.6)	(1.1)	1.2	3.6	6.6	9.3
DPS	NA	NA	NA	NA	NA	NA	NA	NA	NA
Price			2.50	1.64	0.96	0.96	0.96	0.96	0.96
M-Cap (m)			191.5	146.9	86.0	86.0	86.0	86.0	86.0
Net Debt (cash) (m)			2.8	(24.7)	(20.5)	(19.4)	(19.9)	(22.6)	(26.8)
Non-controlling interest (m)		na	NA	NA	NA	NA	NA	NA	NA
Provisions (m)		na	NA	NA	NA	NA	NA	NA	NA
EV (m)		0.00	194.3	122.2	65.5	66.6	66.1	63.4	59.2
EV/Sales			11.0x	6.1x	2.8x	2.4x	2.0x	1.6x	1.3x
EV/EBITDA			NM	NM	306.9x	26.7x	11.8x	6.6x	4.6x
P/E			NM	NM	NM	0.8x	0.3x	0.1x	0.1x

Estimates: Pitt Street Research

Key share price catalysts

Cyclopharm's stock is currently trading below our base case valuation. We think the stock can re-rate to our valuation range based on positive news flow around the FDA approval, signing of major partnership or distribution deals, value-enhancing acquisitions, better-than-expected results from Europe and Canada and a better-than expected penetration of the US market next year.

Key investment risks

The main risks that we see to our investment thesis include:

- **Execution risk:** A significant proportion of future growth for the company is expected to come from the US market. Any interruption or delay in receiving the FDA approval will delay commercial progress and consequently jeopardise investor sentiment.
- **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.

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.

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