PITT STREET RESEARCH

Cyclopharm Ltd.

Finally FDA approved

Share Price: A$2.55

ASX: CYC

Sector: Healthcare Equipment & Services

11 October 2023

Cyclopharm's (ASX: CYC) core radiopharmaceutical product Technegas has finally been approved by the US Food and Drug Administration (FDA). The development has been a long time coming for shareholders and the journey has not been without setbacks. But now the company has access to a market worth US$180m, a market larger than any other of the 64 it is currently in.

Ready to hit the ground running

As outlined in our last report from late April, we noted that the company has been doing groundwork to ensure a hassle-free entry and rapid expansion post Technegas' approval. The company kept inventory reserved the US market. It has ensured Technegas will be reimbursable by health insurers from day one and CYC has designed an ideal business model – a service model rather than upfront sale of generators, thereby resulting in accelerated and more predictable revenue over the generator's lifecycle. CYC has roughly 200 generators sitting in its Kingsgrove headquarters, ready for shipment to meet some of the 420 formal expressions of interest in the product. It anticipates having up to 300 generators placed by the end of CY24.

Shareholders can expect more from the company

Although investors have long treated the company as if it had little to no business outside the US, it has business in over 60 countries and generated over US$15.7m in sales revenue during 1H23. We are also excited about further clinical applications including Chronic Obstructive Pulmonary Disease (COPD), Asthma and Long-Covid which represent substantially larger opportunities than PE. Indeed, the fact that the FDA approval was not just for the diagnosis of PE but for its visualisation too, bodes well for future applications.

Valuation range of A$4.58-$6.40 per share

We valued CYC at $3.09 per share base case and $4.37 bull case, using a DCF approach based on sales forecasts up to CY30. The key catalyst was FDA approval and indeed it proved to be. Given CYC's approval, outlined ambitions for the US market and its success in existing markets (greater than what we previously modelled), we update our valuation to A$4.58 per share base case and $6.40 per share bull case. The company's Remaining risks, outlined in further detail on page 6, include execution risk and competition risk.

Market cap. (A$ m)	239.2
# shares outstanding (m)	93.8
# shares fully diluted (m)	93.8
Market cap full. dil. (A$ m)	239.2
Free float	31.8%
52-week high/low (A$)	3.15 / 1.17
Avg. 12M daily volume ('1000)	17.9
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$)	4.58–6.40
WACC	10.1%
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 6 for key investment risks.

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The world's largest market is unlocked

The USA is the world's largest nuclear medicine market.

The USA is the world's largest nuclear medicine market. Roughly four million diagnostic procedures are conducted each year on PE patients. Out of all these diagnostic tests being conducted, 15% are based on nuclear medicine imaging and 85% of them are CT Pulmonary Angiograms (or CTPAs). CTPAs are CT scans that look for blood clots in the lungs, which is pulmonary embolisms manifested. These 600,000 nuclear medicine ventilation procedures being conducted annually represent a market opportunity of US$90m.

Cyclopharm's target is 480,000 of these, equating to US$76.5m and we believe based on its experience in the Canadian market, Technegas can achieve a 50% share of the US market over 2-3 years and an 90% share achievable over a 5 to 7-year period. And we also think its market can grow. The US is expected to see a growing number of cases of PE driven by lifestyle diseases, smoking, longer life expectancy and more sensitive diagnostic tests.

Importantly, the FDA approval was not just for the diagnosis of PE but for visualisation as well. This underpin's CYC's so-called Beyond PE strategy which envisions the use of Technegas to diagnose other conditions such as COPD, asthma and Long COVID (all of which represent bigger markets than PE).

Positioned to hit the ground running

CYC management has been doing the groundwork to ensure a hassle-free entry and rapid expansion.

While awaiting FDA approval, CYC management has been doing the groundwork to ensure a hassle-free entry and rapid expansion post Technegas' approval. Management has ensured that Technegas will be reimbursable by health insurers from day one making its adoption easier by patients and hospitals. It plans to supply Technegas generators to US hospitals through a service model rather than an upfront sale of generators.

Through this model, the company will retain ownership of the generators over their lifecycle and charge an ongoing annual fee attributed to preventative maintenance, raining and product support. This approach will result in accelerated consumables revenue and provide a more predictable revenue base over the generators' lifecycle.

CYC advised us at our April site visit that it had over 400 expressions of interest from US hospitals for Technegas. Furthermore, it has several dozen generators all ready to be shipped to the US. The company rationalised its supply chain pre-COVID so it has been unaffected by supply chain issues post-pandemic.

An even bigger future awaits

Shareholders will be relieved that FDA approval has come. But they should not fall into the trap of thinking all the future holds is growth in the US. The company is investing in new clinical trials that may find further opportunities for Technegas that represent larger opportunities than PE. This is its Beyond PE program.

It has several research projects in its pipeline that are being conducted in collaboration with leading academic institutions. These projects were impacted due to the COVID-19 pandemic as recruitment of patients slowed down, but this has picked up pace. The most exciting opportunity is COPD because this global market is roughly 30 times the size of the PE market.

Valuing Cyclopharm

Our new valuation is $3.02 per share base case and $3.82 per share bull case

We first valued Cyclopharm in our initiation report dated 1 March 2022. We did so again on 24 June 2022 and most recently on 20 April 2023. Please see those reports for further details on our model, particularly the most recent one.

We have tweaked our existing model on CYC (Figures 1 and 2), updating our modelled revenues for non-US markets, accounting for the company's 1HY23 result and also slightly increasing our US growth assumptions to account for CYC's FDA approval against both visualisation and diagnosis of PE not to mention the company's ambitions (which are above what we had previously modelled).

Our base case assumes it sells 1 generator each to 300 hospitals by the end of CY24 (in line with the company's aspiration and ahead of the 200 our model in April estimated). This is not even half of the expressions of interest received) while our bull case starts with 350. We assume gradual growth to 690 hospitals in our base case and 1,000 in our bull case by FY27. We also model PAS kits, assuming one is used per screening and each hospital undertakes roughly 60 screenings a year, 70 in our bull case.

Even so, the US market remains a small proportion of its revenues.

Figure 1: Revenue forecasts for FY23-FY27 (base case)

Technegas sales ($A)						
Year		*FY23*	*FY24*	*FY25*	*FY26*	*FY27*
	Asia-Pacific	10.3	14.5	18.0	27.1	32.7
	Europe	16.1	22.7	28.1	42.3	50.8
	Canada	3.9	5.4	6.7	10.1	12.2
	US	0.0	14.6	26.8	33.8	40.2
	Other	0.4	0.5	0.8	0.9	1.1
	Total sales	**30.6**	**57.8**	**62.7**	**92.33**	**96.3**

Estimates: Pitt Street Research

Figure 2: Revenue forecasts for FY23-FY27 (bull case)

Technegas sales ($A)						
Year		*FY23*	*FY24*	*FY25*	*FY26*	*FY27*
	Asia-Pacific	10.6	16.1	20.8	26.8	34.6
	Europe	16.3	24.8	32.0	41.3	53.3
	Canada	3.9	5.9	7.7	9.9	12.8
	US	0.0	24.3	35.1	48.4	63.0
	Other	0.4	0.6	0.7	0.9	1.2
	Total sales	**31.1**	**71.7**	**96.2**	**127.3**	**164.8**

Estimates: Pitt Street Research

Our updated valuation is $4.58 per share in our base case and $6.40 per share in our bull case (Figures 3 and 4).

Valuation per share of A$1.03 base case and A$1.15 bull case

Figure 3: DCF valuation for Cyclopharm

Valuation (AU$m)	Base case	Bull case
Present value of FCF	125.4	162.0
Present value of Terminal FCF	321.8	456.8
Enterprise Value	**447.2**	**618.8**
Net debt (cash)	(18.1)	(18.1)
Equity value (A$'000s)	**429.1**	**600.7**
Shares outstanding	93.8	93.8
Implied price (A$ cents)	**4.58**	**6.40**
Adjusted Current price (A$ cents)	2.74	2.74
Upside (%)	*79.6%*	*133.6%*

Source: Pitt Street Research

Figure 4: DCF value in A$ cents using various WACCs

Sensitivity Analysis						
WACC	**10.1%**					
Terminal Growth Rate	**2.00%**					
Implied Price (A$ cents)	**4.58**	*8.1%*	*9.1%*	*10.1%*	*11.1%*	*12.1%*
Change in Terminal Growth Rate	*0.50%*	$5.59	$4.71	$4.00	$3.47	$3.02
	1.00%	$5.92	$4.94	$4.17	$3.60	$3.12
	1.50%	$6.29	$5.20	$4.36	$3.74	$3.23
	2.00%	$6.73	$5.51	**$4.58**	$3.80	$3.35
	2.50%	$7.24	$5.85	$4.82	$4.08	$3.49
	3.00%	$7.85	$6.26	$5.09	$4.26	$3.64
	3.50%	$8.59	$6.73	$5.41	$4.51	$3.80

Source: Pitt Street Research

Key share price catalysts

Cyclopharm's stock nearly surpassed our previous price target ($3.07 per share) after FDA approval. We think now that it has FDA approval, a significant risk has been removed and that it can make significant inroads to the US market and shares can re-rate accordingly. The company is also growing its business in 64 other countries Technegas is already in and we see this can be a catalyst for the company.

We also note that we have not included *any* future upside from future indications that the company could target. Even though commercialisation of Technegas against 'Beyond PE' indications is realistically a few years away, shareholders may be excited if and when the company begins clinical trials.

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. Although the biggest impediment to the US market has been removed, a delay in US commercialisation could occur for a variety of reasons (such as supply chain issues) 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.
- **Regulatory risk:** CYC's ability to distribute Technegas is subject to regulatory approval. The withdrawal of existing approval or the failure to gain approval in new markets and/or for new indications will inhibit the company's growth potential.
- **Key personnel risk:** There is the risk that CYC loses key individuals and is unable to replace them and/or their contribution to the business.

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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