

Speculative

See key risks on Page 4 and Biotechnology Risk Warning on Page 7. Speculative securities may not be suitable for Retail Clients.

Analyst

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Cyclopharm (CYC)

US Clinical Trial Gathering Momentum

Authorisation

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Recommendation

Buy (unchanged)

Price

\$1.00

Valuation (12 months)

\$1.30 (previously \$1.13)

Risk

Speculative

GICS Sector

Pharmaceuticals & Biotechnology

Expected Return

Capital growth	30.0%
Dividend yield	1.0%
Total expected return	31.0%

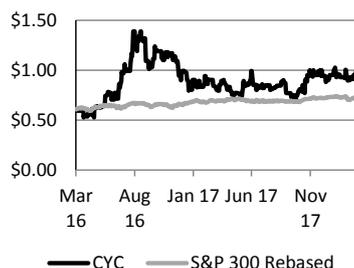
Company Data & Ratios

Enterprise value	\$59.6m
Market cap	\$68.3m
Issued capital	68.3m
Free float	100%
Avg. daily val. (52wk)	\$14,614
12 month price range	\$0.705 - \$1.025

Price Performance

	(1m)	(3m)	(12m)
Price (A\$)	0.93	1.00	0.83
Absolute (%)	7.53	0.00	20.12
Rel market (%)	9.96	0.85	16.27

Absolute Price



SOURCE: IRESS

Entry to US market inching closer

For the year ended 31 December 2017, Cyclopharm reported revenues of \$13.2m which was in line with our forecast but 8% lower than pcp. Reported EBITDA declined to \$1.0m from \$2.0m in pcp. FY16 included the one off benefit of a large initial order for the Chinese market. Excluding the impact of this item, revenues increased by 1.4% primarily driven by 17% growth in patient administration sets in western europe.

Cyclopharm's future earnings growth remains very much dependent upon the success of its US clinical trial. Three sites are now actively recruiting patients with an additional two sites to join shortly. Thirty three patients have now been imaged. Following completion of the 40th patient, the company will present interim data to the US FDA and this is expected to occur in the June quarter of this year. More than 7m patients have been imaged with Technegas globally with no serious adverse events. Technegas is the standard of care for lung imaging where patients are contraindicated for CT Scan. For these reasons it is highly unlikely that the FDA would have any material concern regarding the safety outcome of the US trial.

The total cost of the trial is estimated at A\$10m with the vast majority of this expense expected to be incurred in the current fiscal year.

The company's outlook statements for FY18 are bullish. It expects continued growth in demand for generators and patient administration sets in each of its key markets. Asia is expected to return to growth following a large one off sale in 2016.

Maintain Buy Recommendation

Following our initial review of the result there are no material changes to our outlook for revenues, however, we have accelerated the timing of the spend on the clinical trial. Consequently the FY18 EBITDA loss increases by \$4.1m to -\$3.6m. This additional charge is largely reversed in the following year. The company has made encouraging progress with the recruitment of the US clinical trial which is indicative of a future commercial launch. Our valuation is increased to \$1.30.

Earnings Forecast

December Year End	FY17	FY18e	FY19e	FY20e
Revenues	13.2	13.9	15.7	19.0
EBITDA \$m	1.0	-3.6	3.3	3.3
NPAT (underlying) \$m	-1.5	-3.9	2.1	2.1
NPAT (reported) \$m	-1.5	-3.9	2.1	2.1
EPS underlying (cps)	-2.2	-5.8	3.1	3.1
EPS growth %	-216%	157%	-154%	0%
PER (x)	-0.4	-0.2	0.3	0.3
FCF yield (%)	-4%	-9%	2%	-13%
EV/EBITDA (x)	61.5	-16.3	17.9	17.9
Dividend (cps)	1.0	1.0	1.0	1.6
Franking	0%	0%	0%	0%
Yield %	1.0%	1.0%	1.0%	1.6%
ROE %	3.8%	-31.6%	21.8%	20.0%

SOURCE: BELL POTTER SECURITIES ESTIMATES

US Clinical Trial Gathers Momentum

We summarise the full year result as follows:

Figure 1 - FY17 Result Highlights

\$m	FY16	FY17	% change	FY18
	Actual	Actual		Forecast
Patient Administration sets	10.8	10.9	1%	10.0
Generator Revenue	3.6	2.3	-37%	3.7
Total revenues	14.4	13.2	-8%	13.7
EBITDA	2.0	1.0	-51%	0.1
NPAT	1.1	-1.5	-237%	-0.1
EPS	1.6	-2.2	-245%	0.0
Final dividend	0.5	0.5		0.5

SOURCE: COMPANY DATA

The decline in Generator revenues was due to the one off impact of the 50 units sold to a distributor in China in FY16. Excluding the impact of this order, generator sales (units) declined by approximately 19% to 56 units.

The ongoing revenues from patient administration sets (PAS) was within 1% of pcp. The prior period included revenues from a large one off sale to the China market. Excluding the impact of the large on off sale, we estimate sales units increased by ~6%.

Excluding the total value of the China order from pcp, revenues increased by 1.4%

EBITDA is inclusive of \$2.5m in costs related to the conduct of the US clinical trial. Offsetting this was a windfall gain from the research and development tax incentive scheme. The company was permitted to include a portion of the expenses associated with the company's offshore R&D activity in the claim. Consequently CYC reported other income of \$2.4m vs \$0.5m in pcp. The company expects to continue to receive an R&D tax incentive amount similar to that received in 2017 through to at least FY2020.

This may represent a windfall of up to \$7m - \$8m (over 3 years) over and above our prior expectation and this makes a meaningful impact on the company's future funding requirement.

OUTLOOK

The company expects ongoing growth in unit sales in the key markets of Western Europe and Canada. These markets represent 82% of total sales of PAS and a similar proportion of Generator revenues. In FY17 PAS sales in each market grew by 3% and 17% respectively. The company also expects first revenues from the sale of its Ultralute product albeit these will be small initially.

In relation to the clinical program, the key factor will be the recruitment rate for the US clinical sites. One of the sites is recruiting quickly at two patients per week. The company is hopeful of deriving first revenues from Technegas sales in late FY19. The next milestone for the trial is the imaging of the 40th patient and this is expected to occur within weeks. Cyclopharm is expected to publish the key points from the interim data after submission to the FDA.

Figure 2 - Key changes to earnings

Changes to Earnings	2018			2019		
	Prior	New	% change	Prior	New	% change
Revenues	14.6	13.9	-5%	16.7	15.7	-6%
EBITDA	-0.5	-3.6	Large	0.8	3.3	Large
NPAT	-0.7	-3.9	Large	0.5	2.1	Large
EPS	-1.0	-5.8	Large	0.7	3.1	Large

SOURCE: BELL POTTER SECURITIES ESTIMATES

Revenues are lowered primarily due to the impact of a stronger A\$ relative to our previous forecast. We increased the R&D expense in FY18 associated with the US clinical trial. This is offset by an increase in other income associated with the R&D tax credit. This increased clinical trial expense reverses in FY19.

The company has no debt and cash of \$8.7m as at 31 December 2017.

Our valuation on Cyclopharm is raised to \$1.30 for the following key reasons:

- The R&D tax incentive is an estimated \$7m - \$8m windfall over the next two to three years. It should provide vital working capital to not only complete the US trial, but support a product launch in late 2019 or early 2020.
- The US clinical trial is on the verge of recruiting its 40th patient. While there are no clinical results to date, the mere fact that recruitment is accelerating is a good indicator that physicians in the US are seeing value in the Technegas system. As there have been more than 7m patients uses of Technegas worldwide in dozens of countries, there is a low risk that the trial does not meet its objectives. Two more clinical sites in the US will start recruitment shortly.

In our view this is sufficient cause to reduce the risk rating on future US revenues.

For these reasons the valuation of the future US business is increased and this drives the overall valuation to \$1.30.

Cyclopharm Limited

A Growing Medical Device Company

Cyclopharm is a medical device company operating in the specialist field of nuclear medicine. The main revenue driver is Technegas - a system indicated for functional lung imaging. The primary use of Technegas is diagnosis of pulmonary embolism in patients contra indicated for a CT scan.

Diagnosis of pulmonary embolism and other pulmonary conditions requiring structural analysis of the lungs via Technegas is a safer, more accurate, cost effective solution for thousands of patients around the world each year.

Imaging for pulmonary disease and the use of nuclear medicine is standard practice around the world, hence the products manufactured by the company fit within accepted medical practice. Cyclopharm is therefore not a biotechnology stock or drug developer, rather its status as a medical device company is well established.

KEY RISK AREAS

CLINICAL TRIAL RISK

The major risk to our valuation is the fate of the pivotal study being conducted in the US. This study is essential for FDA Approval, notwithstanding the extensive use of Technegas outside of the US.

Previously Cyclopharm had attempted to enrol a 750 patient trial to compare the Sensitivity of Technegas V/Q SPECT for Diagnosis of PE to the sensitivity of Xenon V/Q Planar imaging based on blinded readers assessment and final diagnosis at 30 days follow up.

The inclusion criteria for this earlier trial was suspected pulmonary embolism. Unfortunately this meant a lot of emergency room patients where the treating physician typically does not have the time to wait for multiple parties to co-ordinate a VQ scan. Consequently only about 30 patients were ever enrolled. The trial also had some important exclusions. Hospital inpatients were excluded for example.

In contrast to this previous study, the current trial enrolling in the US does not have a long list of exclusions. The trial will accept all patients where lung function assessment is required, including inpatients. This should include a range of patients including suspected PE, Asthma, COPD, lung transplant, lung cancer and pulmonary hypertension.

We are hopeful that this broader admission criteria will accelerate patient recruitment. Further details of the current trial are included later in this report.

The US market represents approximately 60% of our valuation for Cyclopharm, hence it is important that this trial is a success and that enrolment proceeds in a timely manner.

New Technology

The Technegas system was commercialised almost 30 years ago. It remains relevant today, however, medical imaging technology continues to move quickly and is continually improving. Technegas will continue to face the risk of loss of market share through improvements in medical imaging technology.

Supply Chain

Cyclopharm assembles the Technegas generators from components manufactured both in Australia and offshore. Any supply disruption may temporarily constrain or disrupt the company's ability to continue supply.

The capability of a hospital nuclear medicine department to make Technegas is dependent upon supply of the radioactive isotope from one of a handful of groups which manufacture

these products. There are suppliers in Australia, the US, South Africa and Europe. While it is unlikely all suppliers would go offline at the one time, their ongoing supply capability is crucial.

Regulatory Risk

The regulatory environment surrounding the manufacture and supply of nuclear isotopes for medical use are strict in every country. Handled incorrectly they are potentially dangerous, hence any changes to the regulatory environment surrounding these materials could potentially jeopardise a portion of Cyclopharm's revenue.

Patents

The key patents on the Technegas generator expires in 2026. Cyclopharm may face competition then, or beforehand if the patent is successfully challenged.

Table 1 - Financial summary

Profit & Loss (A\$m)	FY16	FY17	FY18e	FY19e	FY20e	Valuation Ratios (A\$m)	FY16	FY17	FY18e	FY19e	FY20e
Year Ending June						Reported EPS (cps)	1.6	-2.2	-5.8	3.1	3.1
Total Revenues	14.4	13.2	13.9	15.7	19.0	Normalised EPS (cps)	1.9	-2.2	-5.8	3.1	3.1
COGS	-3.5	-2.6	-2.8	-3.1	-3.8	EPS growth (%)	-60%	-216%	157%	-154%	0%
Gross profit	10.9	10.5	11.1	12.6	15.2	PE(x)	0.5	-0.4	-0.2	0.3	0.3
GP margin	75.5%	79.9%	79.9%	80.0%	80.0%	EV/EBITDA (x)	29.3	60.2	-16.0	17.5	17.5
Operating expenses (net of R&D refund)	7.8	7.0	7.8	8.2	11.9	EV/EBIT (x)	30.9	89.6	-14.8	19.2	19.2
US Clinical trial costs	1.1	2.6	7.0	1.0	0.0	NTA (cps)	24.5	30.1	21.0	23.2	33.0
EBITDA	2.0	1.0	-3.6	3.3	3.3	P/NTA (x)	0.0	0.0	0.0	0.0	0.0
Depreciation and Amortisation	-0.1	-0.3	-0.3	-0.3	-0.3	Book Value (cps)	20.8	25.2	18.2	20.3	22.2
EBIT	1.9	0.7	-3.9	3.0	3.0	Price/Book (x)	0.0	0.0	0.1	0.0	0.0
EBIT margin	13.1%	4.9%	-28.4%	19.3%	16.0%	DPS (cps)	1.0	1.0	1.0	1.0	1.6
Net other income	0.0	0.1	0.0	0.0	0.0	Payout ratio %	52%	0%	0%	0%	50%
Pre tax profit	1.9	0.7	-3.9	3.0	3.0	Dividend Yield %	1.0%	1.0%	1.0%	1.0%	1.6%
Tax expense	(0.8)	-2.2	0.0	-0.9	-0.9	Franking %	-372%	0%	0%	0%	0%
NPAT - normalised	1.1	-1.5	-3.9	2.1	2.1	FCF yield %	-2%	-4%	-9%	2%	-13%
Net abnormal items	(0.3)	-	-	-	-	Net debt/Equity	0%	0%	0%	0%	0%
Reported NPAT	0.8	-1.5	-3.9	2.1	2.1	Net debt/Assets	0%	0%	0%	0%	0%
Cashflow (A\$m)	FY16	FY17	FY18e	FY19e	FY20e	Gearing	net cash				
Gross cash flow	1.3	-0.1	-3.7	2.9	2.6	Net debt/EBITDA (x)	n/a	n/a	n/a	n/a	n/a
Net interest	0.0	0.1	0.0	0.0	0.0	Interest cover (x)	n/a	n/a	n/a	n/a	n/a
Tax paid	-0.6	-0.2	-1.6	-0.8	-0.9	PAS Unit sales	FY16	FY17	FY18e	FY19e	FY20e
Operating cash flow	0.7	-0.3	-5.3	2.1	1.7	Europe	4,141	4,238	4,492	4,717	4,906
Maintenance capex	-1.8	-0.6	-0.2	-0.2	-5.2	Growth	8%	2%	6%	5%	4%
Other capitalised intangibles	-0.4	-1.1	-0.4	-0.4	-0.4	USA	-	-	-	40	270
Free cash flow	-1.6	-2.0	-5.9	1.5	-3.9	Growth	0%	0%	0%	0%	575%
Business acquisitions	0.0	0.0	0.0	0.0	0.0	Total Patient Admin Sets Sold	4,141	4,238	4,492	4,757	5,181
Proceeds from issuance	0.0	6.5	0.0	0.0	0.0	Average revenue per sale A\$'000	2,516	2,574	2,574	-	-
Movement in debt	-0.2	0.0	0.0	0.0	5.0						
Dividends paid	-0.6	-0.6	-0.7	-0.7	-0.8						
Change in cash held	(2.3)	3.9	(6.6)	0.8	0.3						
Cash at beginning of period	6.4	4.6	8.7	2.1	2.9						
Cash at year end	4.6	8.7	2.1	2.9	3.2						
Balance Sheet (A\$m)	FY16	FY17	FY18e	FY19e	FY20e						
Cash	4.6	8.7	2.1	2.9	3.2						
Receivables	3.7	5.3	5.6	6.4	7.7						
Inventory	2.6	2.7	2.8	3.0	3.1						
Other current assets	0.1	0.1	0.1	0.1	0.1						
Property, Plant and Equipment	2.3	2.7	2.6	2.5	7.4						
Intangible assets	1.7	2.7	3.1	3.5	3.9						
Deferred tax assets	1.2	1.1	1.1	1.1	1.1						
Total assets	16.3	23.3	17.5	19.4	26.5						
Trade payables	2.8	2.8	3.1	3.5	4.2						
Debt	-	0.2	0.2	0.2	5.2						
Tax payable	-	1.6	-	0.1	0.1						
Other liabilities	0.2	0.4	0.4	0.4	0.3						
Deferred income tax liability	-	-	-	-	-						
Provisions	1.0	1.2	1.3	1.3	1.4						
Total Liabilities	3.9	6.1	4.9	5.4	11.2						
Net Assets	12.4	17.2	12.6	14.0	15.3						
Share capital	15.0	21.5	21.5	21.5	21.5						
Retained earnings	(2.3)	(4.3)	(8.9)	(7.5)	(6.2)						
Reserves	(0.3)	-	(0.1)	(0.1)	(0.1)						
Shareholders Equity	12.4	17.2	12.6	14.0	15.3						

SOURCE: BELL POTTER SECURITIES ESTIMATES

Recommendation structure

Buy: Expect >15% total return on a 12 month view. For stocks regarded as 'Speculative' a return of >30% is expected.

Hold: Expect total return between -5% and 15% on a 12 month view

Sell: Expect <-5% total return on a 12 month view

Speculative Investments are either start-up enterprises with nil or only prospective operations or recently commenced operations with only forecast cash flows, or companies that have commenced operations or have been in operation for some time but have only forecast cash flows and/or a stressed balance sheet.

Such investments may carry an exceptionally high level of capital risk and volatility of returns.

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