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Cyclopharm (CYC)

Recruitment Commences

Speculative
Refer to key risks on page 3 and Biotechnology Risk Warning on page 5. Speculative securities may not be suitable for retail clients.

Recommendation
Buy (unchanged)
Price
$0.74
Valuation
$1.13 (unchanged)
Risk
Speculative

GICS Sector

Healthcare Equipment and Services

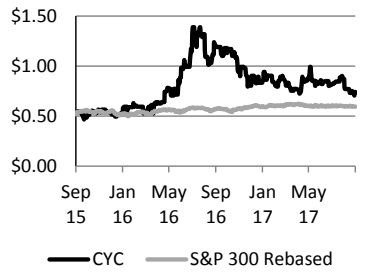
Expected Return	
Capital growth	**52.7%**
Dividend yield	**1.4%**
Total expected return	**54.1%**

Company Data & Ratios	
Enterprise value	**$40.6m**
Market cap	**$50.6m**
Issued capital	**68.4m**
Free float	**94%**
Avg. daily val. (52wk)	**$17K**
12 month price range	**$0.71 - $1.20**

Price Performance

	(1m)	(3m)	(12m)
Price (A$)	0.09	0.13	0.13
Absolute (%)	-1.61	-26.80	-26.80
Rel market (%)	-1.77	-24.29	-29.89

Absolute Price



SOURCE: IRESS

First Patients Enrolled in US Pivotal

Cyclopharm has now completed the recruitment of the first two patients in its US pivotal study. Both patients were seen at Washington University, St Louis Missouri. Both were lung transplant patients – which in itself is highly significant, while the delivery of the Technegas and subsequent imaging were completed without incident.

Technegas is a lung imaging system that has been delivered safely to more than 3.6m patients in 55 countries outside of the US. Due to its extensive use, the probability of a significant mishap or unforeseen clinical trial result remains very low. Technegas is the standard of care for diagnosis of pulmonary embolism (PE) in patients contraindicated for CT scan.

It appears Pulmonologist clinicians involved in the trial have more expansive plans for this system than diagnosis of pulmonary embolism alone and this is highly encouraging. If successful in this pivotal study, the FDA is likely to indicate Technegas for structural lung ventilation which vastly expands the scope of use and potentially the revenue base. To date the vast majority of Technegas use has been for diagnosis of PE.

Over the next few days the company expects both Duke University Hospital and Emory University to commence patient enrolment. The next catalyst for the stock is completion of the first 40 patients which is the interim reporting point to the FDA. The company is expected to release the data package from the first 40 patients in due course. The remainder of this note contains an overview of the trial design.

We expect enrolment of these patients together with submission of the data package to be completed by 31 March 2018. Patient enrolment in the trial was identified as a key risk to meeting long term revenue and earnings targets, hence the successful completion of the first two patients is a small but significant step. There are no changes to earnings estimates or valuation. We retain our Speculative Buy recommendation and valuation of $1.13.

Earnings Forecast

December Year End	FY16	FY17e	FY18e	FY19e
Revenues	14.4	13.7	14.6	16.7
EBITDA $m	2.0	0.1	-0.5	0.8
NPAT (underlying) $m	1.1	-0.1	-0.7	0.5
NPAT (reported) $m	0.8	-0.1	-0.7	0.5
EPS underlying (cps)	1.9	-0.1	-1.0	0.7
EPS growth %	-60%	-105%	904%	-166%
PER (x)	0.4	-7.3	-0.7	1.1
FCF yield (%)	-3%	-1%	-3%	-1%
EV/EBITDA (x)	20.4	478.2	-74.1	50.2
Dividend (cps)	1.0	1.0	1.0	1.0
Franking	0%	0%	0%	0%
Yield %	1.4%	1.4%	1.4%	1.4%
ROE %	15.2%	-0.3%	-4.1%	3.9%

SOURCE: BELL POTTER SECURITIES ESTIMATES

Trial Design Aimed At Approval

The key points for the current study (known as CYC009) study are:

- 240 patients;
- The trial has a Special Protocol Assessment (SPA). An SPA agreement indicates concurrence by the FDA with the adequacy and acceptability of specific critical elements of overall protocol design. These elements are critical to ensuring that the trial conducted under the protocol has the potential to support a future application for approval;
- Interim reporting on first 40 patients;
    - Participants on the trial will undergo two separate imaging studies – the first using Xenon^{133,} the second using Technegas;
    - Physicians will be blinded as to the patient identification and will assess both sets of images, assigning a ventilation function score to each image;
    - Investigators will compare the independently assessed scores for each image and each patient;
    - The primary outcome is the percent agreement between Technegas and Xe^{133} blinded ventilation assessments;
    - The imaging technology for this trial will be the relatively low tech planar imaging (2 dimensional images). This was selected because it is the standard of care in the US for lung imaging with nuclear medicine; and
    - Trial is open to all comers, regardless of co-morbidites, medication or prior treatment.

This is a non-inferiority trial design which we regard as pragmatic – it achieves the bare minimum in order to gain approval. By comparison a previous 750 patient study was benchmarked to the higher standard of diagnostic equivalence (i.e. of PE) with many exclusion criteria – consequently recruitment rates were abysmal.

We expect the trial will now recruit rapidly following these first two patients. The trial is open to all comers, not just emergency room patients, or patients with suspected PE. Patients with any pulmonary complaint may be admitted to the trial, hence this should remove a significant barrier to patient recruitment.

The treatment of the first patients was later than expected, however, there should be an ample number of patients to allow for rapid recruitment. The company hopes to have an additional 6 sites recruiting patients by the end of November. Duke University and Emory University should commence enrolments within days. Up to 15 sites may eventually be added.

There are no changes to earnings estimates or valuation. We retain our buy recommendation and price target of $1.13.

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.

BUSINESS MODEL

The Technegas system has two major components being the Technegas Generator and its consumables. The generators sell for between $26K - $50K and the single use consumables sell for between $70 - $100 per patient. The consumables generate the majority of revenues.

In Australia, NZ, Canada and Germany the company performs its own distribution direct to hospital customers. In other jurisdictions it uses a distributor model.

End users are generally the Nuclear Medicine departments of large hospitals in each of the 55 countries (excluding the US) around the world where Technegas is approved. The company's head office is in Sydney along with its manufacturing/assembly and R&D facilities.

ENTRY TO US MARKET

The medium term catalyst for Cyclopharm is entry into the US market. It has now commenced a pivotal clinical study in the US which we expect will lead to FDA approval of the Technegas system. As is normally the case, the US market should attract premium pricing in addition to being the largest, best funded medical market in the world. Following FDA approval, the revenue base in the US is expected to rapidly exceed cumulative revenues from all other markets. In most other markets where Technegas has been introduced, the competing radiopharmaceutical has been withdrawn from sale. The most recent example of this was in Canada which is now the largest single market for Technegas.

The short term catalyst should be the release of clinical trial data on the first 40 patients in the US trial which the company is required to submit to the FDA. Technegas has been used in more than 3.6m patient exams with no known side effects. The product is known to be safe and produce high quality images for analysis and accordingly we believe the clinical risk associated with the trial is far lower than with the drug developer. First substantial revenues from the US market are expected in calendar 2019.

The major key risk in the trial is patient recruitment. Cyclopharm has previously attempted to recruit patients into a much larger study and made virtually no progress. The flaws in the trial design were identified and the current trial is vastly different with a primary end point of non-inferiority.

Cyclopharm
as at 27 September 2017

Recommendation	Buy, Speculative
Price	$0.74
Valuation	$1.13

Table 1 - Financial summary

Profit & Loss (A$m)	FY15	FY16	FY17e	FY18e	FY19e
Year Ending June					
US Revenues	-	-	-	-	1.2
ROW Revenues	12.5	14.4	13.7	14.6	15.5
Total Revenues	12.5	14.4	13.7	14.6	16.7
COGS	-2.7	-3.5	-2.7	-2.9	-3.3
Gross profit	9.8	10.9	11.0	11.7	13.3
GP margin	78.6%	75.5%	80.0%	80.0%	80.0%
Operating expenses	6.9	7.8	7.9	8.2	10.5
Clinical trial costs	0.7	1.1	3.0	4.0	2.0
EBITDA	**2.3**	**2.0**	**0.1**	**-0.5**	**0.8**
Depreciation and Amortisation	-0.1	-0.1	-0.2	-0.2	-0.2
EBIT	2.1	1.9	-0.1	-0.7	0.7
EBIT margin	17.2%	13.1%	-0.5%	-4.8%	4.3%
Net other income	0.1	0.0	0.0	0.0	0.0
Pre tax profit	2.2	1.9	-0.1	-0.7	0.7
Tax expense	0.7	-0.8	0.0	0.0	-0.2
NPAT- normalised	2.9	1.1	-0.1	-0.7	0.5
Net abnormal items	1.9	(0.3)	-	-	-
Reported NPAT	4.8	0.8	-0.1	-0.7	0.5

Cashflow (A$m)	FY15	FY16	FY17e	FY18e	FY19e
Gross cashflow	1.9	1.3	0.4	-0.7	0.6
Net interest	0.0	0.0	0.0	0.0	0.0
Tax paid	0.1	-0.6	0.0	0.0	-0.2
Operating cash flow	4.2	0.7	0.4	-0.7	0.4
Maintenance capex	0.0	-1.8	-0.2	-0.2	-0.2
Other capitalised intangibles	-0.6	-0.4	-0.4	-0.4	-0.4
Free cash flow	3.5	-1.6	-0.2	-1.3	-0.2
Business acquistions	0.0	0.0	0.0	0.0	0.0
Proceeds from issuance	0.0	0.0	7.0	0.0	0.0
Movement in debt	0.0	-0.2	0.0	0.0	0.0
Dividends paid	-0.3	-0.6	-0.6	-0.7	-0.7
Change in cash held	3.2	(2.3)	6.2	(2.0)	(0.8)
Cash at beginning of period	0.0	6.4	4.6	10.8	8.8
Cash at year end	6.4	4.6	10.8	8.8	8.0

Balance Sheet (A$m)	FY15	FY16	FY17e	FY18e	FY19e
Cash	**6.4**	**4.6**	**10.8**	**8.8**	**8.0**
Receivables	4.4	3.7	3.6	3.8	4.4
Inventory	2.2	2.6	2.8	2.9	3.0
Other current assets	-	0.1	0.1	0.1	0.1
Property, Plant and Equipment	0.6	2.3	2.4	2.4	2.5
Intangible assets	1.3	1.7	2.1	2.5	2.8
Deferred tax assets	1.5	1.2	1.2	1.2	1.2
Total assets	16.5	16.3	22.9	21.7	22.0
Trade payables	1.8	2.8	3.0	3.2	3.7
Debt	0.2	-	-	-	-
Tax payable	0.5	**-**	**-**	**-**	**0.0**
Other liabilities	-	0.2	0.2	0.2	0.2
Deferred income tax liability	-	-	-	-	-
Provisions	1.0	1.0	1.0	1.1	1.1
Total Liabilities	3.4	3.9	4.3	4.5	5.0
Net Assets	13.1	12.4	18.6	17.2	17.0
Share capital	15.0	15.0	22.0	22.0	22.0
Retained earnings	(2.5)	(2.3)	(3.0)	(4.4)	(4.6)
Reserves	0.7	(0.3)	(0.3)	(0.4)	(0.4)
Shareholders Equity	13.1	12.4	18.6	17.2	17.0

Valuation Ratios (A$m)	FY15	FY16	FY17e	FY18e	FY19e
Reported EPS (cps)	8.1	1.4	-0.1	-1.0	0.7
Normalised EPS (cps)	4.9	1.9	-0.1	-1.0	0.7
EPS growth (%)	151%	-60%	-105%	904%	-166%
PE(x)	**0.0**	**0.4**	**-7.3**	**-0.7**	**1.1**
EV/EBITDA (x)	17.7	20.4	478.2	-74.1	50.2
EV/EBIT (x)	18.9	21.5	-624.3	-58.2	61.5
NTA (cps)	19.8	24.5	30.4	28.2	28.0
P/NTA (x)	0.0	0.0	0.0	0.0	0.0
Book Value (cps)	22.0	20.8	27.4	25.2	24.9
Price/Book (x)	0.0	0.0	0.0	0.0	0.0
DPS (cps)	1.0	1.0	1.0	1.0	1.0
Payout ratio %	20%	52%	0%	0%	0%
Dividend Yield %	1.4%	1.4%	1.4%	1.4%	1.4%
Franking %	-73%	0%	0%	0%	0%
FCF yield %	5%	-3%	-1%	-3%	-1%
Net debt/Equity	0%	0%	0%	0%	0%
Net debt/Assets	0%	0%	0%	0%	0%
Gearing	net cash	net cash	net cash	net cash	net cash
Net debt/EBITDA (x)	n/a	n/a	n/a	n/a	n/a
Interest cover (x)	n/a	n/a	n/a	n/a	n/a

PAS Unit sales	FY15	FY16	FY17e	FY18e	FY19e
Europe	3,820	3,935	4,053	4,174	4,299
Growth	4%	3%	3%	3%	3%
USA	-	-	-	-	40
Growth	0%	0%	0%	0%	0%
Total Patient Admin Sets Sold	**3,820**	**3,935**	**4,053**	**4,174**	**4,339**
Average revenue per sale A$'000	2,656	2,845	3,047	3,264	3,497

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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