BELL POTTER

17 July 2017

Speculative

Refer to key risks on page 4 and Biotechnology Risk Warning on page 19. Speculative securities may not be suitable for retail clients.

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Cyclopharm (CYC)

Under Valued Nuclear Medicine Business

Recommendation
Buy (Initiation)
Price
$0.85
Valuation
$1.13 (Initiation)
Risk
Speculative

GICS Sector

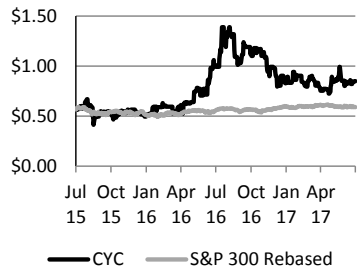
Healthcare Equipment and Services

Expected Return	
Capital growth	**32.9%**
Dividend yield	**0.0%**
Total expected return	**32.9%**
Company Data & Ratios	
Enterprise value	**$48.3m**
Market cap	**$58.3m**
Issued capital	**68.6m**
Free float	**100%**
Avg. daily val. (52wk)	**$19,000**
12 month price range	**$0.72 - $1.45**

Price Performance

	(1m)	(3m)	(12m)
Price (A$)	0.85	0.83	1.06
Absolute (%)	0.00	2.10	-19.85
Rel market (%)	-0.29	4.90	-28.43

Absolute Price



SOURCE: IRESS

Strong Repeat Revenue Business With Growth

Cyclopharm owns the intellectual property and is the exclusive supplier of the Technegas System for functional lung imaging. The technology is primarily used for the diagnosis of pulmonary embolism (blood clots) in the lung. This potentially fatal condition is difficult to diagnose without imaging, hence Technegas meets this need particularly in patients contra indicated for CT scan. Technegas has been used in at least 3.5m patient exams with no known side effects. The key patents extend until 2026. In addition, Cyclopharm operates in a relatively small market, therefore we are not expecting competitors even in the longer term.

Upside From Entry To US Medical Imaging

Technegas was first approved in 1986 and is currently distributed in 55 countries generating revenues of ~$14m. Approximately 80% of revenues are generated from single use consumables, hence there is an attractive, high margin repeat income stream. Cyclopharm has hundreds of customers globally being the hospitals which deliver the product to patients.

In the 4 years to 2016 revenues have grown at 8.7% CAGR. In FY15/FY16 Cyclopharm produced an underlying EBITDA margin of ~21%. We expect the underlying margin (before costs associated with the clinical trial currently under way in the US) is sustainable at this level. The reported earnings forecast includes the estimated $10m cost of a clinical trial over the next three years. The major opportunity for revenue growth is entry to the US market, potentially as soon as 2019, however this remains subject to a clinical trial risk.

We initiate coverage with a Buy (Speculative) recommendation and valuation of $1.13. Despite consistency in revenue and growth in the underlying profitability, Cyclopharm is likely to reporting an operating loss from FY17 – FY19 after including the cost of the clinical trial. For this reason the stock attracts a speculative risk rating.

Earnings Forecast

December Year End	FY16e	FY17e	FY18e	FY19e
Revenues	14.4	13.7	14.6	16.5
EBITDA $m	2.0	0.1	-0.5	-0.9
NPAT (underlying) $m	1.1	0.0	-0.7	-1.1
NPAT (reported) $m	0.8	0.0	-0.7	-1.1
EPS underlying (cps)	1.9	0.0	-1.0	-1.6
EPS growth %	-60%	-102%	Large	-62%
PER (x)	43.9	-2,466.2	-86.1	-53.0
FCF yield (%)	-2%	-1%	-3%	-3%
EV/EBITDA (x)	24.3	377.8	-92.0	-51.1
Dividend (cps)	1.0	1.0	1.0	1.0
Franking	0%	0%	0%	0%
Yield %	1.2%	1.2%	1.2%	1.2%
ROE %	15.2%	-0.1%	-3.9%	-7.1%

SOURCE: BELL POTTER SECURITIES ESTIMATES

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Investment Case

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.

Pulmonary Embolism can be fatal if left untreated even for short periods. Diagnosis of this condition without medical imaging is difficult and is often required in an emergency situation. 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 3.5m 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.

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 Cylopharm'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.

Overview of Technegas

- More than 3.5m patient studies since first approved in 1986;
- Technegas is the dominant radio pharmaceutical used for the diagnosis of PE in 55 countries including in Australia;
- The largest country markets for Technegas are Canada and France;
- 80% of revenues are from high margin single patient use consumables; and

Technegas is a lung imaging agent. It is used primarily to diagnose the presence of blood clots in the lungs know as Pulmonary Emboli (PE) although its indication covers all pulmonary disease where lung function/imaging is required.

Technegas is the brand name for the product which is comprised of Tc-99$_m$ labelled carbon nanoparticles dispersed in high purity argon gas. Tc-99$_m$ is a commonly used nuclear isotope with many applications in nuclear medicine. Tc-99$_m$ is a preferred for medical imaging because of its relatively low energy levels and short half-life of about 6 hours. The short half-life leads to very fast clearing from the body after the medical imaging process is completed.

Tc-99$_m$ is indicated for a variety of imaging procedures in the US and internationally including cardiac and bone amongst others. The parent isotope of Tc-99$_m$ is Molybdenum[1]. Current estimates are for between 34,000 to 46,000 curies/week in the US for Mo-99.

Technegas is produced by a Technegas generator such as the model shown in figure 1 below. Molybdenum(Mo^{99}) is produced by providers of such material - in Australia this includes ANSTO and there are various producers internationally.

Figure 1 - Technegas generator manufactured by Cyclopharm

SOURCE: COMPANY DATA

There are several manufacturers of the Mo^{99} generators which produce Tc-99. These include Lantheus (LNTH:Nasdaq) in the US. Lantheus is one of two distributor of Xenon-133, the dominant radiopharmaceutical imaging agent for lung and pulmonary function in the US.

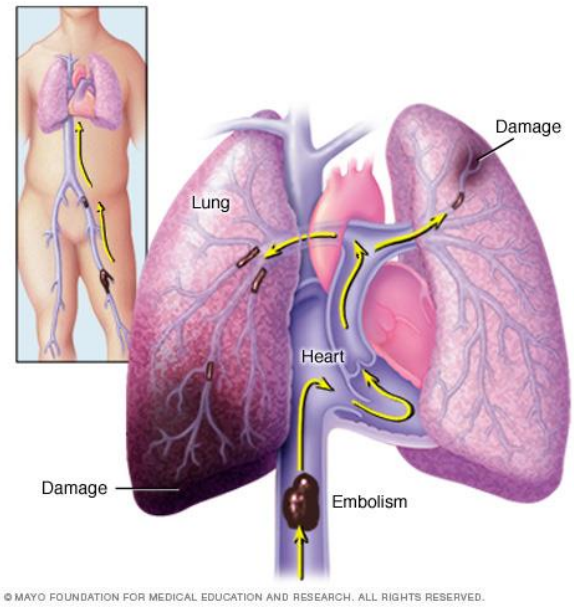
The other element of Technegas is Argon (Ar) which is completely harmless and inert gas.

Over time we would expect competitors to develop to Technegas, particularly as the US market for the product expands. The Technegas Plus Generator is patented until 2026

[1] Technetium99 is an artificially produced substance. It is the product of Molybdenum 99 (^{99}Mo) caused by radioactive decay. ^{99}Mo has a long half life of 66 hours, so the generator and the ^{99}Mo can be easily transported to the place where the decay product Tc-99 is required.

(including in the United States), however, the validity of the patent has not been tested in court as far as we are aware. In our view one of the key risks is the strength of those patents.

Figure 2 – Pulmonary Embolism



SOURCE: COMPANY DATA

INCUMBENT TECHNOLOGY FOR PULMONARY IMAGING

Pulmonary embolism (PE) is a blockage in one of the pulmonary arteries in the lungs. A PE can prevent blood flow to the lungs and can result in sudden death. In most cases, pulmonary embolism is caused by blood clots that travel to the lungs from the legs or, rarely, other parts of the body (deep vein thrombosis).

CTPA is popular for diagnosis of PE due to convenience, speed and acceptable efficacy. A CT scan can be performed at any hour of the day or night, compared to a VQ scan which is only available when nuclear medicine is open

There are several methods used to diagnose PE however most hospitals use Computed Tomography Pulmonary Angiogram (CTPA).

- The process is minimally invasive and uses only an IV line to deliver an iodine based contrast agent;
- A normal CTPA scan will show the contrast filling the pulmonary vessels, appearing as bright white. Any mass filling defects, such as an embolus, will appear dark in place of the contrast, filling/blocking the space where blood should be flowing into the lungs;
- **The key downside of CT is the high radiation dose,** however, this does not appear to have caused much concern in the US medical community.

CTPA replaced the ventilation and perfusion scan (VQ scan) as the dominant method of diagnosing PE in approximately 1990. The VQ scan involves the use of medical isotopes to evaluate the circulation of air and blood in a patients lungs. Patients are required to inhale the isotope (in a gas state) followed by an imaging process using one of several imaging modalities. The ventilation part of the scan looks at the ability of air to reach all parts on the lung while perfusion relates to blood circulation.

We consider Technegas is the leader in functional lung ventilation imaging outside of the US. Crucial to the re-emergence of this assay has been the significant improvement in imaging technology since 1990.

In the United States the there are two popular nuclear isotopes used for the VQ scan. They are DTPA (DTPA – Diethylenetriamine pentaacetate) and Xenon-133.

DTPA is not indicated for lung ventilation scanning in the US and its use, though common, is off label. DTPA is indicated for kidney diagnostics. DTPA is used in preference to Xenon 133 because of its ease of use, higher energy levels and therefore superior quality imaging it provides. Xenon is also quite cumbersome to administer.

There is regional variation in the choice of VQ imaging mode. In the US when CTPA cannot be used because of contraindication and nuclear medicine is used as the alternative, planar imaging (2 dimensional) is common.

In Europe and Australia VQ SPECT (single photon emission computed tomography) with low dose CT is the preferred methodology.

WHEN IS VQ SCANNING APPROPRIATE USE

The Appropriate Use Criteria were established by a working body comprised of representatives from industry bodies[2]. Their key recommendations were as follows. VQ scans are appropriate use in the following circumstances:

- When CTPA scanning is contraindicated. Main CTPA contra indications are:
  - Pregnancy;
  - Poor renal function (CTPA uses an iodine contrast agent, which can be harmful to kidney function);
  - Intolerance to iodine contrast media; and
  - Women of child bearing age (absorption of radiation by breast tissue is 40% to 70% higher in CTPA).
- CTPA may be a driver of over diagnosis – particularly for small, clinically insignificant blood clots, hence not appropriate in lower risk patients particularly because of exposure to radiation;
- PE likely, in patients where clots are detected by ultrasound in lower extremity;
- In patients suspected of PE, who show normal chest scan – deemed appropriate use because of high specificity of VQ scan with added benefit of lower radiation exposure;
- PE likely, CTPA Inconclusive; and
- PE likely, prior diagnosis with VQ scan. Generally once a diagnosis has been made with a particular modality, physicians will stick with that test so that comparison of exams are valid.

The working group concluded that the ventilation portion of the VQ scan provides crucial information in many scenarios. More than 50% of patients with suspected PE show symptoms consistent with other acute or chronic pulmonary disorders that cannot be diagnosed elsewhere.

Despite these recommendations, CT is likely to continue as the dominant imaging modality for functional lung images – except where CT is contra indicated. The key driver of the continued use of CTPA is it ease of use, particularly in the emergency setting.

HOW DO THE IMAGING MODALITIES COMPARE FOR DIAGNOSIS OF PE

Much of the literature on this topic points out that diagnosis of PE is difficult because of non-specific symptoms, therefore imaging is essential to diagnosis.

The analysis presented by Hess et al on this topic is based on a meta analysis of many prior studies. We summarise the conclusions as follows:

[2] Including Society of Nuclear Medicine and Molecular Imaging (SNMMI), European Association of Nuclear Medicine (EANM), the American Society of Hematology, and the American College of Emergency Physicians (ECEP), American College of Radiology and Society of Thoracic Surgeons. Findings published in j Nucl Med 2017, May 58(5)

- VQ SPECT/ with low dose CT was clearly the superior modality for patients suspected of PE[3]. It showed both high sensitivity (ability to correctly identify the disease) and specificity (ability to correctly identify those without the disease);
- VQ SPECT was only marginally lower on both measures of sensitivity and specificity; and
- CTA (CTPA) was clearly less sensitive than all VQ techniques but scored well on specificity.

The investigators estimate the 15-20% of PE may be missed by CTPA.

The Hess paper did not include Planar imaging specifically, but it did note a key significant reduction in the rate of false positives (from planer imaging) using SPECT. SPECT has largely replaced planar imaging in cases where CTPA is contraindicated.

The investigators further observed there is no single modality available as the gold standard for diagnosis of PE. We agree with investigators that neither CTPA or VQ SPECT is appropriate in all circumstances and the decision as to which modality to use will depend upon the preference of the hospital, the physicians and the individual patient circumstances (i.e. emergency cases will rarely have time to wait for a VQ scan, despite possible contraindications involved with CT).

Compared with CTPA, SPECT has higher sensitivity, a lower radiation dose, fewer technically suboptimal studies, and no contrast-related complications. In our view these have been the key drivers of the re-emergence of VQ scan.

Any nuclear medicine department equipped with a modern hybrid scanner can now perform combined VQ SPECT with CT (using low-dose protocols) to further enhance diagnostic accuracy. VQ SPECT (with or without CT) has application in other pulmonary conditions and in research.

GUIDELINES FOR VQ SPECT

The use of VQ SPECT for diagnosis of PE is fully endorsed in the guidelines of both the British Nuclear Medicine Society and the European Society of Nuclear Medicine.

In the UK, the NICE Guidelines recommend diagnosis of PE via CTPA with antico-agulants (blood thinners). V/Q SPECT is recommended for patients contra indicated for CTPA.

OTHER INDICATIONS FOR TECHNEGAS INCLUDING COPD

The CE Mark for Technegas is as a lung ventilation system – covering a wide variety of medical conditions. Cyclpharm estimates the dominant use of the product is for diagnosis of PE. Functional lung imaging for other disease (including COPD, lung cancer, pulmonary hypertension) is likely to be modest, but growing.

Prior clinical studies conducted in China provide some evidence that Technegas can assist in the early diagnosis of lung disease (COPD), however, in our view it is unlikely that there is a high unmet clinical need such that further imaging would improve patient outcomes. The cause of most COPD is well known and symptoms are generally easily recognised. The disease can be controlled to some extent with medication. This is quite different from PE which, left undiagnosed often leads to death.

Beyond 2019 when the company expects to be on market with Technegas in the US, it may consider new initiatives to expand the use of Technegas in other specific indications. To achieve this, data will need show a benefit to patients in the form of more accurate diagnosis and better disease management compared to standard of care.

The trial currently recruiting in the US is the largest ever study involving Technegas. Participants enrolling in the trial are likely to have a variety of complaints including PE, lung

[3]SPECT/CT is described in further detail in Appendix 1. This scan is a low dose, non-contrast CT scan.

cancer, lung transplant, luminary hypotension etc. The trial data may yield useful material for podium presentations initially and set a direction for future studies, if any.

ULTRALUTE

Earlier in this section we referred to the parent isotope in of Tc-99 as Molybdenum. ^{99}MO has a half life of 66 hours and therein lies the driver for the invention of Ultralute. ^{99}MO is sourced by a hospital nuclear medicine department from reactors where it is manufactured. In practice the product is delivered 'hot' on Monday to the hospital where it is used during the course of the week to produce isotopes for nuclear medicine – including Technegas and others. The cost of the generator is the same irrespective of whether Nuclear Medicine produces one dose or 500 from the generator (noting that the generators come in different sizes).

Ultralute has been developed to extend the useable life of Molybdenum by up to 50% at very low cost to the hospital user. The product is in late stage development, however the company expects revenues within the next 12 months.

The first generation product is targeted at Europe which still uses full service Nuclear Medicine Departments as opposed to the centralised Radiopharmacy model common in the United States and Australia. A second generation product is in development for the Radiopharmacy model.

Ultralute is a consumable item and the company expects it has revenue potential at maturity of ~$12m, however, it is likely to take several years to reach this point. We have not included any revenues from the sale of Ultralute in the forecast.

US Market Overview

In order to gain an FDA label, Cyclopharm is required to complete a clinical study in the US. This process has been under way since at least 2011, however, a previous trial protocol was highly restrictive to patient recruitment such that only a handful of patients were able to be recruited for this 750 patient study over a period of several years. Cyclopharm abandoned this earlier trial in 2015.

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;
- The specific elements of the trial design have not been published, however, the key elements are as follows:
    - 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. By comparison the 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.

Experience from other markets provides strong testimony to suggest Technegas should replace Xenon and DTPA as the standard of care for functional lung imaging within 3 to 5 years from introduction (as was the case in Canada). The trial design is pragmatic in that it achieves the bare minimum to get approved and onto the market.

We expect the trial will recruit rapidly once the initial patient is admitted to the trial. 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.

Timing – there is one centre in the US currently able to enrol patients. The admission of the first patient to the trial is expected in July 2017. The trial will be conducted in up to 15 centres, with 7 hospitals (including prominent University Hospitals) now in various stages of approval. We expect patients will be recruited over the remainder of calendar 2017 and

2018 with reporting in 2019. We also expect the interim reporting of the first 40 patients in late calendar 2017 or early 2018.

Label Claim – following completion of the trial, we expect Cyclopharm to make an application for a label claim for lung structural ventilation assessment (which is not a diagnostic). Technegas is likely to be classified as a combination product (i.e. drug and device).

The trial is listed on clinical trials.gov at the following reference: https://clinicaltrials.gov/ct2/show/NCT03054870

Reimbursement is not impacted as a structural ventilation indication fits into the existing reimbursement structure for pulmonary disease including PE. Cyclopharm will not be required to seek additional reimbursements codes for the product.

We consider the label claim is broad, therefore potentially opening the door to numerous disease states including Asthma and COPD which may also benefit from quantifiable data for lung ventilation, albeit as we have indicated previously, CT is likely to remain as the dominant imaging modality for patients with no contraindications.

There are more than 7,000 Radiopharmacy departments in the US with each potentially requiring a Technegas generator.

In the short term adoption may be limited by the capacity to supply the Technegas generators as we believe Cyclopharm can assemble, test and ship about 250 generators annually with approximately 50 of these going to markets outside of the US.

Figure 3 - US Market Revenue Potential

	2018	2019	2020	2021
US$				
Technegas Generator revenue per device sale	-	50,000	50,000	50,000
Total units sales		100	200	200
Revenue $m		5.0	10.0	10.0
Service revenues $m		0.1	0.3	0.5
Revenues from Technegas generators (inc service) $m		5.1	10.3	10.5
Cumulative install base of Technegas generators		100	300	500
Revenue per unit of consumables US$		5,000	5,000	5,200
Patient Admin Sets sold per technegas generator		2.0	6.0	8.0
Total Patient Admin Sets (PAS) Units sold		200	1,800	4,000
Growth in PAS		0%	800%	122%
Total exams		10,000	90,000	200,000
Estimated penetration to US market (of 480,000 annual exams)		2.1%	18.8%	41.7%
Consumables revenues US$m	**-**	**1.0**	**9.0**	**20.8**
TOTAL US REVENUES	-	6.1	19.3	31.3
Growth rates (inclusive of currency, volumes and price)		na	na	131.1%

SOURCE: COMPANY DATA AND BELL POTTER SECURITIES ESTIMATES

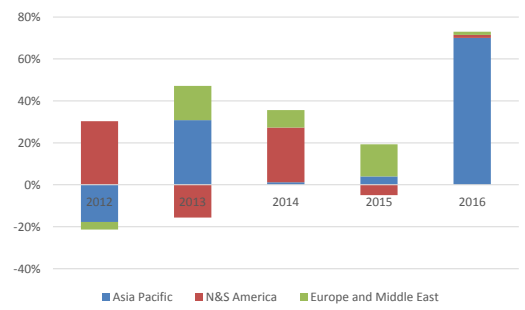
The company estimates ~600,000 PE exams in the US each year using either Xenon or DTPA. This estimate is reasonable based on the historical revenues of Lantheus (the main supplier of Xenon gas). Based on this estimate the maximum revenue potential for Technegas is US$60m from consumables. Generator revenue sales are additional.

Based on this estimate of revenue potential (which is not a forecast) the value of revenues from the US market could exceed the entire ROW market by mid way though year 2 following launch. As with all new technology, it is likely there will be a delay in adoption, primarily because the product is likely to require extensive marketing despite its wide use outside of the US.

Financials

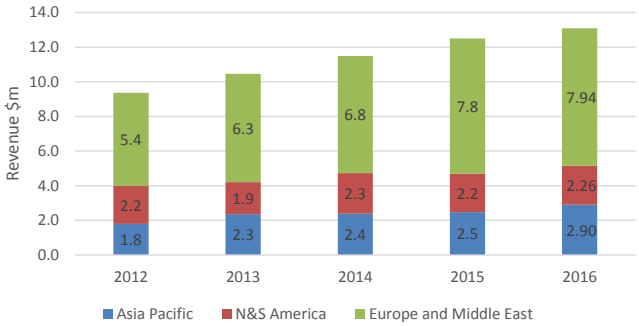
We summarise recent revenues by geography and growth rates as follows:

Figure 4 – Revenue growth rates by market



SOURCE: COMPANY DATA

Figure 5 - Revenues Summary



SOURCE: COMPANY DATA

- EME has now reported 4 years of revenue growth, as has the Asia Pacific region;
- North America is essentially Canada. Canada is the largest single country market for Technegas ahead of France;
- In 2016 CYC received a $1.3m once off order from its Chinese distribution partner. Excluding this item, the Asia Pacific region still grew revenues by 17% in FY16;
- In the 4 years to 2016 revenues have grown at 8.7% CAGR (ex the China order in 2016) or 11.3% including that large initial order from China. Excluding the one time Chinese order, the long term split of revenues to generator revenues is ~80:20; and
- In FY15/FY16 Cyclopharm produced an EBIT margin of ~21% before one off items. The margin declined in FY16 due to a less favourable revenue mix (i.e. a higher proportion of lower margin generator sales) and a $0.5m increase in R&D expense. Going forward, we expect the sustainable gross profit margin should be ~80% and operating margin (EBIT) should be at least 20%.

The company estimates there are approximately 1,600 Technegas generators in the market today. Of these about 80% are regularly in use.

Each PAS (patient admin set) consists of 50 item of single use consumable (tubing and inhalation device). We estimate revenue per PAS set at ~$2,800 with each generator consuming between 2.5 and 3.0 sets per annum.

We estimate the CYC sold approximately 3,900 PAS set in FY16 and approximately 105 Technegas generators. In a normal year the company sell between 50 and 60 generators.

Based on our observations the manufacture of the Technegas generator is quite labour intensive. The selling price is approximately $26K/unit, hence the margin on the generator is likely to be modest compared to the margin on the PAS set.

This suggests breakeven point is approximately 50 generators annually and approximately 2,900 PAS sets. The fixed cost base at CYC is ~$8m.

Cyclopharm's operating cash flow is relatively consistent as the fluctuations in working capital are minor. Inventory remains relatively consistent irrespective of turnover. Receivables turnover is approximately 3.8x.

The major use of cash over the next three years will be $9.4m (US$7m) for the US trial, however, there should be no major capex requirement.

Figure 6 - 4 year overview of underlying profitability

$'000	2013	2014	2015	2016	2017e	2018e
Patient Administration Sets	8,583	9,384	10,145	10,782	11,641	12,470
Technegas Generator Sales and Service	1,874	2,106	2,363	3,604	2,074	2,096
Revenue	**10,457**	**11,490**	**12,508**	**14,386**	**13,715**	**14,566**
Growth	*11.6%*	*9.9%*	*8.9%*	*15.0%*	*-4.7%*	*6.2%*
Underlying EBITDA (before clinical trial expense)	**2,246**	**2,638**	**2,980**	**3,072**	**3,128**	**3,475**
Underlying EBITDA Margin	21%	23%	24%	21%	23%	24%
Clinical trial expenses	(478)	(478)	(686)	(1,098)	(3,000)	(4,000)
Reported EBITDA	**1,768**	**2,160**	**2,294**	**1,974**	128	(525)
Depreciation and amortisaton	(220)	(223)	(137)	(106)	(150)	(150)
EBIT	1,548	1,937	2,157	1,868	(22)	(675)
Margin	**14.8%**	**16.9%**	**17.2%**	**13.0%**	**-0.2%**	**-4.6%**

SOURCE: COMPANY DATA

In Figure 6 we note the company has spent $2.5m over the last 4 years on clinical trials and in negotiation with the FDA in attempting to progress Technegas into the US market. It has been a frustrating process, however, we are encouraged that current clinical study has a Special Protocol Assessment inclusive of the non-inferiority protocol. We believe there is good reason to believe these measures have removed most of the barriers to entry for the clinical trial.

Looking forward, we expect the company will expense the $9.4m in clinical trial cost over the next 2.5yrs.

Following the recent $7.0m rights issue and placement, we expect CYC has sufficient cash to complete the trial program. We do not anticipate it will require further cash from shareholders, assuming the US clinical trial results meet expectation.

We expect CYC should get the FDA approval for Technegas in CY2019. Until then we expect the underlying EBIT (excluding clinical trial costs) to continue to grow in line with the recent past.

US MARKET ESTIMATES

For the year ended December 2016 Lantheus reported Xenon revenues of US$29m, down from US$49m in 2015. International sales of Xenon were negligable at just US$8K. The company cited decreased selling price from competitive forces as the major driver of lower revenues. The new competitor in 2016 was Malinkrodt which re-introduced Xenon to its nuclear medicine business.

There is no generic of Technegas and none is likely to emerge until at least 2026 due to the patent protection on the Generator. The experience of Technegas in markets outside of the US suggests it is a superior product to Xenon and DTPA and able to command a price premium to these agents. For this reason we do not consider Xenon and DTPA revenues are a reliable guide to Technegas revenue potential in the US.

The company estimates Technegas can generate consumable revenue of US$100/patient in the US with Generators selling at US$50,000. Both are priced at a significant premium to non US markets, however, given that this product is unique in function, we believe these estimates are realistic. We expect first revenue from the US in later calendar 2019.

DIVIDENDS

CYC will expense the clinical trial expense over the course of FY17/FY18/FY19. We expect this will cause Cyclopharm to generate small losses at the EBIT line in FY18 and FY19. As the company has recently raised cash to provide it with sufficient funding during this period the Board may contemplate suspending the dividend, however, there is no indication that it intends to do so at this time. Accordingly we have assumed an ongoing 1.0cps dividend.

Board, Management, Key Shareholders

Figure 7 - Summary Data

Board	Position		Non-Beneficial (NBI)/Benefical Interest (BI)	No. of Shares	% ownership
D J Heaney	Chairman	Independent, Non Executive	BI	172,058	0.3%
Vanda Gould	Director	Non Executive Director, Not considered independent	NBI	11,931,314	17.4%
James McBrayer	Managing Director	Non Independent	BI	3,550,330	5.2%
Tom McDonald	Director	Independent, Non Executive	BI	19,830	0.0%
Subtotal				**15,673,532**	**22.8%**
Total shares on issue (m)				68,636,501	100%
Major shareholders					
Vanda Gould - inclusive of Chemical Trustee Limited				11,931,314	17.4%
Anglo Australian Christian and Charitable Fund				13,211,332	19.2%
Barings Acceptance Ltd				11,433,424	16.7%
CVC Limited (Stinoc Pty Ltd)				9,470,393	13.8%
Chemical Trustee Limited				9,176,470	13.4%
Australian Ethical Investments				4,802,443	7.0%
Subtotal				**48,094,062**	**70.1%**

SOURCE: COMPANY DATA

There are no share options on issue.

The Company has no debt as at its last reporting date.

Managing Director James McBrayer is the driving force behind the company's international expansion and in particular in the United States. Mr McBrayer is a US national now based in Sydney. He is vastly experienced in Nuclear Pharmacy after years of working in the US hospital system where he trained as a Nuclear Pharmacist. He joined Cyclopharm in 2008 as Managing Director and has been instrumental in its growth since then.

Mr Vanda Gould has been a Non-Executive Director since 2005. The details of his non beneficial interest are described on page 17 of the company's 2017 Annual Report.

Valuation

Our valuation estimate comprises two distinct components being the US and Rest of World (ROW).

In relation to ROW, figure 6 indicates growth in underlying revenues and EBIT over a 4 year period. The use of Technegas is clearly increasing and there is an established, verifiable track record of replacing Xenon^{133} and DTPA for lung imaging where patients are contra-indicated for CTPA.

In our view the sustainable underlying EBIT from the current business is in the range of approximately $2.8 - $3.0m. This estimate excludes the cost of the clinical trial in the US which is being reported in the income statement. The three year CAGR for underlying EBIT is ~13.5%.

There are no directly comparable standalone business for valuation comparison, therefore we draw on the following comps from other medical device companies in Australia and the US.

Figure 8 - Comparable valuations

	Company	Current Yr PE	Current EV/EBIT
NAN AU Equity	Nanosonics	45.0	47.9
COH AU Equity	Cochlear	39.5	28.7
ELX AU Equity	Ellex	43.3	28.5
ICUI US Equity	ICU Medical	42.2	30.5
VAR US Equity	Varian	27.1	20.4
LNTH US Equity	Lantheus	18.4	14.6

SOURCE: BLOOMBERG

In our view a capitalisation multiple of 16x EBIT for ROW is reasonable. Each of these peers has significant business in the US, hence once the FDA indication is given (which is not a certainty), we expect there will be a significant uplift in value for Cyclopharm.

We believe the opportunity for Cyclopharm in the US is significant, albeit the company faces some hurdles to achieving this potential.

There are two key obstacles to realising this potential and they are significant. The US trial has to be successfully completed, and the market has to adopt the technology.

The risks section of this research piece outlines the key matters which slowed the recruitment of an earlier clinical trial, hence the current trial design has benefited from this experience and is better positioned to recruit more quickly, particularly with some large clinical sites yet to begin enrolling patients.

We have valued the US opportunity using a discounted cash flow model under two scenarios. The first assumes 90% market penetration by year 5, the second 50%. The model uses a discount rate of 15% and a A$/US$ cross rate of $0.75.

In addition to revenues in the US market, the other key is the low level of touch required to service the market. In Canada for example, the entire market is serviced by just one sales person, albeit there are numerous support staff.

In the US we expect Cyclopharm will hire up to 10 dedicated sales reps supported by a medical distributor to provide logistics and perform the service function. We have allowed for a US$5m initial cost base in the US once the sales function begins.

The discounted cash flow yields a NPV in the range of $26m - $54m which is reasonable considering the discount rate and time period between now and substantial cash flows. We summarise the valuation as follows.

Figure 9 – Valuation summary

	Low	High
Underlying sustainable EBIT - ongoing business $m	**2.8**	**3.0**
Multiple (x)	16	16
Enterprise value $m	44.8	48.0
less Cash (estimate) $m	-10.0	-10.0
Equity value $m	34.8	38.0
US potential value $m	26.2	54.9
Total Equity value $m	**61.0**	**92.9**
Shares on issue (m)	68.6	68.6
Implied valuation per share (cps)	**88.9**	**135.4**
Target price (cps)	**113**	

SOURCE: COMPANY DATA

We initiate coverage with a Buy (speculative) recommendation and valuation of $1.13.

We expect the underlying business of Cyclopharm will continue to grow during the period of the clinical trial in the US. The company will expense the cost of the trial in the US and this is likely to result on operating losses over the period, hence the speculative rating.

Appendix 1 - What is a SPECT-CT scan?

(from inside radiology.com.au)

SPECT-CT is where two different types of scans are taken and the images or pictures from each are fused or merged together. The fused scan can provide more precise information about how different parts of the body function and more clearly identify problems such as tumours (lumps) or Alzheimer's disease, etc.

Single photon emission computed tomography (SPECT): SPECT images are obtained following an injection of a radiopharmaceutical that is used for nuclear medicine scans. The injected medication sticks to specific areas in the body, depending on what radiopharmaceutical is used and the type of scan being performed, for example, it will show bone for a bone scan, and gall bladder and bile ducts for a hepatobiliary scan.

The radiopharmaceutical is detected by a nuclear medicine gamma camera. The camera or cameras rotate over a 360 degree arc around the patient, allowing for reconstruction of an image in three dimensions.

Computed tomography (CT): CT images are obtained while you lie on a bed that moves into a ring, or "donut" shaped X-ray machine. Again, the X-ray machine rotates over a 360 degree arc around the patient, allowing for image reconstruction in three dimensions. The X-ray machine from the CT scanner rotates much faster than the gamma camera, so the CT part of the study takes less time than the SPECT study.

The similarity between SPECT and CT in the method of image processing allows the images to be combined. Combining the information from a nuclear medicine SPECT study and a CT study allows the information about function from the nuclear medicine study to be easily combined with the information about how the body structure "looks" in the CT study.

Cyclopharm
as at 17 July 2017

Recommendation	Buy, Speculative
Price	$0.85
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	15.3
Total Revenues	**12.5**	**14.4**	**13.7**	**14.6**	**16.5**
COGS	-2.7	-3.5	-2.7	-2.9	-5.0
Gross profit	9.8	10.9	11.0	11.7	11.6
GP margin	78.6%	75.5%	80.0%	80.0%	70.0%
Operating expenses	6.9	7.8	7.8	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**	**-0.9**
Depreciation and Amortisation	-0.1	-0.1	-0.2	-0.2	-0.2
EBIT	2.1	1.9	0.0	-0.7	-1.1
EBIT margin	17.2%	13.1%	-0.2%	-4.6%	-7.1%
Net other income	0.1	0.0	0.0	0.0	0.0
Pre tax profit	2.2	1.9	0.0	-0.7	-1.1
Tax expense	0.7	-0.8	0.0	0.0	0.0
NPAT- normalised	2.9	1.1	0.0	-0.7	-1.1
Net abnormal items	1.9	(0.3)	-	-	-
Reported NPAT	4.8	0.8	0.0	-0.7	-1.1

Cashflow (A$m)	FY15	FY16	FY17e	FY18e	FY19e
Gross cashflow	1.9	1.3	0.4	-0.7	-1.1
Net interest	0.0	0.0	0.0	0.0	0.0
Tax paid	0.1	-0.6	0.0	0.0	0.0
Operating cash flow	4.2	0.7	0.4	-0.7	-1.1
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	-1.7
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	(1.9)	(2.4)
Cash at beginning of period	0.0	6.4	4.6	10.8	8.9
Cash at year end	6.4	4.6	10.8	8.9	6.4

Balance Sheet (A$m)	FY15	FY16	FY17e	FY18e	FY19e
Cash	**6.4**	**4.6**	**10.8**	**8.9**	**6.4**
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	21.8	20.5
Trade payables	1.8	2.8	3.0	3.2	3.7
Debt	0.2	-	-	-	-
Tax payable	0.5	-	-	-	-
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	18.7	17.3	15.5
Share capital	15.0	15.0	22.0	22.0	22.0
Retained earnings	(2.5)	(2.3)	(2.9)	(4.3)	(6.1)
Reserves	0.7	(0.3)	(0.4)	(0.4)	(0.4)
Shareholders Equity	13.1	12.4	18.7	17.3	15.5

Valuation Ratios (A$m)	FY15	FY16	FY17e	FY18e	FY19e
Reported EPS (cps)	8.1	1.4	0.0	-1.0	-1.6
Normalised EPS (cps)	4.9	1.9	0.0	-1.0	-1.6
EPS growth (%)	151%	-60%	-102%	Large	-62%
PE(x)	**0.0**	**43.9**	**-2,466**	**-86.1**	**-53.0**
EV/EBITDA (x)	21.1	24.3	377.8	-92.0	-51.1
EV/EBIT (x)	22.5	25.6	-2191.5	-71.6	-44.1
NTA (cps)	19.8	24.5	30.5	28.3	25.8
P/NTA (x)	4.3	3.5	2.8	3.0	3.3
Book Value (cps)	22.0	20.8	27.3	25.3	22.7
Price/Book (x)	3.9	4.1	3.1	3.4	3.7
DPS (cps)	1.0	1.0	1.0	1.0	1.0
Payout ratio %	20%	52%	0%	0%	0%
Dividend Yield %	1.2%	1.2%	1.2%	1.2%	1.2%
Franking %	0%	0%	0%	0%	0%
FCF yield %	4%	-2%	-1%	-3%	-3%
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	4,258
Growth	4%	3%	3%	3%	2%
USA	-	-	-	-	40
Growth	0%	0%	0%	0%	0%
Total Patient Admin Sets Sold	**3,820**	**3,935**	**4,053**	**4,174**	**4,298**
Average revenue per sale A$'000	2,656	2,845	3,047	3,264	3,463

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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