

Cyclopharm Limited

Building a profitable and growing market leader in nuclear medical imaging and pulmonary healthcare

FY2015 Audited Results

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17 March 2016





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CYC's 10 Fast Facts



- 1. Technegas is a well established proprietary world leader in functional lung ventilation imaging technology with major revenues generated by single patient consumables
- 2. Technegas is sold in 55 countries with significant expansion opportunities in the USA following USFDA approval of Phase 3 clinical trials
- 3. Chronic Obstructive Pulmonary Disease (COPD) and Asthma represent tremendous opportunity for substantial growth world wide
- Ultralute[™], a new innovative technology with global application, to be commercialised in 2016
- 5. Ultralute[™] technology is a platform for additional product development
- 6. Stable management and workforce
- 7. Another year of solid financial results in FY 2015 with strong foundations for growth: \$12.58m sales; \$4.79m NPAT (Including \$2.1m insurance settlement net proceeds), and \$4.15m operating cash flow (\$2.74m from Technegas). Strong balance sheet with \$6.44m in cash at 31 December 2015.

An Australian Biotech that is:

- 8. Profitable ,Generating cash & paying dividends.
- 9. Net cash on the balance sheet to fund growth and
- 10. Set to leverage tangible major growth opportunities.

Our History





cyclopet Nuclear Medicine

Cyclopharm Our business lines



cyclomedica Nuclear Medicine (Technegas)	Manufacturer and distributor of pulmonary ventilation imaging devices and equipment	 Track record of growing revenue, profits and cash flows FDA trials for sales in USA progressing Preliminary results of trials indicate that Technegas can be an effective tool to diagnose and monitor COPD
ultralute	Technology which extends the life of nuclear isotopes by up to 50%	 Fine tuning in early 2016 IP Secured First sales expected in late 2016
	Joint Venture with Macquarie University Hospital	Growth tied to hospital ramp-upNow EBIT positive
cyclopet Nuclear Medicine (Cyclotron Facility)	Cyclotron business (suspended operations in April 2014)	 Insurance settlement reached in December 2015 with net proceeds of \$2.1m Facility's medium to long term status under evaluation



CYC has clear strategy to leverage our position as a leading player in the global nuclear medicine imaging market and strong balance sheet to expand the use of our proprietary products and introduce new innovative technology.

We will do this by:

- Attaining approval to distribute Technegas in the USA
- Expanding the use of Technegas beyond the traditional diagnosis of Pulmonary Embolism into significantly larger applications such as COPD₁ and Asthma and CTEPH₂ for both diagnosis and patient management.
- Identifying, developing and commercialising complementary innovative technology such as Ultralute[™]
- Leverage our core global regulatory strengths, fiscal discipline, strong balance sheet and well developed expertise in nuclear medicine and pulmonary healthcare to seek out complementary technologies and businesses



Technegas

- Indication Expansion
 - Complete COPD Trial in China and publish results by Q4 2016
 - Implement clinical marketing strategy targeting the referring physician Q2 2016
- United States Food and Drug Administration Approval
 - Finalise partnership model with DraxImage or determine independent path to USA commercialisation by Q2 2016
 - USFDA clinical trial program underway
 - Attain USFDA manufacturing compliance readiness to include the relocation of Cyclopharm manufacturing premises in Q3 2016

<u>Ultralute</u>

• Bring Ultralute to market with sales in H2 CY2016

Product and Service Offering Expansion

• Continue to identify and evaluate business prospects targeting growth, product extension, diversification, accretion and enhanced returns

Growth Opportunities and <u>**Key Performance Indicators**</u>





Technegas

USA	 The USA represents the single largest market with half of the world's nuclear medicine departments located there Existing market for PE in the USA equates to ~480,000 patients per annum First priority following USFDA approval is to repeat our Canadian experience by replacing the Xe133 50% USA market share valued at \$47m USD
Currency	< 15% of revenues are \$AUD related; Currently > 60 % of Technegas revenues linked to Euro.
Seasonality	Historically 2H revenues are stronger due to higher procedure volumes during northern hemisphere winters
Pricing & Product Margins	In 2015 the average selling price for PAS=\$52.02 AUD & Technegas Generators = \$27.6k AUD. Despite downward pressure on healthcare products globally, Technegas has been able to achieve price increases. Consolidated GM of 80.6% in 2015 is primarily made up of PAS, the profitability engine room, accounting for 81% of total Technegas revenues.
Sales Volumes	PAS boxes sold in 2015= 3,901equating to 195,050 patient studies Technegas generators continue to average 50-60 units per year
Competitive Products	 Xe133 has been eliminated from the Canadian market with the introduction of Technegas. USA is the only major market that still uses Xe133 for ventilation imaging Kr89 – excellent imaging properties. Only available in a few countries due to limited availability and high cost DTPA in low patient volume sites continue where Technegas is available. Used in the USA off-label CTPA continues to dominate the PE space; however concerns with high CTPA radiation dose and improved nuclear medicine imaging techniques are bringing referrers back to nuclear medicine VQ imaging
Intellectual Property	TechnegasPlus Generator patented until 2026 A new generation of Technegas generators is under development with the goal to extend patent protection
Clinical Indications	Primarily used for PE. Also used in preplanning and effectiveness evaluation for lung reduction intervention The incidence of COPD is 30x that of PE. Furthermore, COPD represents an opportunity for ongoing patient management
Distribution	Cyclopharm continues to evaluate the effectiveness of Distributors/Agents/Partnerships/Independent
Facility Relocation	After 20 years of tenancy, ANSTO has notified Cyclopharm that our lease will not be renewed. The cost of relocation will have an impact in 2016 with an ongoing increase in facility costs.

Growth Opportunities and <u>**Key Performance Indicators**</u>



Ultralute

Market Penetration	Europe targeted as the primary market to launch due to the highest concentration of end user Mo99 generators in the world 1 st Generation targeted for launch in Germany at the EANM in October 2015 with initial sales to follow H22016	
Margins	Product launch estimates 50% GM with margin improvement expected from leveraging volume growth	
Product Development	1 st Generation targeting end users in hospitals and clinics to be commercialised in 2016 2 nd Generation developed for Radiopharmacy will be introduced in 2017	
Other Applications	Discussions underway with interested parties for extended applications with other isotopes	
MMI		
Revenue	Volumes closely aligned with the hospital. Continued double digit growth expected per annum in the foreseeable future	
Profitability	EBIT positive as of mid CY 2014	
MRI Licensing	Significant increase in profitability if Government funded MRI licensing is achieved	
Cyclopet		
Molecular Imaging	Following competition for government owned enterprises, Cyclopharm's Board decided to suspend commercial operations in the production of FDG. Subsequent to this decision the company successfully mediated an outcome that resulted in ANSTO paying \$2.65M to Cyclopharm. Cyclopharm has no immediate intention of re-entering the FDG market under the current competitive landscape.	
Facility	Fully written off. Discussions underway relating to the long term to include divestment of the facility	



2015 Financial Results and Performance



FINANCIAL

- ✓ Record sales of \$12.6 million (+4.4% vs. 2014)
- ✓ Record Technegas division operating EBITDA of \$2.3 million (+6.2% vs. 2014)
- ✓ Record NPAT of \$4.8 million (vs. \$4.1m in 2014), includes:
 - Technegas division NPAT: \$1.7 million; and
 - Net insurance settlement income of \$2.1 million
- ✓ Cashflow from operations of \$4.2 million (\$2.74m from Technegas)
- ✓ Minimal debt with net cash reserves of \$6.4 million at year end sufficient to fund growth objectives
- ✓ Maiden dividend in 2015

OPERATIONAL

- ✓ USFDA reengaged to leverage a faster less costly path to approval with USA partnership under final negotiations
- ✓ Preliminary results of trials in China show that Technegas can be an effective tool used to diagnose and monitor COPD
- ✓ Ultralute[™] Patent protection secured & commercialisation advanced
- ✓ New Generation Technegas Generator project takes shape







Second Consecutive Year of Record Results

- Another record financial result in FY15
- PAS margins enhanced by improved local prices in Asia and Latin America
- Strong financial performance supports ongoing investment in R&D and costs associated with expansion into new markets

- Year ended 31 December (\$000's)	2015	Change	2014	Change	2013
<u>Technegas Results:</u>					
Sales Revenue					
PAS	10,145	^ 8.1%	9 <i>,</i> 384	1 9.3%	8 <i>,</i> 583
Generators/service	2,363	12.2%	2,106	12.4%	1,874
Total Sales	12,508	↑ 8.9%	11,490	1 9.9%	10,457
Underlying EBITDA	2,980	13.0%	2,638	17.5%	2,246
Underlying EBITDA Margin	23.8%	1 0.8%	23.0%	1 .5%	21.5%
FDA Expenses	(686)	13.5%	(478)	-	(478)
EBITDA	2,294	1 6.2%	2,160	122.2%	1,767
D&A	(137)	-38.6%	(223)	-	(220)
EBIT	2,157	11.4%	1,937	1 25.2%	1,547
EBIT Margin	17.2%	↑ 0 .3%	16.9%	1 2.1%	14.8%

Underlying Results represent Technegas Division performance excluding one off items (Insurance/Litigation settlement and costs + impairment expense), CLSA deposit, FDA expenses and MMI equity accounted earnings.

strongly



Record Sales and Underlying Profit

2015 2014 Year ended 31 December (\$000's) Underlying Results¹: Technegas continues to perform 12,583 12,047 Revenue Price increases and ongoing cost Technegas EBITDA 2,980 2,638 reduction initiatives drove Cyclopet EBITDA (138)(266)improved gross margins **Underlying EBITDA** 2.842 1.822 Operating cash flow of \$4.2m Depreciation and amortisation (144)(266)in line with reported NPAT – **Underlying EBIT** 2,698 1,556 assisted by a net insurance settlement of \$2.1m **Reported EBIT** 4,115 3,578 Cyclopet losses in 2015 were Interest (25)(107)minimised compared to 2014 due Tax benefit 703 595 to suspension of operations **Reported NPAT** 4,793 4,066 Reported Basic EPS (cents) 8.2 7.0

> Underlying Results represent Technegas Division performance excluding one off items (Insurance/Litigation settlement and costs), CLSA deposit, FDA expenses and MMI equity accounted earnings.

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Group Balance Sheet





Balance Sheet strong

- Improved cash position driven by strong cash flows from operations
- Capacity to fund growth initiatives and ongoing R&D
- The medium to long term future of the Cyclopet facility, to include divestment, is under consideration
- Debt free Mortgage Debt of the Dublin operational facility retired in March 2016

Year ended 31 December (\$000's)	2015	2014
Cash	6,445	3,268
Other current assets	6,653	5,582
Non-current Assets	3,443	2,111
Total Assets	16,541	10,961
Current Liabilities	3,176	2,874
Borrowings	197	246
Non-current Liabilities	66	85
Total Liabilities	3,439	3,205
Net Assets	13,102	7,756





Cash Flow

- Strong cash reserves available to fund near to medium term growth opportunities
- Investment Activities in 2015 included FDA, Ultralute & Technegas product development
- Significant one-off cash upside in 2014 (\$2.65m) from litigation mediation and in 2015 (\$2.10m) from an insurance settlement
- Majority of underlying cash flow in 2015 was generated by Technegas (\$2.74m)
- Relocation expense of \$500k expected in 2016
- Dublin facility mortgage (€128k) retired in March 2016

	31-Dec-15	31-Dec-14	31-Dec-13
Operating Activities	\$4,154,834	\$4,468,780	\$1,185,110
Investing Activities	(\$651,654)	(\$238,756)	(\$1,209,113)
Financing Activities	(\$326,664)	(\$2,171,525)	(\$1,207,588)
Net Inc /(Dec) in Cash	\$3,176,516	\$2,058,499	(\$1,231,591)
Opening Cash	\$3,268,425	\$1,220,646	\$2,346,556
Foreign Exchange	\$54	(\$10,720)	\$105,681
Closing Cash	\$6,444,995	\$3,268,425	\$1,220,646
Other Income in Operating Activities	\$2,104,689	\$2,650,000	\$ -
Payments for Deferred Expenditure in Investing Activities	(\$639,242)	(\$279,319)	(\$485,616)
Repayment of Bank Borrowings in Financing Activities	(\$48,355)	(\$2,171,255)	(\$1,204,310)



TECHNEGAS

The world leader in diagnostic lung ventilation imaging



Technegas



- More accurate and sensitive ventilation imaging agent widely used in diagnosing Pulmonary Embolism
- ✓ Three parts to the technology: generator (TechnegasPlus Generator), aerosol tubing (Patient Administration Set / "PAS") and crucible (creates the nanoparticles for inhalation)
- ✓ PAS is a consumable used in every Technegas patient procedure.
- Technegas generators is used at the clinical site to manufacture Technegas
 - Third generation Technegas Generator under development
- ✓ Sales and marketing initiatives targeting technicians, clinicians and referring physicians (pulmonologists/respirologists)
- ✓ Strong growth of 8.9% in CY2015 sales globally despite global downward pressures for healthcare products
- ✓ Revenue model based on recurrent sales and ongoing service fees
- ✓ Shift in distribution model in some markets to agents to improve margins and accelerate sales
- ✓ Positive pricing trends continue





Technegas advantages

- Over 3.5m patient studies without a single reported adverse patient event
- A superior alternative to CTPA (angiograms) in nuclear medicine imaging
- Better clinical results at a fraction of the high radiation does used in CTPA
- More accurate and sensitive measurement in diagnosing Pulmonary Embolism
- Works well with conditions CTPA is contraindicated ...e.g. renal impairment
- Dry nanoparticle aerosol that mimics a true gas.
- Improved patient comfort with only 3-4 breaths required for delivery
- Allows for 3D images

Competitive Nuclear Medicine products

- Xenon 133, being a true gas patient has to re-breathe gas patient discomfort, doesn't provide 3D images. 50% of USA PE ventilation market in 2015
- DTPA, liquid aerosol, coalesces into larger droplets reduced penetration with inferior images in patients with COPD. Off-label use in the USA
- Generic Barrier to Entry
 - R&D on 2nd generation generators that can only uses Technegas
 - Need all three to capture market share generator, PAS and service capability

Technegas Sales Revenue

Consistent Organic Revenue Growth

Patient Administration Sets (PAS)

- PAS revenue up 8% from 2014
- PAS volumes up 3% from 2014
- French sales rebound in second half as predicted
- PAS volumes up in majority of major markets

Technegas Generators

- Generator revenue and volume up 20% from 2014
- Consistent year-on-year demand
- Improved revenue from volume and price increases partly offset by decline in service revenue





Technegas Volume – Generators and PAS



Organic Growth in the majority of markets





- Europe remains our largest regional Technegas market
- France volumes rebounded in second half 2015 as advised
- Canada is now our largest single country market with 12 consecutive years of PAS growth
- Canada represents a strong indicator of USA acceptance and Xe133 displacement



Technegas Overview Average Unit Price and Margins



Technegas Margins 100.0% 90.0% 80.0% 70.0% 60.0% 50.0% 40.0% 30.0% 2010 2011 2012 2013 2015 2014 77.0% 87.7% -PAS 80.1% 80.3% 78.6% 84.1% 43.0% 47.8% 50.5% Generator 45.3% 49.4% 48.6%

- Technegas Revenues are heavily weighted on PAS
 - PAS = 81% of Technegas sales
 - Generators = 13% of Technegas sales
- Unit price improvements for PAS and Generators continue in 2015
- PAS margins improvement continues driven by ongoing cost down initiatives
- Generator margins slightly down year on year
- Europe represents 64% of Technegas sales
- 2015 € FX was relatively flat as compared to 2014





Technegas Expanding the global footprint

- Technegas sold in 55 countries
 - Europe is the largest regional market for Technegas
 - In 2014 Canada became largest country market for Technegas surpassing France
- Over 3,500,000 patient studies since 1986
- 1,500 Technegas generators sold globally
- Expanding operations in North America pending clinical trial and approval of United States FDA
- Expanding the use of Technegas targeting COPD with trials being finalised in China
- Expansion of clinical development program in 2016
- Patent protection until 2026 with optionality for extension





Nuclear Medicine

TECHNEGAS OVERVIEW Agency vs Distributor Models





- The majority of Technegas sales are generated through Distributors
- Technegas is distributed directly in Australia, New Zealand, Canada and Germany
- Distributors allow for low cost market entry at the compromise of full market penetration and control
- From 2015 Cyclopharm is currently piloting an agency program in Japan, China and • Benelux
- Agency agreements in place ran through the end of 2015 at which time the program is under review during 2016

Agency Model:

- CYC controls end-user sell price
- CYC gets to see every customer invoice ٠
- CYC receives the agent's margin •
- CYC pays agent's out-of-pocket • expenses
- CYC pays the agent a consulting fee
- CYC pays the agent a commission •
- CYC owns stock on consignment to distributor

Distributor Model:

- Distributor purchases goods from CYC
- Distributor controls the end-user sell price
- CYC does not see customer invoices
- Margin remains with distributor
- Stock is owned by distributor



Technegas – **Clinical Trial Program Overview**

USA – Region Expansion **Targeting existing Pulmonary** Embolism (PE) market

Structural ventilation study comparing Xe133 vs. Technegas to allow the sale of Technegas in the USA

Market Size:

- Half the world's nuclear medicine departments are in the USA
- USA represents a potential PE market of ~480,000 patients per annum. (Current volumes = 200,000 patients per annum)

Timeline:

- \geq Q3 2016- Finalise Clinical trial program
- H2 2016 Stage one trial completed \geq
- H2 2017 Stage two trial completed \geq
- Mid 2018 USFDA Approval

Study Specifics:

- \geq Patient size: To be determined but the USEDA proposal is targeting <300 patients
- "All Comers" protocol to eliminate previous obstacles in patient recruitment
- Total estimated cost = <\$7m USD



*VQ- Ventilation Perfusion test is a two part nuclear medicine procedure used to determine the functional relationship between the circulatory system and lungs functional ability to capture oxygen



Nuclear Medicine

Technegas – **Global Indication Expansion**





Targeting Chronic Obstructive Pulmonary Disease (COPD) market

Evaluating the effectiveness of Technegas in early detection of COPD and the presence of the comorbidities associated with the disease

Market Size:

- 30x the size of total PE market \geq
- 65 million people have moderate to severe (COPD). \geq
- Estimates show that COPD becomes by 2030 will be the \geq third leading cause of death worldwide

Timeline:

- Q1 2016 China trial recruitment completed \geq
- \geq Q3 2016 Results published and presented at the Asian Pacific Society of Respirology Congress
- Plans to extend COPD initiative to additional markets \geq following China results. Preliminary discussions underway in Canada, South Africa, Australia and several European countries

China Study Specifics:

- Patient size: 150 patients
- Total cost = <\$400K

Additional indications and applications under review to include Asthma, Lung **Reduction and CTEPH***

Technegas can provide the clinician the ability to visualise and quantify lung ventilation by region. No other diagnostic tool can provide consistent, accurate and reliable functional imaging in comparison.

Cyclopharm will leverage this market advantage in 2016 by initiating a clinical program targeting Technegas indication expansion to include:

Asthma

334 million people globally

Lung Reduction Intervention

Application in determining ventilation pre and post lung reduction intervention

Chronic Thromboembolic Pulmonary Hypertension

- Ventilation / Perfusion imaging is the recommended
- Up to 40 million people globally

Technegas Indication Expansion – COPD



- The Global incidence of Chronic Obstructive Pulmonary Disease (COPD) is 30x greater than that of Pulmonary Embolism (PE)
- It is estimated that by 2020, C.O.P.D. will be the 4th highest cause of death globally. By 2030 COPD will be the 3rd highest cause of death globally.
- Cyclopharm is undertaking a trial in China to assess the use of Technegas for the diagnosis and management of COPD
 - Patient enrolment is scheduled to conclude April 2016
 - Preliminary research with Technegas suggests early detection than traditional Spirometry with 3 abstracts presented at the 2015 Asia Pacific Society of Respirology conference in December
 - Spirometry- a basic measurement of forced air volume provides no underlying pathophysiology and required significant disease progression to diagnose
- Expanding the use of Technegas from Pulmonary Embolism (PE) diagnosis to COPD would represent significant expansion of the market size
 - In China, at any time more than 56.6 million people in China have COPD
 - According to the Lancet 2008, it is predicted that China will see 65 million deaths from COPD and 18 million deaths from lung cancer between 2003 and 2033
- Key drivers of the Chinese COPD market include:
 - China is the greatest producer and user of tobacco in the world*
 - Rapidly Aging Population
 - High use of biomass burning at home for cooking
 - Elevated incidence of post-pulmonary tuberculosis
 - Poor air quality in metropolitan areas

*Fang X et al. Chest 2011; 139: 920-929

²⁶

New Clinical Indications Clinical Marketing Project



Program Objectives

Expand the use of Technegas in our major markets by engaging referring respiratory physicians by targeting chronic lung conditions

Program Overview:

Cyclopharm will initiate and support a series of clinical investigational trials targeted at expanding the use of Technegas to include COPD, Asthma, Lung Reduction Intervention and Chronic Thromboembolic Pulmonary Hypertension

Program Elements:

1.CYC will develop a set of standard protocols that each centre must agree to comply with

2.CYC will sponsor up to 10 centres over two years with clinical development funding in support of the trials

3.In order for a clinical site to qualify they must

- a) Agree to provide their data to CYC for consolidation and use
- b) Include a respiratory physician in their research team
- c) Agree to be monitored for base protocol compliance
- d) Agree to publish results





ULTRALUTE™

Innovative, first-in-class, disruptive, proprietary technology used to improve radiopharmaceutical manufacturing efficiency and health care cost effectiveness

Ultralute[™]



Product Overview:

- Disruptive Technology changes 60 years of how radiopharmaceuticals are manufactured
- Extends the effective life of Mo-99 generator up to 50%
- Each cartridge consumable designed for a maximum of 10 uses
- Patents secured in 2014
- Will be designated as laboratory equipment
- Market introduction represents a base platform for additional applications
- Product launch was in late 2015 with revenues commencing H2 2016

Technology features:

- Enables a user to extend the usable life of a Mo99 Generator
- Allows the user to purchase a smaller Mo99 Generator
- Provides greater flexibility in manufacturing products
- Provides a saving of between 30% to 40% in the cost of Tc-99m
- Enhances radiolabelling efficiency and imaging quality
- Purifies contaminants from the Tc99m eluate
- Provides a platform for further product development



Ultralute[™] Targeting Direct Users of Mo99



Ultralute[™] v1 is targeted at the clinical end-user market that sources Mo99 Generators directly from manufacturers

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Nuclear Medicine

- The European Mo99 generator market is completely Direct
- Ultralute registration in the EU has been determined to be a laboratory apparatus
- The largest single market for Mo99 generators in Europe is Germany
- Ultralute[™] v2 is being developed for the Radiopharmacy user market

Ultralute[™]

Generational Overview







Molybdenum Manufacturing and Supply Chain

- There are 4,000 Mo99 generators sold worldwide <u>each week</u>.
- Approximately 50% are sold to Radiopharmacies with the remaining sold directly to end users in hospitals and clinics



SUMMARY & OUTLOOK

Summary & Outlook



- CYC is a well established, profitable biotech, with recurring cash flows predominantly generated from a line of consumable products
- CYC is financially stable, fiscally disciplined and has recorded its second year of consecutive record revenue and profit in its key product line
- CYC already holds the distinction of being a world leader in the diagnosis of Pulmonary Embolism
- Sales in 2016 are expected to be consistent to that of 2015 as the result of customer supply chain management initiatives. Expect underlying positive demand to continue.
- CYC is developing several near term tangible growth opportunities leveraging off well established products and new innovative first-in-class technologies by delivering on:
 - ✓ Introducing new technologies to include Ultralute in H2 2016
 - Expanding the use of Technegas beyond PE to include COPD, Asthma and CTEPH with significant steps forward occurring in 2016 to include the publication of the China COPD trial in Q3 2016
 - ✓ Attaining USA approval for Technegas targeted for H2 2018



APPENDIX SECTION

- MMI
- OVERVIEW OF RISKS
- DISCLAIMER

Macquarie Medical Imaging

- Joint venture with:
 - 50% Alfred Health Solutions
 - 30% Macquarie University
 - 20% Cyclopharm
- Comprehensive suite of imaging modalities
- State of the art research platform
- Growth and profitability linked to ramp-up of Macquarie University Hospital
- EBIT positive since 2014
- Sales revenue increased 5% in 2015 as outpatient initiatives implemented at Macquarie University Hospital take effect



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Review of Major Risks



Risks	Overview
Competing Technegas technologies	 Even after 30 years of clinical use, Technegas' unique characteristics combined with improved imaging equipment and techniques is more effective today in diagnosing Pulmonary Embolism than it was when it was first introduced in 1986. However, introduced technologies such as CTPA have had a significant impact on the global use of Technegas. While there are no new technologies that would impact Technegas commercially in the foreseeable future, advancements in diagnostic imaging techniques are ever evolving
USFDA clinical trial is unsuccessful	Half the world's nuclear medicine are located in the USA. Failure to attain marketing approval for Technegas in the USA will significantly impact the growth potential for the product
A global shortage of Mo- 99m, the parent isotope to Tc-99m	The global shortage of Mo-99m in 2009 and 2010 and the limitation it placed on producing radiopharmaceuticals, to include Technegas, had a significant impact on the use of nuclear medicine as an imaging modality. Since 2010, the global nuclear medicine community and governments coordinated by the IAEA have been implementing strategies to minimise another global shortage.
Ultralute technology is slow to accept	Ultralute is a disruptive technology to the way radiopharmaceuticals have been manufactured for the past 60 years. Adoption may be slower than expected; conversely, if there is another global shortage of Mo-99m, consumer acceptance is expected to be greatly accelerated
Increased regulatory requirements	Technegas is used in 55 countries throughout the world in one of the most heavily regulated industries. Any significant increase to regulatory requirements may result in a market becoming commercially unsustainable.
Foreign Exchange	The majority of Technegas revenues, predominantly from Europe and Canada, are exposed to fluctuations in Foreign exchange.

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