cyclopharm
Nuclear Medicine

cyclomedica
technegas
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ultralute

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The Manager
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Managing Director's Address

Slide 7 Managing Director's Address
Good morning ladies and gentlemen, my name is James McBrayer, and I am the Managing Director of Cyclopharm.

Slide 8 Building for Growth
It is my pleasure to provide you with a summary of Cyclopharm's 2019 performance, which seems quite a long while ago now, as well as update you on our more recent progress.

For those new to our business, Cyclopharm is a leading nuclear medicine company specialising in lung health. Our underlying business is profitable and growing. Cyclopharm generates cash from its ongoing operations and we have a history of paying dividends.

2019 was a year of significant investment in our strategic priorities, outlined in this slide, which drives our financial performance and will deliver the next phase of Cyclopharm's growth strategy.

Slide 9 Building for Growth – Company Development
During the year, we recorded a solid underlying sales and earnings performance from our continuing operations, supporting our USFDA trials, Research and Development and ongoing dividends.

Our core Technegas business is stable with predictable baseline earnings. 80% of Technegas revenues come from recurring sales of our Patient Administration Sets (PAS), a single use consumable. Our gross margins continue to remain consistent through time, at also around 80%.

Cyclopharm recorded an underlying profit before tax of approximately $0.89 million, a decrease of $0.52 million on the prior year. This performance primarily reflects the ongoing investment required for Cyclopharm to meet global regulatory requirements that also encompass the requirements of the USFDA.

Our principal product Technegas is sold in 60 countries. While sales into Europe continue to represent the majority of our revenue, we are growing sales in our other markets such as Canada, China, South America and more recently via our entry into Russia.

Technegas is now positioned to access a significant opportunity to expand into the USA, the world's largest diagnostic imaging market. We have made excellent progress

towards securing USFDA approval and expect to begin marketing the product there in early 2021.

Cyclopharm is also developing opportunities to broaden Technegas applications beyond our traditional indication for diagnosing pulmonary embolism into exponentially larger addressable markets such as Chronic Obstructive Pulmonary Disease ("COPD") and Asthma. We call this significant long-term growth opportunity – 'Beyond PE'. I will talk more of this later.

Slide 10 FY 2019 Results Highlight

Cyclopharm's revenue increased to $14.08 million during 2019.

In total, revenue from Generator sales increased 21% over the year to $2.16 million, driven by a 16% increase in volumes and expanded margins.

In 2019, PAS revenue remained consistent at $10.61 million. Canada remained a highlight and returned as the largest country market by volume with 908 PAS boxes sold. With 50 patient studies per PAS box, this is equal to 45,400 patient procedures conducted in Canada.

In Australia PAS sales were depressed by a series of disruptions to the supply of nuclear medicine isotopes from the Australian Nuclear Science and Technology Organisation (ANSTO). ANSTO's supply disruptions were resolved in November 2019.

Our strong underlying financial performance provided the basis for ongoing investment of approximately $3.8 million in FDA trials, in supported our New Drug Application, which was lodged with the USFDA earlier this calendar year.

This strong financial performance, along with a successful share placement in late 2019, at a premium to the then share price, ensured your company finished 2019 with an enviable balance sheet, that positions us well for future investment and growth.

Slide 11 FY 2019 Operational Highlights

Our operational highlights in 2019 included.

- Record revenues for Technegas in the key markets of Canada and France;
- Completion of all internal documentation ahead of our Q1 2020 USFDA submission for Technegas;
- The receipt of a $2.93m R&D tax incentive;
- Entering into new third party distribution partnerships with Draximage, Tema and Rotop;
- Building our management team with key hires in the areas of Sales/Quality/Regulatory and Service. With these new staff we now have the management team in place to initiate our US and broader growth plans; and
- As I mentioned earlier, the successful $9.2m capital raising has provided the resources to initiate and execute on our growth opportunities.

Slide 12 Our Strategic Priorities

We are executing these opportunities with clear strategies to leverage our current position as a leading player in the global nuclear medicine imaging market through the expansion of our proprietary products and the introduction of new and innovative technologies.

Throughout 2019 and in 2020, we made significant progress towards achieving each of our strategic growth drivers including:

1. Making commercial sales of Technegas in the USA in 2021;
2. Expanding the use of Technegas Beyond the traditional diagnosis of Pulmonary Embolism (PE) into significantly larger applications.
3. Identifying, developing, and commercialising complementary innovative technology such as Ultralute™; and
4. Leveraging 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.

Slide 13 Ultralute Update

Before I move on to discuss our core technology, Technegas, I would like to update you on the status of Ultralute™.

The European Union (EU) is currently undergoing significant change in the regulatory regime from what is referred to as MDD to the MDR. Consequently, authorised notified bodies are required to reassess and recertify the conformity of all existing medical devices in accordance with the new and more onerous MDR[1] standards. The Company has been advised that due to the enormity of the number of reassessment reviews in progress, as a result, any new products being introduced within the region is taking longer than would otherwise be the case.

Since notifying shareholders of the delay earlier this year in our annual report, these delays have only been increased due to the inability of auditors to conduct onsite audits as a result of the COVID-19 pandemic.

We share shareholders' disappointment in the regulatory delays we are having to deal with these delays are only magnified by the current pandemic environment. At this stage we do not expect to see meaningful sales from Ultralute™ until 2022.

Slide 14 Technegas: World's Best Functional Lung Ventilation Imaging

Moving to the star of the show Technegas…..Why are we bullish on Technegas' growth prospects? Because it has clear clinical and operational superiority than its competitive products.

Technegas is recognised as the world's best functional lung ventilation imaging agent.

While this may seem a bold statement, it is evidenced by its real-world experience globally. In each of the markets in which we operate :

- Technegas Is considered the most preferred agent for lung ventilation imaging by clinicians, particularly in the diagnosis of pulmonary embolism.
- Technegas is recommended by the relevant peak industry bodies throughout Europe and Canada; and more recently,
- Technegas is increasingly being recognised for its efficacy in the diagnosis and monitoring of conditions such as COPD and Asthma, which impact a significant proportion of the global population.

Even in markets where Technegas is unavailable like the USA, these advantages in light of the COVID-19 pandemic, the superiority of our technology is being recognised for both its clinical and safety profile with an ever increasing sense of urgency.

At this point I would like to address what COVID-19 means for Technegas. A US study published as recently as this morning found that 37.1% of patients with confirmed

[1] European Medical Device Regulations

COVID-19 had pulmonary embolism. Whilst most of the published studies have been conducted using CTPA, we know that nuclear medicine plays a significant role in diagnosing PE. As the best clinically and well tolerated ventilation imaging agent used in nuclear medicine to diagnose PE, we know we have a part to play in diagnosing and managing these patients.

Slide 15 Coming to America

The most important near term objective of the company is to gain entry into the US market.

Over the past few years, we have invested significant financial and operational resources to progress trials and lodge the our application required to gain approval.

I am delighted to advise that we are now on the home stretch.

Slide 16 Technegas – USA Market Opportunity

Many of you will be familiar with this slide. But it is one worth repeating, because it clearly demonstrates to our shareholders the potential of the US market opportunity.

With over half the world's nuclear medicine departments, the USA will clearly evolve to be the single largest market for Technegas. There are over 600,000 Nuclear Medicine Ventilation procedures performed there, totalling over $90m USD, per annum.

The target market for Technegas in the USA equates to ~480,000 patient procedures of the 600,000 that I just mentioned.

With the significant interest and support we have fostered from US clinicians over the past few years, and our experience in rapidly becoming the standard diagnostic product in the Canadian market, I am highly confident Technegas will achieve its potential in the US market.

Slide 17 Technegas FDA Clinical Trial Process and Design

To recap our progress to date in gaining USFDA approval, in 2019, we invested $3.84 million to progress approval for Technegas in the US.

We have enrolled 204 patients, as at 30 June this year, in our 240-patient study across 9 sites in the US. Unfortunately, because of the pandemic, it is not likely that we will be able to enrol the remaining 36 patients in the near future.

However, fortunately for the company, in parallel with the clinical trial, we instigated in 20108 an alternative pathway known as a 505(b)2 application. This pathway allows Cyclopharm to include the positive historical outcomes from Technegas' used in non-US markets as part of our submission. Based on feedback to date, we remain confident our 505(b)2 New Drug Application is sufficient for USFDA approval.

Slide 18 USA 2020 Commercial Plan

In anticipation of USFDA approval in 2020 we have a clear road to commercialisation of Technegas in the USA.

In 2019 and this year, we are continuing to focus on developing and enhancing Cyclopharm's quality systems and processes as we pursue compliance with all relevant compliance benchmarks, including the USFDA and MDR requirements.

As part of this process, the Chairman mentioned earlier, in 2019 we expanded our team to include senior sales, regulatory compliance and technical management personnel to our team.

Furthermore, as the company progresses towards the anticipated USFDA approval to market Technegas® in the USA, this half, we will invest in building our inventory and distribution capabilities to facilitate rapid market entry.

Slide 19 Beyond PE: Clinical Initiatives

Cyclopharm's strategy to expand Beyond PE is our next significant long-term growth opportunity. We are building the opportunity by targeting new applications through clinical studies; educating clinicians; and engaging directly with respiratory medicine referrers.

To progress this strategy, in 2019, we supported five clinical trials and other initiatives targeting the use of Technegas® beyond PE. These include an exciting study by The University of Newcastle, Hunter Medical Research Institute (HMRI) and John Hunter Hospital into the use of Technegas® in patients with severe small airways disease. Initial publications for this HMRI study is expected in the coming months.

In Europe, we saw a publication in May, by the European Journal of Nuclear Medicine and Molecular Imaging , the official journal of the European Association of Nuclear Medicine, of imaging results illustrating the effectiveness of Technegas® for identifying tracheobronchitis in a patient with no prior history of lung disease and who tested positive for COVID-19.

Two weeks ago the trial in partnership with the Woolcock Institute and Sydney University in using Technegas in patients with small airways disease, was initiated with it's first patient scanned.

The implication in advancing these initiatives is they could collectively expand the use of Technegas® by improving the diagnosis and management of patients with COPD and other small airways diseases. These markets represent significant opportunities to expand sales of Technegas® and drive shareholder value over the medium term.

Slide 20 Three Value Horizons

In turning to the future, the development of modern imaging technologies and analytics software is creating market opportunities for Technegas that potential to dwarf the Pulmonary Embolism market.

From where we are today we see exponential potential growth opportunities for Technegas as we

- first expand our offering in the United States.
- secondly, displace competing technologies; and
- ultimately leverage the technologies full capabilities to include diagnosis and patient management.
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COPD is currently rated by the World Health Organisation as the 4th leading cause of death and disease, behind heart disease, stroke and cancer. By 2030, it is estimated it will be 3rd leading cause of death and disease.

Asthma affects 334 million people globally, while Pulmonary Hypertension affects a further 40 million. There is a real opportunity to use Technegas to improve diagnoses treatment and management.

We estimate the global Chronic Obstructive Pulmonary Disease market is 30 times the size of the PE market, and over 500 million patients suffering with COPD and Asthma could benefit from the use of Technegas® in diagnosis and ongoing patient monitoring/management.

Slide 21 Cyclopharm Investment Case
The investment case for CYC is clear.

We have a proprietary medical technology business which is superior to existing imaging competitive products.

Our underlying business has a history of profitability, steady growth in existing markets and issuing dividends.

From that steadily growing business, we derive recurring revenues from consumables. USFDA approval is expected to more than quadruple the revenue of the existing business and leverage additional growth opportunities as we penetrate into the CTPA market.

There is significant optionality in our Technegas business, beyond PE, into other chronic respiratory disease management which has the potential to deliver exponential growth.

I look forward to continuing to report to you on the progress the company is making against the drivers of the next growth phase at Cyclopharm, which are expected to deliver positive returns for our shareholders and support our strategic priorities.

Slide 22 Thank you and Business Q & A
Finally, I would like to thank all my colleagues who have contributed to the growth of the Company over recent years and assure you that the Cyclopharm management team, with the ongoing support of the Board, we remain absolutely committed to delivering positive health outcomes for our patients and growing financial rewards to our shareholders.

James McBrayer
Managing Director and Company Secretary

This ASX announcement was approved and authorised for release by James McBrayer, Managing Director, CEO and Company Secretary.

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Cyclopharm Limited

Cyclopharm is an ASX Listed radiopharmaceutical company servicing the global medical community. The Company's mission is to provide nuclear medicine and other clinicians with the ability to improve patient care outcomes. Cyclopharm achieves this objective primarily through the provision of its core radiopharmaceutical product, Technegas® used in functional lung ventilation imaging.

Technegas®

The Technegas® technology is a structured ultra-fine dispersion of radioactive labelled carbon, produced by using dried Technetium-99m in a carbon crucible, micro furnaced for a few seconds at around 2,700° C. The resultant gas like substance is inhaled by the patient (lung ventilation) via a breathing apparatus, which then allows multiple views and tomography imaging under a gamma or single photon emission computed tomography (SPECT) camera for evaluating functional ventilation imaging. Historically used in the diagnosis of pulmonary embolism, Technegas, together with advancements in complementary technology to multimodality imaging and analytical software, is being used in other disease states to include COPD, asthma, pulmonary hypertension and certain interventional applications to include lobectomies in lung cancer and lung volume reduction surgery.