cyclopharm
Nuclear Medicine

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technegas
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The Manager
Company Announcements Office
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Managing Director's Address

Slide 6 Managing Director's Address
Good morning ladies and gentlemen, my name is James McBrayer, the Managing Director of Cyclopharm.

Slide 7 – Financial Highlights
To begin, I would like to provide a review of our financial performance in 2020. During the year, we reported record Group Sales of $14.7 million, up 4.2% from the previous year, and buoyed by $2.2 million of new third-party distribution revenue. This new third-party sales growth more than offset the negative revenue impact of COVID-19 across the business. These results places the Company in a strong financial position as we return to more normal trading conditions and growth, post-COVID.

The Company recorded a net loss before tax of approximately $5.84 million, increasing from a loss of $2.42 million on the prior year. The increased loss on the prior year primarily reflects the ongoing investment needed for Cyclopharm to meet the global regulatory requirements necessary to complete the USFDA approval process. The loss includes expenses of $3.3 million associated with USFDA approval, and $600,000 of foreign exchange losses linked to the timing of the payment and the fee-waiver refund associated with our USFDA New Drug application fee.

In February 2021, we successfully raised $33 million via a well-supported institutional placement and an oversubscribed retail share purchase plan. This capital raising has placed us in a strong financial position to pursue our strategic objectives, which are predominantly focused on an accelerated expansion into the US market. I will talk more about this later in my presentation but I do want to take this opportunity to express my gratitude to our existing shareholders for your continued support and our new shareholders for your belief in our company.

Slide 8 – Operating Highlights
Our operational highlights in 2020 included;

- A strong recovery in sales, up 51.4% during the second half of 2020.
- Our US Phase 3 clinical trial confirmed that Technegas met both our primary and secondary efficacy endpoints.
- Inventory reserves, along with distribution, service, and installation support are in place for a rapid entry into the US market once USFDA approval is granted.
- Continued market expansion with Technegas is now being supplied to over 60 countries.
- Trials are in place to explore and develop new markets outside of Pulmonary Embolism.

We are now well positioned to realise the benefits of our growth opportunities, particularly in the US market.

Slide 9 – Building for Growth
Why is Technegas such an appealing commercial proposition?

Put simply, Technegas is a de-risked technology which has substantial upside, specifically in the US market where USFDA approval is eminent, and through expansion of its use beyond its traditional pulmonary embolism market….We call 'Beyond PE'. The Technegas technology has many advantages including;

- Its wide acceptance in over 60 countries, with over 4,300,000 patient procedures to date.
- The underlying operations of Cyclopharm are profitable with stable gross margins of greater than 80%.
- Approximately 80% of historical revenue is consumable sales that are recurring in nature.
- Safety concerns are relatively non-existent in comparison with rival nuclear medicine products. Technegas is a comparatively significantly safer diagnostic procedure when considering risks associated with COVID-19.
- There is significant demand in the US for Technegas. We have an aggressive generator placement rollout strategy that we expect to initiate, post USFDA approval, in the latter half of this year.

Slide 10 and 11 – USA Transition
With approximately half of the world's nuclear medicine departments located there, the United States represents the single largest market opportunity for Technegas.

Slide 10 and 11 –US Market Slide
In determining the presence of PE in the USA, there are over 600,000 Nuclear Medicine Ventilation procedures annually pre-COVID. This volume of procedures generate revenues totalling over $90 million US Dollars. Whilst this market has been impacted by COVID-19, we believe that these numbers will return when Technegas is introduced.

We have maintained that the target market for Technegas in the US equates to approximately 480,000 patient procedures of the 600,000 I just mentioned.
USFDA approval is expected to be fully granted this year, after which time, your company will pursue a strategic plan to rapidly deploy Technegas into the US market.

Our first priority, following USFDA approval, is to repeat our Canadian experience by progressively displacing the current standard diagnostic agents with our proven and superior Technegas technology as the new standard of care.

Slide 12 – USA Commercialisation Pathway
The risks associated with USFDA approval are largely behind us, with the regulatory process to approve the use of Technegas in the USA now in its final stages.

This time last month the USFDA conducted an onsite 7-day pre-approval inspection of our facility here in Sydney. With USFDA onsite overseas inspections a rarity during this pandemic, we are very grateful that the FDA has categorised the review of our facility as 'mission critical' and made the trip. We look forward to receiving their formal inspection report in the coming weeks.

We have a clear pathway and are both well positioned and well-funded to rapidly enter the US market.

A key part of our US commercialisation pathway is building generator inventories to install at targeted US hospitals, pursuing agreements for third party distribution, service, and installation, along with administrative support and our own specialist training.

Slide 13 – USA Pricing and Business Model

I would now like to explain in a bit more detail our business model for Technegas in the US.

Our entry into the US is a key driver of shareholder value in the short term, as your company continues to expand its global footprint.

In terms of our objective for a rapid rollout of Technegas generators in the US, we have planned and put into place steps to install generators at no cost for selected US sites. We expect that by removing the impediment for an initial capital expenditure outlay, hospital administrators will be more amenable to adopting our new technology as it will eliminate the requirement to apply for and access funding.

The initial rollout of Technegas generators will be focused on high volume sites to ensure that our technology is placed in the locations where it can have the greatest clinical impact. This strategy has the economic benefit of that it will also provide a faster payback on our initial investment. Cyclopharm will retain ownership of the generators over their extended ten to fifteen year lifecycle and provide consumables, generator maintenance and operator training on an ongoing basis to hospitals, in return for a continuing, long duration service fee and consumable sales.

Slide 14 – USA Demand Established

Our initial research indicates that Technegas will be quickly adopted by clinicians in the US.

During 2020 and into 2021, many leading clinicians and front-line workers requested that the USFDA expediate approval of Technegas for use in the US market. Most recently, in January of this year, the 16,000-member *Society of Nuclear Medicine and Molecular Imaging* requested Fast Track Approval and cited both clinical and safety concerns that exist with competitive products. All requests to expediate USFDA approval have been unsolicited by Cyclopharm.

This unprecedented support gives the Board even more confidence that there will be strong demand for Technegas following the expected upcoming USFDA approval and the subsequent rollout of generators starting in the second half of this year.

Slide 15 – Canada Case Study

Canada currently is our largest country market by patient numbers. It shares many similarities with the US market and provides us with a key indicator of how Technegas will be accepted in the US.

The Canadian experience, prior to COVID-19, recorded 14 years of consecutive growth in patients volumes per annum from its introduction in 2004. The increase in patients using Technegas has resulted in a proportionate increase in active generators.

As many of the consumable sales are associated with the ongoing use of the generators, there is a direct correlation with the number of active generators and annual consumable sales. We expect that the adoption of Technegas will present a far more rapid growth profile to Canada, with total revenue projected to grow with the increasing number of active generators rolled out in the US.

Slide 16 – Expanding Indications
With the advent of improved imaging techniques and equipment, supported by improved analytical software, Technegas is now more relevant today than it was when it was first commercialised.

Slide 17 – Building from a strong foundation
To know Technegas is to love Technegas.

As investors in looking at a multitude of listed companies you have to sift through vacuous announcements based on speculative bias verses opportunities based on factual evidence.

If you are looking for what is 'fact', there is nothing more 'factual' than clinical guidelines.

Guidelines equate to a clinical bible.

Guidelines are based on rigorous clinical data that transcends the company spin that you see from so many companies still in their development phase.

Guidelines are years in the making and based on extensive evidence – for example, the 2019 European Association of Nuclear Medicine Guidelines, an update to a 2009 edition, is based on 193 articles.

Technegas is rare in the clinical world in that our brand is named in, and synonymous with, superior clinical outcomes.

This is what both the European and Canadian guidelines say about Technegas.
In referring to what these guidelines say about Technegas
It is important to note that approximately 75% of our total global volume for Technegas attributed to those regions…. such is the acknowledged reputation of Technegas.

I encourage you to dwell on this slide after this presentation.

This overwhelming clinical acceptance and actual clinical use is the foundation in which we will leverage the true potential of this revolutionary product.

Slide 18 – Beyond PE Overview
We know that Technegas has utility in other disease states.

Even our recent US clinical trial of 204 patients had listed up to 15 different indications for use.

In order to commercialise any medical technology, you must have your assumptions based on clinical data and peer reviewed publications. Without that, you have nothing but opinion and speculation.

This is a glimpse, by category, of some of those initiatives.

Slide 19 – Clinical Activity Using Technegas
Ultimately, we see Technegas used in patient management of chronic diseases…..the impact for those applications have exponential commercial implications that will dwarf the tangible opportunities of the soon to open USA pulmonary embolism market for Technegas.

This strategy is not speculative in nature. We see Technegas, as noted by these recent clinical papers, being used in a multitude of clinical applications….with an emphasis on actual clinical use mostly 'Beyond PE'. The implication in advancing these initiatives is they could expand the use of Technegas by improving the diagnosis and management of patients with Chronic Obstructive Pulmonary Disease and other small airways diseases.

These markets represent significant opportunities to expand sales of Technegas and drive shareholder value over the medium to longer term.

Slide 20 – Company Sponsored Initiatives

Despite the wide use of Technegas in other disease states, we have initiated pilot clinical trials targeted at respiratory medicine referrers and researchers to clinically validate the anecdotal use we see in our everyday clinical use.

Cyclopharm's strategy to expand 'Beyond PE' is being delivered by targeting new applications through clinical studies; educating clinicians; and engaging directly with respiratory medicine referrers.

To progress this strategy directly, we have supported several prospective clinical trials and initiatives targeting the use of Technegas beyond Pulmonary Embolism. These include an exciting study by The University of Newcastle, Hunter Regional Medical Institute (HRMI) and John Hunter Hospital into the use of Technegas in patients with severe small airways disease.

Slide 21 – Three Revenue Horizon

We are building from a well established global base leading to significant growth as we enter the USA market by first displacing existing competitive nuclear medicine technology followed by conversion of competing technology used in diagnosing pulmonary embolisms.

However, the real prize is 'Beyond PE'.

The development of modern imaging technologies and analytical software is creating market opportunities for Technegas that potentially eclipse our existing Pulmonary Embolism market.

Chronic Obstructive Pulmonary Disease is a market opportunity 30 times larger than Pulmonary Embolism. 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.

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 across all of these respiratory conditions.

Slide 22 – Key Catalyst next 2 Years

What is immediately before us now? In the following two years, the key drivers of shareholder value will be our successful entry into the US market, and results from clinical studies investigating a wider application of Technegas.

As I have explained to you, USFDA approval is expected soon with a rapid rollout of Technegas generators to begin thereafter. We will keep you, our shareholders, informed as generators are placed in US hospitals.

Slide 23 – CYC Investment Case

The investment case for CYC is clear.

We have a proprietary medical technology business which is superior to existing imaging peers, is profitable, growing steadily and offers significant optionality beyond the PE market.

Growth in recurring revenues from consumables will underpin our future.

USFDA approval is set to quadruple the size of the existing business and leverage penetration into the broader chronic respiratory disease management market which has the potential to deliver exponential growth beyond our immediate expectations.
In closing 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 both positive health outcomes for our patients and financial rewards to our shareholders.

Finally, to you our shareholders…. I want to thank you for your support and confidence. The future is bright for your company and I look forward to providing you updates to our goals as and when they occur.

I will now answer any question relating to the company's business activities.

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.