cyclopharm
Nuclear Medicine

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technegas
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The Manager
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Managing Director's Address

Slide 6 Managing Director's Address
Thank you, David. 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 2021. During the year, we reported record Group Sales of $17.7 million, up a healthy 20.6% from the previous year, supported by continued growth in Technegas™ sales and the pleasing contribution of additional third-party distribution revenue of $4.1 million. It is gratifying to see both our core business rebound and our complementary third-party nuclear medicine sales and service strategy become increasingly successful as key markets recover from the impact of COVID-19. With a growing Technegas™ market and complementary revenue streams on third party products, we are well placed to deliver strong financial results and returns for shareholders.

During 2021, we invested a further $1.3 million to meet the regulatory requirements necessary to complete the USFDA approval process. The overwhelming majority of these costs were incurred in the first half of the year, as part of our initial application process.

As the Chairman mentioned, we finished the year in a strong financial position, supporting our ongoing dividends and providing us with the capital to pursue our strategic objectives, which are largely focused on an accelerated expansion into the US market. I will talk more about this later in my presentation.

Slide 8 – Operating Highlights
Our operational highlights in 2021 included;

- Record group sales of $17.7 million, up 20.6%.
- The process to obtain USFDA approval to enter the US market has moved into its final stages, with clarity and confidence to resolve the outstanding matters of the regulator
- 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.
- Expansion of our direct sales and service presence in 10 markets with the establishment of offices in Belgium and the UK.
- Trials are in place to explore and develop new applications for Technegas™ Beyond Pulmonary Embolism.
- And renewal of our CE Marketing Authorisation under the stringent new European Medical Device Regulations extends our approval beyond Europe via regulatory reciprocation.

Slide 9 – Building for Growth
This slide gives you an overview of why Technegas™ is such an appealing commercial proposition for health care providers.

Technegas™ is a system. The generator is a piece of capital equipment and the consumable is a repeat purchase which provides an annuity style income stream for your company. Generators typically have a life of over 15 years, and once installed the system has effectively 100% client retention.

Other particularly notable elements on this slide that I would like to highlight are:

- Europe is our largest region with France leading the way there
- Canada is our largest single country market
- Margins at the current mix are stable at greater than 72%

Technegas™ margins are expected to increase significantly because of the higher unit price we will be able to achieve for our consumable in the US market, as compared to the Rest of the World despite the rising cost of regulatory compliance.

Put simply, Technegas™ is a de-risked technology. It has substantial upside, both through our market expansion plans in the US following USFDA approval and our clinical expansion plans beyond pulmonary embolism.

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™.

At present health care providers in the USA use a mixture of Xenon-133 and DTPA. We have definitively demonstrated in our other markets such as Europe and Canada that Technegas™ offers users superiority and less risk and can be quickly adopted by practitioners to become the primary standard of care.

Slide 11 – USFDA Update

Given that we distribute Technegas™ to over 60 countries worldwide, we are subject to routine, regular and frequent regulatory inspections. As you may recall, in March last year, the FDA sent an investigator to conduct a required Pre-Approval Inspection. Prior to that inspection our site had been externally inspected 19 times over a 3-year period by various regulatory bodies. The FDA was our 20th , since then we have had another 8 external inspections since the FDA's visit. In fact, as I am speaking with you today my quality and management teams are involved in another regulatory audit today.

Following 2 weeks in hotel quarantine, the USFDA inspector conducted a 7-Day audit. 7 days is a long time for a site audit, the reason being Technegas™ in the USA is uniquely designated to be a Combination Product, meaning, the review covered elements pertaining to both Drug and Device manufacturing, adding an extra level of complexity to the review.

Since the inspection, we have been providing updates to the FDA every 60 days. Since the FDA audit….we have created 193 new documents and revised another 514. Thank goodness we have recently installed a document management system, otherwise, with the paper required for that body of work, we would have decimated several forests. Perhaps that alone gives us a strong ESG score.

The CRL

On 26 June last year, we received a Complete Response Letter or CRL. A CRL is issued by the FDA when, after a fulsome review of a New Drug Application, further manufacturing and product characterization information is required to be supplied by the sponsor before final approval is granted.

With the CRL, the FDA have provided a finite list of items that we need to address –giving us clarity as to process and outcome.

As highlighted before, we have made significant progress in addressing their information request. Nothing is unattainable and, most importantly, given that no safety or efficacy matters were raised, there is no need to initiate another clinical trial.

The more challenging aspects of the CRL request centre around additional work in describing and characterizing the Technegas™ particle in the methodology required by the FDA. This involves some additional laboratory analysis work to be conducted. We are well on our way to address this matter.

Importantly, earlier this year the company held a meeting with the FDA to discuss both our progress to date and our proposals to address the remaining elements outlined in the CRL. As a result of the feedback provided during the meeting, we expect we will be able to submit our formal and complete response to the USFDA in Q3 this year. Following this submission, the USFDA has up to 6 months to complete its review. These dates are important for investors.

Despite the additional work, we remain committed to our launch into the USA market as soon as possible. To that end we continue to build a fleet of Technegas™ generators to support the launch and accelerate commercial success.

Slide 12 – USA Update

The photo on this slide is evidence of both our commitment and confidence in gaining USFDA approval. The image shows some of the fleet of generators we are building in anticipation of our launch.

Slide 13 – Market Opportunity

Our first priority, following USFDA approval, is to repeat our Canadian success and market leadership by progressively displacing the current nuclear medicine ventilation imaging agents with Technegas™ as the new standard of care.

In the United States there are approximately 4 million procedures conducted annually to rule out the presence of pulmonary embolism. Of those procedures 85% are imaged through CTPA. Our immediate addressable market for these 4 million procedures equates to US$90 million per annum. We predict rapid adoption of Technegas™ in the United States not only because of Technegas™' clinical, operator safety and operational superiority but also because of the pricing model we will be implementing that I will speak to shortly.

The takeaway on this slide is

- We expect to convert 80% of the $90mUS = $72m. Since COVID, I think we can do better than that.
- Once Technegas™ is available we expect a further conversion of CTPA use from 15% to 30%, growing the market potential to $180m USD pa.

Slide 14 – USA Demand Established

Our conviction of being successful in the US is backed by pent-up demand and our positive experience in delivering commercial outcomes in multiple markets.

Moreover, the overwhelming and humbling support we have received from the US nuclear medicine community over the past couple of years has confirmed what we believed.
Why am I so sure?

For one, the hundreds of signatures from KOL's, heads of departments, front line workers and even the United States Society of Nuclear Medicine have written to the USFDA in support of Technegas™' approval.

Secondly, we have received and logged formal expressions of interest from numerous Nuclear Medicine departments across the United States.

Thirdly, we will be introducing a distribution and sales business model for Technegas™ in the USA market that will ensure rapid deployment and accelerate the real revenue engine for us…. patient consumables.

Without reservation, I am confident in saying that the 200 generators we are readying for launch, already have good homes to go to….. and that is just the beginning.

Slide 15 – USA Pricing and Business Model

This accelerated rollout strategy is a model where we will provide the generator at no capital cost on an annual license fee. We expect that by removing the impediment for a capital outlay, supported by existing procedural reimbursement codes for products such as Technegas™, clinicians and frontline workers will be enabled to drive our technology adoption.

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 also providing greater repeat demand for consumables and generating a faster and higher return on our initial investment.

Slide 16 & 17 – Expanding Indications

Technegas™' unique gas-like properties has the potential to be used more broadly in COPD, asthma, long COVID and other respiratory disease states as shown in this slide. This advantage provides us with substantive product growth opportunities.

Slide 18 – Beyond PE Initiatives

As the previous slide highlights, we know that Technegas™ has utility in other disease states.

For example, our clinical trial of 204 patients recently performed in the USA had listed up to 15 different indications for use (to include PE) ….and that was using simple planar imaging.

How can we capitalise on these opportunities?

First, in order to commercialise any medical technology your offering must be based on clinical data, peer reviewed publications that support an economic and clinical benefit. Without that, you may have something novel but in the end all you will have are pretty pictures…..and let me assure you pretty pictures won't get you reimbursement.

To drive this strategy, we are funding pilot clinical trials targeted at respiratory medicine referrers and researchers to clinically validate the anecdotal use we see everyday.

This slide provides a glimpse of some of our initiatives. In total we currently have 392 patients enrolled in company sponsored trials. You can clearly see by noting the various stages of completion, that we are delivering on a long-term strategy of expanding Technegas™ Beyond PE. In fact, as we speak McMaster University is presenting today and tomorrow at the American Thoracic Society conference their early findings on both studies listed here. Following their presentations, we will be publishing these updates over the next couple of days.

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 USA PE market.

Despite the impact that COVID has had on research and development, we are pleased to report that throughout the year there continued to be publications highlighting the very promising use of Technegas™ in patients with lung cancer, severe asthma and more recently the use in diagnosing and managing Long COVID.

Slide 19 – Three Value Driver Horizons

Technegas™ is more relevant today than when it was first invented.
What do these combined new commercial opportunities look like? This slide illustrates our potential revenue.

What has changed since the first-generation technology of Technegas™? Complementary technology has evolved. There have been significant advancements to include better cameras, hybrid imaging and advancements in Artificial Intelligence … collectively they are enabling TechnegasTM to leverage its full capabilities.

Once we are established in the United States, we will then target CTPA by seeking to double the nuclear medicine's market share in diagnosing PE.

Then, the greatest opportunity for "next level" growth is the work that we are doing to expand the use of Technegas™ into new indications.

Pulmonary embolism is a one-off procedure. Most studies are negative but if you do have a blood clot, it is a life-threatening condition that they treat straight away. We typically don't see follow-up exams for PE.

In contrast there are over half a billion sufferers in the world suffering from the chronic diseases of asthma and COPD. Of these 500 million sufferers, there are 125 million residing in markets where nuclear medicine is well established….North America, Australasia and Europe... these are our existing markets. This is our market Beyond PE.

Because of COVID-19, we are re-evaluating Horizons 1 & 2, as we believe these commercial outcomes may be achieved more rapidly than initially estimated.

Slide 20 – Key Catalysts

As investors, these are the milestones that you can expect to see over the next 2 years.
Certainly, the USA is our nearest term significant opportunity.
Once approved, we expect rapid market penetration.
From that launch we also expect to leverage off that momentum as we expand into more substantive applications beyond pulmonary embolism.

Slide 21 – CYC Investment Case

To summarise….Cyclopharm is:

- A Profitable and Growing Medtech with a very strong balance sheet
- Clinically recognised First in Class in diagnosing Pulmonary Embolism
- Technegas™ generates recurring revenues with high margins
- Entry into the USA market is our nearest term large growth opportunity
- The use of Technegas™ in chronic indications like COPD and Asthma will transform our market potential. In closing, I want to thank our shareholders for their support and hopefully I have piqued the interest of a few more potential investors.

Finally, to you our shareholders…. I want to thank you for your support and confidence. It is a privilege to work for a company that makes such a significant impact in people's lives every day. 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^{o} 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.