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cyclomedica
technegas
ultralute

Cyclopharm Ltd
ABN 74 116 931 250
Unit 4, 1 The Crescent
Kingsgrove NSW 2208 Australia
T 61 2 9541 0411
F 61 2 9543 0960
www.cyclopharm.com.au

The Manager
Company Announcements Office
Australian Securities Exchange Limited
20 Bridge Street
Sydney NSW 2000

CYCLOPHARM PRESENTS AT BELL POTTER HEALTHCARE CONFERENCE 2021

The following is a transcript accompanying the presentation provided at Bell Potter HealthCare conference on the 10th November 2021.

The correlating presentation is available on our Cyclopharm website at the following link:

https://investor.cyclopharm.com/site/PDF/01da2890-0c20-4617-824c-79d75cfc41d9/BellPotterHealthCareConference

Slide 1 **Cyclopharm Investor Update Bell Potter HealthCare Conference**
Thanks Darren….. It is good to be with you today.

Good afternoon I'm James McBrayer, Cyclopharm's CEO and Managing Director.

Slide 2 **Safe Harbour Statement**

Slide 3 **Company Overview**
I want to thank Bell Potter for the opportunity to provide a brief overview of Cyclopharm.

Whilst 20 minutes cannot cover the clinical depth and commercial potential of Technegas, I have for your convenience provided background information throughout these slides for everyone to reference a later time.

Furthermore, we lodged this presentation on the ASX yesterday evening. It can also be found on our website

A little about me…. My background is in Nuclear Medicine– I started in this industry some 32 years ago. I am a pharmacist that specialized in Nuclear Pharmacy…. As a pharmacist, I am hard-wired to present information that is substantiated by clinical facts not supposition, hype or opinion:

Regarding our Product Technegas…

- I will point you to a global track record of acceptance, an unmatched safety profile for our products and the ever-important element of any medical technology – established reimbursement.

- As always - I will illustrate our unique selling proposition based on peer-reviewed applications and proven clinical outcomes.

Our company is best known for our proprietary product Technegas.

Technegas is currently available in 60 countries. The USA represents our nearest term major opportunity and, whilst we have had a minor setback recently with the FDA, I remain extremely optimistic that we will gain approval in mid-2022.

Technegas is considered the gold standard and world leader in nuclear medicine functional lung ventilation imaging.

We have over 4.4 million patient studies to date, supported by hundreds of peer reviewed publications.

Given the unique properties of Technegas, most recently, we are seeing applications in diagnosing the complications arising from COVID-19 and what is now termed Long COVID.

We have recurring revenue that is generated predominantly from single patient consumables.

When we exclude our investments in gaining FDA approval, we have a history of being a profitable growing company that holds a rare feature in this ASX listed space by paying dividends to our shareholders.

Whilst the USA represents a significant near-term opportunity, we are particularly enthusiastic about the applications 'Beyond PE' such as COPD and Asthma. Use in these chronic conditions will dwarf our current pulmonary embolism market.

Slide 4 Presentation Highlights

For ease of reference, at the outset, these are the takeaway messages today:

- We are seeing recovery from the global impact of COVID19.
- Technegas sales remain strong with new revenues now generated from third party distribution in our 10 direct markets;
- Our belief in applications beyond PE are being supported by new clinical data along with company sponsored research that is scheduled to be published in the first half of 2022; and
- Importantly, we have the cash in the bank supported by positive cash flow to deliver both on our plans to expand into the USA and to develop the clinical evidence required to leverage beyond the traditional applications for Technegas.

Slide 5 **Technegas®**

What is Technegas?

Technegas is a radioactive carbon nanoparticle so small that when inhaled the Technegas particle acts like gas.

Given it's gas-like properties, anywhere Oxygen goes in the lung, Technegas goes.

We are not a computer algorithm…. We are a true representation of ventilation.

With improved imaging cameras already installed throughout the world combined with artificial intelligence (AI), Technegas' clinical applications are relevant across the entirety of respiratory medicine.

Slide 6 **Technegas® System Overview**

How is Technegas supplied to our customers?

First a Technegas Generator must be installed into the nuclear medicine department.

Once the generator is installed, the vast majority of revenues are generated from individual patient consumables and to a lesser extent service and maintenance.

Slide 7 **Building for Growth**

This slide gives you an overview of the typical revenue breakdown of Technegas.

As you will see, the consumable is like an annuity stream.

Other particularly notable elements I would like to emphasise on this slide 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 75%.
- Regarding margins…. 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, margins are expected to increase significantly.

Slide 8 **1H 2021 Financial Highlights**

I won't spend too much time on this slide as it reflects previous market announcements.

However, I will emphasize two elements:

- Firstly, our strong cash position is more than sufficient to deliver on both our USA approval and commercialization strategy as well as our investment in developing applications 'Beyond PE'.

- Secondly, our third-party distribution is becoming a valuable addition to our offering in the 10 countries we are directly present in. This direct presence is

particularly important as we engage one-on-one with respiratory physicians in applications Beyond PE.

Slide 9 **2H 2021 Outlook**

Despite the challenges that COVID has placed on businesses throughout the world, we expect that the second half of 2021 will deliver

1. Stable Technegas Revenues
2. Improved revenues in 3rd Party Sales
3. Significant progress toward USFDA approval

For many of you that follow Cyclopharm, our progress in securing USFDA approval and our plans for that market going forward is of particular interest

Slide 10 **USFDA Update**

Now to the update on our progress:

The Audit:

In March this year, the FDA sent an investigator to conduct a required Pre-approval inspection.

Prior to the FDA audit, our site had been inspected 19 times over a 3-year period. The FDA was our 20th….since then we have had another 4 inspections since the FDA's visit.

Following 2 weeks in managed quarantine, the USFDA inspector conducted a 7-Day audit.7 days is a long time for an audit…. the reason being Technegas in the USA is designated to be a Combination Product, meaning, the review covered elements pertaining to both Drug and Device manufacturing.

Following the inspection, we have been providing updates to the FDA every 60 days. A great deal of progress has been made in addressing the elements raised.

For example, in response to the audit, we have created 157 new documents and revised another 416. 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.

Whilst we are still waiting for formal responses to our updates, we have decided to make some facility improvements in both in workflow and air handling that should address some of the recommendations made by the FDA.

The CRL

On the 26 June this 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 information is required to be supplied by the sponsor before approval is granted.

We were very disappointed to receive the CRL.

During the review process starting in March of last year we had actively engaged with the FDA and provided numerous supplemental submissions to the reviewer's queries….51 in total.

Whilst the CRL is a setback, the FDA have provided a finite list of items that we need to address.

We have already made significant progress in addressing them. Nothing is unattainable and, most importantly, there is no need to initiate another clinical trial.

The more challenging aspects of the CRL request center around additional work in describing and validating what Technegas is. This will require some additional laboratory analysis work to be conducted. We are well on our way to address this finding.

Importantly, just yesterday I received confirmation from the FDA that they have granted the company a 2-hour meeting over 3 hours to discuss both our progress to date and our proposals to address the remaining elements outlined in the CRL. The meeting will be held on 27 January 2022.

Despite the additional work that we are required to deliver up, we have not varied our commitment to launch into the USA market as soon as possible…..to that end, we continue to build a fleet of Technegas generators for that launch.

This next slide taken last week is evidence of both our commitment and confidence in gaining USFDA approval.

Slide 11 USA Update - Building The Fleet

Slide 12 Benefits of Using Technegas®

Why are we so confident?

Technegas is best known for its use in diagnosing pulmonary embolism….it is the Gold Standard in Nuclear Medicine for ventilation imaging.

The slide highlights some of the features and benefits of the technology.

Most recently, Technegas' safety profile as it relates to COVID-19 in comparison to other nuclear medicine ventilation agent has created additional opportunities in what we had considered markets that fully penetrated

Slide 13 Pulmonary Embolism

As I stated previously, we are best known for diagnosing Pulmonary Embolism….

What is PE?

A pulmonary embolism is a blood clot in the lung….. the blood clot starves the body of Oxygen.

It is estimated that approximately 3 million people suffer from a pulmonary embolism every year ……but the number is likely to be much higher than that.

However, what we do know for certain is that if left untreated, 30% of pulmonary embolism is fatal. That is why there's so much effort in trying to diagnose this condition.

This is where Technegas comes in…. With the advent of 3D imaging or SPECT imaging, nuclear medicine provides the most accurate method for diagnosing pulmonary embolism than any other modality.

Slide 14 **What the guidelines say about Technegas®**

I love to say…. "To know Technegas is to love Technegas"…but it is true!

This is a favourite slide of mine.

As investors in looking at listed companies…. Particularly MedTech companies….. you must sift through what is speculative bias vs. what is proven fact.

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 company spin.

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 Technegas is actually named in and synonymous with superior clinical outcomes **in these guidelines**!

Please take the time to refer back to these quotes…..This sort of clinical support for a product is unheard of.

Slide 15 **Nuclear Ventilation Imaging Agent Comparison**

Why are the guidelines in such collective agreement and support for Technegas?

This slide provides a simple answer to that question. Technegas is clearly the superior choice compared to other nuclear medicine alternatives.

Slide 16 **Superior to Competitive Imaging Modalities**

Whilst we are hands down better than any other nuclear medicine competing product, our true competition in diagnosing pulmonary embolism, as it stands right now, is CTPA.

There are also numerous contraindications relating to CTPA to include …. pregnancy, contrast media allergies, diabetes and renal impairment.

Speaking of renal impairment, there is also risk associated with performing a CTPA procedure. Up to 13% of patients develop Acute Kidney Injury after being subjected to a CT study and, in many cases, hospitalisation is required.

However, the biggest competitive advantage that we have in nuclear medicine compared to CTPA, is that we are clinically superior if 3D SPECT imaging is being used with Technegas.

Nuclear medicine using Technegas has several significant advantages over CTPA. Firstly, CTPA delivers a very high radiation dose compared to a nuclear medicine scan. For example, the breast dose is 27 times higher using CTPA versus a nuclear medicine procedure.

SPECT imaging is not new or novel. For example, every nuclear medicine cardiac scan uses this technique. Outside of the USA most nuclear medicine lung imaging is performed using this technique. The European Guidelines actually specify SPECT imaging.

Slide 17 Technegas® The Canadian Case Study

When we try to gauge our potential success in the United States, we simply look north to Canada.

When we entered the Canadian market 16 years ago it looked very much like USA market today…. equally split between Xe-133 and DTPA.

Today, Canada is our largest single country market for Technegas.

In Canada in the first five years, we displaced Xe-133 completely.

In response to COVID-19, as a result of the last few smaller sites committed to converting to Technegas, we now have in effect 100% of the Canadian nuclear medicine ventilation imaging market.

Slide 18 Coming To America

We have every reason to be bullish about the USA….. our history validates this position.

Slide 19 Technegas® Immediate Market Opportunity

In the United States there are 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 that 4 million procedure market is 15% or 600,000 procedures…..this is equal to US$90 million.

At present, most nuclear medicine departments in the USA use planar imaging… guess why…..because they don't have a good ventilation imaging agent like Technegas available to them.

The takeaway on this slide is the

- 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 conversion of CTPA use from 15% to 30%, growing the market potential to $180m USD

Slide 20 **USA Demand Established**

Our certainty for success in the USA is backed by pent-up demand and our experience in delivering commercial outcomes

We know Technegas will be successful once approved in the USA.

However, the overwhelming and humbling support we received from the US nuclear medicine community over the past 18 months has confirmed what we believed.

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

Slide 21 **USA Pricing & Business Model**

Why am I so sure?

For one…. There are hundreds of signatures from KOL's, heads of departments, front line workers and even the Society of Nuclear medicine….they all have written to the USFDA in support of Technegas' approval.

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

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

Slide 22 **Expanding Indications**

Certainly, the USA is the most near-term opportunity for us….. A step that will grow our company dramatically.

But that's not our end game

Our greatest opportunities lie 'Beyond PE'.

Slide 23 **Beyond PE applications of V/Q SPECT (/CT)**

Earlier, I made the statement that given its unique gas-like properties, Technegas has the potential to be used more broadly across all respiratory medicine.

Here are just a few examples, developed independently of Cyclopharm, with supported peer review clinical references.

Slide 24 **Beyond PE : Clinical Initiatives Underway**

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

In order to commercialise any medical technology, you have to have your offering 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 have are pretty pictures….. pretty pictures won't get you reimbursement.

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

This is a glimpse of some of those initiatives.

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 there will be publications in the new year 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 25 **Three Value Horizons**

Technegas is more relevant today than when it was first invented in the 80's.

What do these combined commercial opportunities look like?.....This slide illustrates the additional opportunities for Technegas

What has changed since the 80's is the complementary technology that is used with Technegas. Today we have more sensitive cameras, we use three-dimensional imaging, with every new camera we have hybrid imaging capabilities with low dose non-contract CT added on and, most recently, software companies have developed analytical programs providing the clinicians more interpretive information than ever before.

Collectively these advancements are enabling Technegas to leverage its full capabilities.

Up until now we've been best known for diagnosing pulmonary embolism. In the United States, our nearest term opportunity, we will be seeking to repeat the success that we have achieved throughout the world and most recently in Canada.

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

However, what is providing us the greatest opportunity for growth is the work that we are doing in expanding 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, they treat you straight away. We typically don't see follow-up exams for PE.

There are over half a billion sufferers of asthma and COPD in the world. Of these 500,000 sufferers of Asthma and COPD, there are 125,000 residing in markets where nuclear medicine is well established…. North America, Australasia and Europe...these are our existing markets where Technegas is already established. These are our target markets 'Beyond PE'.

It is important to highlight that there are safety concerns the competitive nuclear medicine products in the USA in relation to spreading COVID-19. As a consequence, we are re-evaluating Horizons 1 & 2 and believe these commercial outcomes may be achieved more rapidly than initially estimated.

Slide 26 **KEY Catalyst for the next 2 years**

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 penetration.

From that launch we also expect to leverage off that momentum as we expand into more chronic applications.

Slide 27 **Cyclopharm Investment Case**

To summarise….Cyclopharm is:

- ✓ A Profitable and Growing Medtech
- ✓ Clinically recognised First in Class in the diagnosing Pulmonary Embolism
- ✓ Technegas generates recurring revenues with high margins
- ✓ Entry into the USA market is our nearest term growth opportunity
- ✓ The use of Technegas in chronic indications like COPD and Asthma will dwarf our current market

In closing, I want to thank our shareholders for their support and hopefully, with the information you have heard today, I have piqued the interest of a few more potential investors.

Slide 28 Thank you

For more information, please contact:

Mr James McBrayer
Managing Director, CEO and Company Secretary
Cyclopharm Limited
T: +61 (02) 9541 0411

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.