cyclopharm
Nuclear Medicine

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technegas
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ultralute

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The Manager
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Managing Director's Address

Thank you David.

It is my pleasure to update you on 2018, a year of significant progress for Cyclopharm's strategic growth objectives. Most notably is the progress we are making toward achieving the approval to sell Technegas products in the US., while also continuing to deliver a solid underlying financial performance for our shareholders.

It is pleasing to inform you that with United States Food and Drug Administration approval for Technegas within sight, your Company is about to enter a new, multi-year growth phase that will drive a significant step change in our performance.

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 issuing dividends. The company does not need cash to deliver on its growth drivers.

Our principal product Technegas is sold in 57 countries. Technegas is now positioned to access a significant opportunity to expand into the USA, the world's largest diagnostic imaging market.

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.

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%.

Since 2010, Technegas sales have totalled more than $104 million. In 2018 over 195,000 patients benefited from the lifesaving information provided by a Technegas scan. During 2018 we also completed our 4 millionth study.

Our core Technegas business is on the brink of accelerated growth with United States sales expected to commence in 2020 following USFDA approval. We estimate, that once the United States market is fully penetrated, Technegas will be used in around 80% of the 600,000 existing patient procedures performed each year in the United States to rule out Pulmonary Embolism. This volume equates to approximately 250% greater than our current market.

Cyclopharm's revenues increased by 2% during 2018, underpinned by improved pricing for TechnegasPlus generator sales in Europe. However, excluding the impact to Germany, PAS sales volumes would have recorded an 8.6% increase over the prior year.

Our company delivered an underlying EBITDA of approximately $1.91 million, down $0.74 million on the prior year. This EBITDA performance reflects investments in Cyclopharm's preparation for meeting USFDA marketing approval. Cyclopharm has a strong balance sheet with $9.19 million of cash reserves at the end of January 2019 and expects continuing modest growth in underlying Technegas volumes from existing markets during 2019. As at 30 April our global cash reserves was $7.14 million with YTD US$5.85million spent on the USFDA trial.

The solid Underlying EBITDA supported the Board's decision to maintain a full year final dividend of 0.5 cent per share, bringing total dividends for 2018 to 1.0 cent per share.

During 2018 we recorded a solid underlying sales and earnings performance from our continuing operations which support our USFDA trials, R&D and ongoing dividends. The strength of your company's underlying performance is expected to allow the Group to maintain its healthy capital position and dividend policy.

Cyclopharm continues to maintain a strong balance sheet with little debt. At the end of 2018, we had a net cash position of $5.85 million, while at the end of January 2019 that cash position was $9.19 million. The increase in cash in January was driven by receipt of proceeds from the Australian R&D tax incentive and the receipt of the proceeds from the civil case win we had over our former German employee.

The strength of our balance sheet enables us to fully fund the regulatory process to gain approval to start selling Technegas products in the US market in 2020.

Expenditure on US regulatory approval of Technegas, in 2018 was $2.96 million, and the Company expects to spend a further US$2.58 million on the USFDA approval process in 2019, bringing total expenditure to gain approval of start selling Technegas in the US in line with the expected US$7.5 million.

Our balance sheet strength also gives us the flexibility to invest in R&D targeted at expanding the use of Technegas beyond Pulmonary Embolism and into new markets.

Our strong cash position is the result of a capital raising of $6.59 million after costs in June 2017 supported by over 90% of you, our shareholders plus the continued global cash generation from Technegas sales along with funds received from the Australian R&D tax incentive scheme.

Some of Cyclopharm's costs associated with the Group's overseas R&D activity have been approved for inclusion in an R&D tax Incentive program by AusIndustry. This has allowed the company to report Other Income of $2,122,351 for the 2018 year compared to $2,390,586 reported in 2017. Cyclopharm expects to receive an R&D tax incentive of an amount like that received in FY2018 through to at least FY2020.

Cyclopharm's core operations continued to generate healthy positive earnings and cash flows in 2018.

Revenues in Europe were in line with the previous year despite the relative absence of sales in Germany due to legal action, initiated by Cyclopharm, against our former German employee. Late last year we informed the market that we were awarded the full claim made against our former German employee for a sum of AUD $335,000. We are currently progressing another civil claim against our former German employee and expect that a hearing date will be set for October.

European sales were supported by the expansion of our direct distribution footprint via the acquisition of 100% of our Scandinavian distributor, Medicall Analys AB.

Sales in Asia Pacific were up 12% reflecting sales to China resuming, following a hiatus in 2017 as stock from a seeding initiative was sold down. We expect a new baseline for the run rate of sales in China to emerge over the next 12 months, which will reflect plans for China to build up to 400 new nuclear medicine imaging facilities in the coming years.

We made significant progress towards attaining USFDA approval to market and distribute Technegas in the United States and are preparing to submit a New Drug Application within the next few months. We expect US regulatory approval for the use of Technegas in 2020.

We are continuing to pursue regulatory approvals to commence sales of Technegas in Russia and additional European markets

In late 2018, the Canadian Association of Nuclear Medicine ("CANM") released guidelines that strongly recommend Technegas above other ventilation imaging agents in the diagnosis of Pulmonary Embolism, particularly in patients with COPD. Cyclopharm views this endorsement of Technegas as a positive indicator of its sales potential once approved in the much larger US market.

Following feedback from potential customers, in order to broaden its overall market acceptance and optimise the commercial value of this technology, the decision was taken to register Ultralute™ as a medical device technology within Europe.

Cyclopharm's patented innovative technology Ultralute™ is undergoing the registration process as a medical device. This process is expected to be finalised in late 2019 with a full commercial launch in Europe targeted in 2020.

Technegas is the world's Best Functional Lung Ventilation Imaging Agent.

Technegas has several advantages over competing nuclear medicine products including:

- Better clinical outcomes with a significant reduction in the radiation doses of competitors
- More accurate when diagnosing Pulmonary Embolism
- Improved patient comfort
- Allows 3D Imaging
- and has been named as the ventilation imaging agent of choice by the Canadian Association of Nuclear Medicine ("**CANM**") and in the European Nuclear Medicine guidelines

Our intellectual property is protected by the patents held for the Technegas Generator until 2026. We are also protected by the integrated systems approach necessary to deliver a Technegas scan. To achieve consistent results the nuclear medicine department needs to use approved consumables in conjunction with a Technegas generator that is installed, maintained and serviced with approved components.

Today our commercial offering is primarily based on diagnosing pulmonary embolism or a blood clot in the lung.

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.

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

This is where Technegas excels. With the advent of 3D imaging or SPECT imaging, nuclear medicine provides the most accurate method for diagnosing pulmonary embolism.

The most significant business opportunity for Cyclopharm is gaining approval to sell Technegas in the US market. This approval will be the catalyst for the significant near-term step change in Cyclopharm's financial performance and growth.
The US market represents half of the nuclear medicine departments globally with 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 is the 80% of non-CTPA, nuclear medicine ventilation imaging scans, which equates to 480,000 procedures. The total nuclear medicine ventilation imaging for diagnosing PE is valued at US$90 million.

In 2018 Technegas was used in 195,000 procedures within the 57 countries we service.

Cyclopharm believes that a 50% total market conversion is achievable over 2 to 3 years with the balance of the target market converted within 5 to 7 years.

It is worth emphasising that the current annual volumes for the Technegas single Patient Administration Set (PAS) is approximately 200,000 patients per annum globally. The existing target market for Technegas in diagnosing PE is 480,000 patients per annum. The current average per patient price for PAS is AUD $55.

The price we are expecting to receive in the USA for Technegas is USD ~$90-$100 per patient. Therefore, whilst the volumes in the USA may be 250% larger than the rest of the world, the revenues that we expect to generate considering current exchange rates will be 620% greater for PE alone.

Furthermore, in quantifying the revenue potential by entering the USA market, Technegas enjoys significant advantages over CTPA scan so, once approved in the United States, we are also going to target another 15% conversion from CTPA to nuclear medicine ventilation imagery over 5 to 10 years; therefore, doubling the existing USA market opportunity.

The USA is our most significant near-term growth opportunity. We are making good progress in our phase 3 USFDA trial. As at 17 May 2019 we had 135 patients enrolled.

In the first half of 2018, Cyclopharm submitted a first 40-patient interim study to the USFDA, which allowed us to explore opportunities to refine or alter the clinical trial program. As a result of that meeting, USFDA provided constructive guidance to Cyclopharm, relating to an alternative 505(b)2 New Drug Application Pathway and approved a variation to the existing trial that is expected to expedite patient enrolment.

In parallel with the clinical elements of our USFDA New Drug Application, in 2018, Cyclopharm implemented an updated Quality Management System at our new manufacturing facility in Sydney that ensures we meet FDA standards.

The company also initiated a comprehensive documentation review of our medical devices to ensure we are compliant with the most recent USFDA guidelines as well as the new International Medical Device Single Audit Program (MDSAP). MDSAP is a regulatory harmonisation initiative between Australia, Brazil, Japan, Canada and the United States that will minimise disruptions due to multiple regulatory audits, provide predictable audit schedules and incorporate the ISO 13485 compliance required for our CE mark in Europe.

I am pleased to confirm that The Company following an audit in February formally received MDSAP certification this past Friday. This achievement will reduce the cost of regulatory compliance and validates the work we have been doing over the past couple of years toward getting our regulatory system USFDA audit ready.

Cyclopharm is currently compiling the necessary elements required for Technegas' USFDA New Drug Application (NDA) which will be submitted within the next few months in anticipation of commercial sales in 2020.

Once the NDA has been submitted the company intends to request an expedited review of the NDA on the grounds that Technegas meets an unmet need in the US market for 3D functional lung imaging.

We expect approval to sell Technegas products in the US market will be granted within 6 to 12 months from lodging the NDA.

Once the NDA for Technegas has been submitted to the USFDA, your company will take advantage of the NDA review period to establish the sales and marketing infrastructure necessary to address the US market, whilst also engaging with the customer base in anticipation of a 2020 market launch.

In preparation for the expected US launch in 2020, we will take a stepped approach to investing in increasing Technegas inventory. The first step will be to double the current production of Technegas Generators and PAS kits, with subsequent steps to scale up inventory to meet the growth in the US market. We anticipate matching or improving on historic gross margins for generators and PAS kits sold in the US.

Once Technegas is established in the US Pulmonary Embolism market we will also, in parallel and supported by the results of our beyond PE clinical trials, look to expand Technegas' use into other applications whilst targeting the much larger CTPA market.

Cyclopharm believes the extension of Technegas into new applications such as the diagnosis and monitoring of COPD, asthma and other respiratory disease states will create opportunities to exponentially expand the market for Technegas beyond its traditional PE market.

These new markets represent an opportunity to drive significant growth in sales of Technegas in mature and new markets, as more than 500 million patients per annum are treated for asthma and COPD.

A major Cyclopharm strategy is to target new applications through clinical studies; education of clinicians; and direct engagement with respiratory medicine referrers.

In August 2017, Cyclopharm funded a $600,000, 100-patient study, in collaboration with the Hunter Medical Research Institute and the University of Newcastle, into the use of Technegas in severe asthma patients. 100 eligible patients have been tested with a 40-patient subset undergoing further tests to determine response to therapy are close to patient recruitment completion. The first articles referencing this trial are expected to be published in the coming months.

In May of 2018, Cyclopharm announced $387,000 of funding for a three-year, 100-patient study by the Woolcock Institute for Medical Research in collaboration with

The University of Sydney and the Northern Sydney Local Health District. The trial is designed to develop better tools to diagnose and manage patients suffering from Asthma and COPD using Technegas. The first patients have been recruited for this study.

The current Beyond PE trials build on the peer reviewed, article published in May 2017, from the Cyclopharm sponsored trial in China targeting the use of Technegas in treating COPD.

Cyclopharm is actively promoting these trials to clinicians globally to encourage the use of Technegas in new applications, such as COPD and asthma, and has received anecdotal feedback that Technegas is already being used in lung volume reduction applications in Australia.

The significant steps forward in imaging technology are occurring at a time when global leaders in respiratory medicine are demanding better diagnostic tools, targeting true personalised medicine. This is creating a creating a pull factor that will allow Cyclopharm to leverage Technegas' fullest potential in clinical conditions Beyond PE.

Several years ago, as part of our strategy of expanding the use of Technegas Beyond PE, Cyclopharm implemented a program of direct engagement with referring respiratory physicians. This program allowed us to identify the need for better diagnostic tools and we have designed our clinical trial development programs to address this need.

The opportunities to combine Technegas with modern imaging technologies and analytics software has the potential to create new markets that will dwarf the Pulmonary Embolism market.

Chronic Obstructive Pulmonary Disease is a market opportunity 30 times larger than PE and 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 largest cause of death.

Asthma affects 334 million people globally, 250 million suffer from COPD, while Pulmonary Hypertension affects a further 40 million. There is the significant opportunity to use Technegas to improve diagnoses treatment and management of these patients.

With regards to our innovative technology Ultralute^{TM}, Ultralute™ has the potential to bring significant cost savings in the delivery of pharmaceuticals used in nuclear medicine by extending the useful life of Molybdenum-99 (Mo-99) generators by up to 50%. It is a technology with the potential to give nuclear medicine departments the ability to dramatically improve operating efficiencies and health outcomes for patients.

Following test sales of Ultralute^{TM}, in 2018, the decision was taken to register Ultralute^{TM} as a medical device technology within Europe, in order to broaden its overall market acceptance and optimise the commercial value of this technology.

A full commercial launch of Ultralute™ in Europe is expected to commence following registration as a medical device targeted in late 2019.

Meaningful commercial sales of Ultralute™ within the medical device category in Europe are expected in 2020.

2018 was a pivotal year of investment in the strategic priorities that will drive the new growth phase at Cyclopharm. During the year, we recorded a solid underlying sales and earnings performance from our continuing operations, supporting our USFDA trials, R&D and ongoing dividends.

The company's core Technegas business recorded consistent underlying sales when adjusted for the reduction of sales in Generators and PAS boxes in Germany. PAS sales volume grew across our other major markets with total PAS sales, ex-Germany, up 8.6% on the prior year.

In 2018, $2.96 million was invested to progress USFDA regulatory approval for the use of Technegas in the US for diagnosing PE, a market valued at US$90 million. USFDA Trials are expected to progress to regulatory approval for use across several indications in 2020, including: lung transplants, Pulmonary Hypertension and acute Pulmonary Embolism. We are also continuing to pursue regulatory approvals to commence sales of Technegas in Russia and additional European markets.

We invested over $0.25 million in a successful clinical trial to expand the use of Technegas into the diagnosis and monitoring of Asthma which represents a much larger market than our current application in the Pulmonary Embolism market. In addition, we completed the acquisition of Medicall Analys AB for a consideration of SEK8.846 million paid over 3 years, to provide supply chain synergies to the Group.

The anticipated underlying solid financial performance will allow the Group to maintain its healthy capital position and dividend policy. I look forward to continuing to report to our shareholders our progress against our next phase growth drivers which are expected to deliver returns for our investors and be supported by our strategic priorities, which remain:

1. Expanding Technegas sales by attaining approval to distribute Technegas in the USA in 2020;
2. Expanding the use of Technegas beyond the traditional diagnosis of Pulmonary Embolism (PE) into significantly larger applications such as Chronic Obstructive Pulmonary Disease (COPD) and Asthma, Lung Cancer, Lung Volume Reduction and Pulmonary Hypertension for both diagnosis and patient management;
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.

2018 was a significant year for the company and for me personally. In June 2018 I marked my tenth anniversary with Cyclopharm. It is an honour and a privilege to be part of a company that makes a difference in people's lives every day. I thank you all for the opportunity.

In closing I want 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, remains absolutely committed to delivering positive health outcomes for our patients and growing financial rewards to our shareholders.

Thank you. I will now hand back to the Chairman.

James McBrayer
Managing Director and Company Secretary

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