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The Manager Company Announcements Office Australian Securities Exchange Limited 20 Bridge Street Sydney NSW 2000 cyclomedica technegas cyclopet ultralute

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## Introduction

Good morning,

Thank you for joining us for today's Annual General Meeting of the shareholders of Cyclopharm Limited. My name is David Heaney, Chairman of the Board of Cyclopharm Limited and I will chair the Meeting.

Before I begin, I kindly request that if you have a mobile phone with you, please switch it off, or turn it to silent mode for the duration of this meeting.

I have been advised that a quorum is present in accordance with the Constitution. Accordingly, I declare the Meeting open.

I am pleased to introduce my fellow Directors (to my left/right), Vanda Gould and Tom McDonald and our Managing Director, CEO and Company Secretary, James McBrayer.

Also with us today are key members of the Cyclopharm's management team and many staff members who are also shareholders. At the conclusion of the AGM, our staff will be available to take shareholders on a tour of this facility.

I also welcome Mr Andrew Hoffmann and Mr Umer Altaf of Nexia Sydney, the Company's Auditor.

Please note that the following documents are tabled and are available for review:

- The Notice of Annual General Meeting,
- Financial Statements,
- Independent Auditor's Report,
- Directors' Report,
- Members' Minute Book,
- Company's Constitution and
- Shareholders' Register.



## Ladies and gentlemen

Before we move to the formal matters of the meeting, I would like to review Cyclopharm's achievements during the past year and then ask James to present his address providing you with more detail on the operational and financial performance of the business.

Let me begin by saying that 2018 was a pivotal year of progress for Cyclopharm. We made great progress in the delivery of our most significant business opportunity, the approval to sell Technegas products in the US market, while also continuing to deliver a solid financial performance from our ongoing operations.

During 2018, following successful initial trial results and positive discussions with the USFDA late last year, we commenced a streamlined process for gaining approval for the sale of Technegas products from the US regulators via the 505(b)2 pathway. This process positions us well to submit Technegas' new drug application, with the FDA, within the next few months. This progress comes despite the disruption to the review process from the US Government shut down earlier this year.

With this process proceeding well, we remain confident of reporting solid sales of Technegas products in the US in 2020. In preparation for this, over the remainder of the year, we will be putting in place the operational building blocks to launch sales into this significant market. Our initial plans are for a modest sales and support team, with a direct to market sales strategy.

As I have said previously, accessing the US market is a transformational opportunity for Cyclopharm that will create significant value for your company. The nuclear medicine diagnosis market for Pulmonary Embolism (**PE**) alone, in the US, is estimated at US\$90 million per annum. In order to get a sense of the scale of the US opportunity it may be useful to note current global demand for Technegas equates to approximately 200,000 patients per annum, while in the US market, each year, there are around 600,000 individual procedures for PE.

Reviewing the Company's financial results for 2018, Cyclopharm remains in a solid financial position. During the year we again generated positive returns from underlying operations, ending the year with a net cash position of \$5.85 million, by 31 January 2019 that climbed to \$9.1m- which is sufficient to fund the approval process for Technegas sales in the US and launch sales into that market - and maintain our dividend for the 2018 financial year at 1.0 cents per share.

Total sales revenue, in the 2018 financial year, of \$13.4 million represents an increase of 2% on the previous corresponding period. In Europe we achieved improved pricing for generator sales via our Scandinavian business and additional sales in France following the renegotiation of our supply contract in that market.

Sales in Germany have been impacted by the ongoing legal action, in that market, against our former employee. Our first civil case was concluded successfully retrieving 100% of our claim of \$335,000. The second civil case is ongoing with a hearing date to be assigned in July. There are additional infringements we are pursuing in relation to this matter and will be utilising the full extent of the law available to us. Despite this temporary setback, we are starting to see the first signs of volumes and service revenues improving in Germany.



Revenues in Asia benefited from the predicted return of sales in China in the second half of 2018, while Canada and Australia continue to deliver a solid sales performance.

The net loss after tax for the year was \$35,456 compared to \$1.52 million in the prior year. Underlying EBITDA of approximately \$1.91 million was down 28% on the prior year after including the early costs of aligning our processes with the United States Food and Drug Administration's requirements.

We expect the total costs associated with gaining regulatory approval and launching sales of Technegas products in the US market will be approximately US\$7.5 million, which are fully funded. In parallel, we are pursuing regulatory approval to sell Technegas in Russia and other European markets.

Turning next to our growth strategies; our strategic growth objectives are built around four key drivers, which are:

- expanding sales of Technegas in existing and new markets, such as the US;
- extending the use of Technegas into new applications through our 'Beyond PE' initiatives;
- the development and commercialisation of innovative technologies, such as Ultralute<sup>TM</sup>, and
- leveraging our core strengths to seek out opportunities in complementary technologies and businesses.

In Cyclopharm's existing markets we have remained active in identifying opportunities to expand sales of Technegas. In 2018, we acquired Medicall Analys AB in Sweden, our Scandinavian distributor, allowing us direct access to the Swedish, Norwegian and Finnish markets and higher margins on our products. With this latest acquisition we have direct market control in seven countries in Europe.

We are also working hard on our 'Beyond PE' initiative to broaden the use of Technegas in applications such as the diagnosis and monitoring of COPD, asthma and other respiratory disease states. Individually COPD and asthma each represents opportunities that are 30 times larger than our existing Pulmonary Embolism market.

Our approach to achieving our Beyond PE ambitions is to demonstrate the utility of Technegas in these disease states not only for diagnosis but for chronic disease management. Our clinical trials are designed to raise awareness of our Technegas technology with both our referring physicians globally and our nuclear medicine customer base both existing and in the much larger and lucrative US market. The first of example of our research is this area was the COPD study we conducted in China. This study was commenced in 2015 and published in 2017

Since the China COPD study, we are sponsoring several small scale Beyond PE clinical trials. The most notable of these trials include a 100 patient severe asthma trial at the Hunter Medical Research Institute; a 30 patient COPD trial at the Montreal University Hospital (CHUM¹); another Canadian based study evaluating complications associated with Lung Transplant in 30 patients; and the soon to commence 100 patient COPD trial with the Woolcock Institute for Medical Research here in Sydney.

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<sup>1 (</sup>CHUM) Centre hospitalier de l'Université de Montréal



We have begun to see traction in our Beyond PE strategy in Australia as some leading respiratory clinicians here have commenced using Technegas for lung volume reduction applications. Whilst it is still early days, we believe that the Beyond PE applications will dwarf the volumes we see in diagnosing Pulmonary Embolism.

We are progressing the registration of Ultralute<sup>TM</sup> as a medical device in Europe. This reclassification will position Ultralute<sup>TM</sup> to drive higher sales post launch in 2020. Utralute<sup>TM</sup> has the potential to deliver significant cost savings and efficiencies for nuclear medicine departments.

Over the past two years we have been rationalising and restructuring our European operations. Beginning in late 2017 Cyclopharm acquired Inter Commerce Medical bvba (IC Medical), our Group's agent for Technegas in Benelux; restructured our German operations; restructured our European operations to make Ireland the distribution hub for our direct European markets and acquired our Scandinavian Business Medical Analys AB.

Our acquisitions will build shareholder value by capturing agency and distributor commissions through the consolidation of our product distribution and service network. This strategy is expected to deliver both an increase in sales and Beyond PE market penetration in the European region.

We have an exciting future at Cyclopharm. We are leveraging our position as a leading player in the global nuclear medicine imaging market and lung health space. Our Governance framework and Director's experience supports our strategy to launch a larger and more profitable nuclear medicine and pulmonary healthcare company. The restructuring and rationalisation of our European operations are initiatives designed to better position Cyclopharm to pursue our strategic growth objective and seek out opportunities both in complementary technologies and businesses. And 2019 promises to be a landmark year where we secure US FDA approval and move forward to commercial sales shortly after.

On behalf of the Board, I congratulate James and his team for their tenacity and ongoing success in developing the global markets for Technegas. I want to thank all our staff and management for their commitment to the company. Most importantly, I thank all our shareholders and business partners for your continuing support.

I now invite James McBrayer, our Managing Director, to address the Meeting.

David Heaney Chairman