

cyclomedica technegas cyclopet 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

29 May 2018

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

## Managing Director's Address

Thank you, David.

### SLIDE 3: 2018 AGM Presentation

It is my pleasure to update you on 2017, a pivotal year of execution of Cyclopharm's growth strategy but before I do I would like to start by saying how privileged and grateful I am, and my team are, for being able to work in a company that positively impacts so many people's lives, through the use of our revolutionary diagnostic products, every day.

I am pleased to report to our shareholders that your Company is now positioned to benefit from a new growth phase that starts this year, that will continue for many years to come and that will drive a step change in performance.

### **SLIDE 4: Company Overview**

Cyclopharm is a leading diagnostic lung imaging company with recurring revenue streams, a track record of profitable growth and a history of dividend payments.

Our lead Technegas product is sold in 56 countries and, subject to the anticipated FDA approval, we are expecting to commence sales in the United States, the world's largest diagnostic imaging market, in 2019.

We are also actively working to expand the use of Technegas beyond the Pulmonary Embolism market into additional applications such as Chronic Obstructive Pulmonary Disease (COPD) and Asthma. Both are significantly larger market opportunities.

## SLIDE 5: Building For Growth – Company Development

Our core Technegas business is stable with predictable earnings through time. 80% of revenues come from recurring sales of consumable Patient Administration Sets or PAS with gross margins stable at around 80%.

Since 2010 Technegas sales have totalled \$90 million. In 2017 over 200,000 patients benefited from the lifesaving information provided by a Technegas scan. In 2018 we will achieve another major milestone in the company's history with our 4 millionth study completed.



By way of illustrating the opportunity for Technegas in the United States, based on our experience entering the Canadian market, we estimate Technegas will be used in 480,000 patient procedures a year once the US is fully penetrated.

### SLIDE 6: FY2017 Results Highlights

Cyclopharm's financial results reveal a solid performance in 2017, despite absorbing a planned hiatus in sales to China following the significant seeding initiative in December 2016.

The strong underlying EBITDA performance gave the board confidence to maintain a full year final dividend, consistent with 2016, of 0.5 cent per share bringing total dividend payments in 2017 to 1.0 cent per share.

The company has a strong balance sheet with \$8.7 million of cash reserves at the end of the 2017 reporting period and expects sales and underlying earnings growth for our Technegas product supported by additional revenues from the launch of our new Ultralute<sup>TM</sup> product this year, which I will speak about later.

### SLIDE 7: 2017 Operating Highlights

Technegas continues to perform well and as expected with healthy growth in sales in Europe and Canada.

We completed development of our new Ultralute<sup>TM</sup> product. The first commercial batch has been validated for sale and we expect to see the first Ultralute<sup>TM</sup> revenues this year.

Following a successful capital raising of \$6.59 million in June of last year we have the balance sheet strength to fund the USFDA trial needed to gain access to the US market, plus ongoing R&D and market development initiatives.

The design of the trial has been approved by the FDA through the Special Protocol Assessment pathway which helps mitigate the risk of downstream regulatory obstacles. Recently, we completed imaging of the first 40 patients in this study. The resultant interim report under development, from which we expect to receive feedback in a few months, will help improve and refine the full 240 patient trial.

In 2017 we made significant progress on initiatives to expand the use of Technegas in applications beyond Pulmonary Embolism. A critical part of which was the launch of a 100-patient small airway disease trial targeting patients with severe asthma in late 2017 with the Hunter Regional Medical Institute. A further 100-patient study in collaboration with the Woodcock Institute, focussing on the use of Technegas in the management and treatment of COPD and Asthma, was announced two weeks ago and will start in the coming months.

In the second half of 2017 we commenced a process of significant restructuring, rationalisation and acquisitions in our European market to support sales, margins and deliver on our strategic objectives.

### SLIDE 8: Group Underlying Performance

In December 2016 we supplied our Chinese distributor with 50 Technegas generators and 250 PAS sets, as part of a seeding initiative. That has led to an absence of China revenue in 2017. We do expect consumable sales to China to restart in the 4th Quarter of 2018.



If we remove the China effect, 2017 was a year of solid underlying sales, up 1.4% with a strong EBITDA performance.

These solid financial results support our relentless focus on our strategic priorities and investment in growth opportunities.

## SLIDE 9: Group Balance Sheet

Cyclopharm's balance sheet is in great shape. We have little debt and, at the end of 2017, we had \$8.7 million of cash on hand. Our strong balance sheet enables us to fully fund the USFDA clinical trial in order to gain regulatory approval to start selling Technegas to the US market in 2019.

We expect to spend AUD\$5.3 million in 2018 on the USFDA trial with total expenditure expected at approximately US\$7.5 million.

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

### SLIDE 10: Group Cash Position

Our strong cash position is the result of a capital raising in June 2017 when over 90% of you, our shareholders, participated. The capital raising was sub-underwritten by Australian Ethical Investments, our largest institutional shareholder.

I would like to thank you, our shareholders, for that endorsement of Cyclopharm's prospects and strategy.

In December of 2017 AusIndustry allowed us to expand the scope of the R&D tax incentives so that we can include some of our overseas R&D initiatives that we are unable to perform in Australia. The result is in an increase in "Other Income" from \$495,000 in 2016 to \$2.39 million. The net cash after tax benefit received in 2018 for the R&D incentive was equal to \$1.46 million. We expect the R&D tax incentive to remain around this pre and post-tax levels through to at least 2020.

### SLIDE 11: Building for Growth

Cyclopharm is a stable business with dependable recurring revenue streams and a track record of delivering shareholder returns.

It is also a business on the cusp of a new growth phase that will drive a significant step change in our performance for the coming years.

### **SLIDE 12: Our Strategic Priorities**

This new growth phase will be driven by execution of our strategic priorities.

We are seeking to:

- expand Technegas sales in existing markets
- get regulatory approval to sell Technegas into the USA, world's largest and highly prospective healthcare market;



- pursue sales of Technegas in new applications such as Chronic Obstructive Pulmonary Disease ('COPD') and Asthma which are significantly larger markets than the Pulmonary Embolism market where Cyclopharm traditionally operates
- ramp up sales of our new Ultralute<sup>™</sup> product
- identify opportunities to develop complementary technologies and businesses

# SLIDE 13: Technegas - Product Overview

Technegas is used with existing nuclear medicine scanning equipment to provide high quality functional lung imaging that helps clinicians to diagnose a range of disease states.

Our product is extremely patient friendly. It only requires the patient to inhale a few breaths of the gas-like particles to deliver Technegas throughout the lungs. Technegas particles are generated from single-use crucibles combined with a small amount of Tc99m sodium pertechnetate that is placed inside our generators and heated to approximately 2700° Celsius to form the very small Technegas particles. Technegas is then delivered to the patient through single-use Patient Administration Sets, which we call PAS kits.

Our Technegas is unique in the world of medical technology and is an ideal biomarker for true functional ventilation. Simply put, Technegas is delivered anywhere in the lungs that oxygen goes. It shows true functional ventilation by imaging all open pathways that lead to the alveoli. An alveolus is the site of gaseous exchange to and from the bloodstream.

Currently Technegas' primary use is in diagnosing blood clots in the lungs known as Pulmonary Embolisms; however, there are opportunities to expand to help improve diagnoses in other indications. In the 56 countries where we operate our product is already being used in other respiratory applications such as lung transplant evaluation, Chronic Thromboembolic Pulmonary Hypertension (CTEPH), interventional studies such as Lung Volume Reduction either through surgery and bronchial valve placement as well as the growing interest in both asthma and COPD.

In comparison other techniques, like CTPA, only infer ventilation by showing structure. CTPA cannot visualise down to the alveolar level. Compared to CTPA a Technegas study has no contraindications and delivers more sensitive and accurate information at a fraction of the dose.

Later in my presentation I will speak about the exciting clinical initiatives we are participating in to unlock the full potential of Technegas but first I will outline some of the advantages of Technegas in comparison to other competitive nuclear medicine products.

## SLIDE 14: Advantages of Technegas

Technegas has several advantages over competing nuclear medicine products including:

- Better clinical outcomes
- More accurate when diagnosing Pulmonary Embolism
- Improved patient comfort
- Allows 3D Imaging
- and has been named as the ventilation imaging agent of choice in European Association of Nuclear Medicine guidelines

Our intellectual property is protected in two ways. First our technology is protected by the patents held for the Technegas Generator until 2026. Secondly, we are protected by the



integrated systems approach necessary to deliver a Technegas scan. To achieve consistent results the nuclear medicine department needs to use our approved consumables in conjunction with our Technegas generator that is installed, maintained and serviced with our approved components.

## SLIDE 15: Technegas - USA Market Opportunity

Accessing the US market will be the catalyst for a step change in Cyclopharm's financial performance and growth.

In just diagnosing PE, The US is a US\$90 million market making it the largest functional lung imaging market in the world, with around 600,000 patient procedures a year. In comparison to the rest of the world in 2017 Technegas was used in 200,000 procedures within the 56 countries we service.

We are targeting a commercial launch of Technegas in the US in 2019 and believe Technegas will quickly become the standard of care diagnostic ventilation imaging product used in 80% of pulmonary embolism procedures which we estimate to be 480,000.

### SLIDE 16: Technegas – The Canadian Case Study

Our confidence in the US take up is based on mirroring our experience in the successful roll out of Technegas in Canada.

Canada quickly became Cyclopharm's largest single market for Technegas. Since this successful launch, Technegas has remained the market leader for diagnosing Pulmonary Embolism with 14 consecutive years of PAS growth.

You can see from the graph how the number of active generators drives the number of patient procedures which supports the year-on-year growth in PAS kit sales.

### SLIDE 17: Technegas – FDA Clinical Trial Process and Design

We are making good progress in our USFDA trial to gain approval to sell Technegas in the United States.

The approval process involves a two-part study. The first, a desktop study that was completed in 2017, while the second, a 240-patient clinical trial, at up to 15 locations, is currently underway.

### SLIDE 18: USFDA Patient Recruitment Update

Patient recruitment for the full USFDA trial commenced in late 2017 and remains on track. 49 patients have been fully enrolled to-date across 4 locations. Last week our 5<sup>th</sup> site became operational. There are another two locations in the final stages of being integrated in to the trail and a further 4 locations in the early to mid-stage discussions.

As part of our agreement with the USFDA, we have conducted an interim read of our first 40 patients enrolled in the trial. I am pleased to report that the findings were as expected.

We plan to submit the interim study results on these first 40 patients next month. Along with the interim results submission, we will be lodging a USFDA meeting request so that



we can schedule a time to discuss face to face our results to date, the overall progress of the clinical trial and open a dialogue regarding opportunities to expedite the trial process.

### SLIDE 19: Pathway to US commercialisation

Cyclopharm has a consistent track record of working towards US commercialisation of Technegas. In November 2016 we relocated to our new manufacturing facility here at Kingsgrove to make sure we could meet the regulatory and manufacturing demands that come with USFDA approval.

In preparation for the expected US launch we will invest in Technegas inventory that will support our commercial sales objectives.

We are targeting to convert over 50% of the US\$90 million US market over the medium term with the long-term target of 80% and anticipate matching or improving on historic gross margins for generators and PAS kits.

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

### SLIDE 20: Technegas Expanding Indications

In 2017 we made progress exploring new indications for Technegas in COPD and Asthma, which represent significantly larger markets than Pulmonary Embolism where Cyclopharm has traditionally operated.

During 2017 we launched a trial using Technegas to evaluate and manage severe asthma with the Hunter Regional Medical Institute, the University of Newcastle and John Hunter Hospital. We also had our first, and positive, peer reviewed article based on our China COPD trial published in the International Journal of COPD.

Two weeks ago, we announced to the market a new clinical trial initiative in partnership with the Woolcock Institute of Medical Research, The University of Sydney and the North Sydney Local Health District. The 3-year study will commence in the next few months. The study, using Technegas, will be aimed at the diagnosis and response to therapy in sufferers of mild to moderate asthma and COPD. I look forward to updating you on our progress as we commence this very exciting trial.

### SLIDE 21: Evolution of Functional Lung Ventilation Imaging

Improvements in Functional Lung Ventilation Imaging combined with advances in analytical software have dramatically improved the effectiveness of Technegas for Pulmonary Embolism and created the potential for Technegas to be used in other clinical applications.

This slide visualises the evolution of Technegas from 2D planar imaging in the late 1980's through to SPECT imaging (SPECT) to multi-modality imaging combining both function. The last image illustrates additional quantifiable measures aided by newly developed analytical software.



## **SLIDE 22: Clinical Call for Action**

Whilst the evolution of the imaging technology has taken enormous leaps forward, it is the call generated from the global leaders in respiratory medicine demanding better diagnostic tools targeting true personalised medicine that is creating a pull factor. Armed with the latest complementary technology, Cyclopharm is leveraging Technegas' fullest potential in clinical conditions beyond PE.

In September last year the Lancet released a commissioned report stating, "We propose a revolution in thinking about asthma that is generalised to all airways disease." The report states that "Progress in reducing hospital admissions and mortality in people with asthma have stalled in the past 10 years." The summary goes on to say, "we need to kickstart a new era of examining, monitoring, treating, and ultimately preventing airways diseases." The Commissioners recommend "to deconstruct airway disease into component parts before planning treatment with a focus on traits that are identifiable and treatable. This approach will require a complete change in how we think about airways diseases with the goal of achieving real precision treatment with better patient outcomes."

We are also hearing similar language coming from the global clinical champions of COPD. As part of our strategy of expanding the use of Technegas beyond PE, several years ago we implemented a program of direct engagement with referring respiratory physicians. As a result of this engagement, we heard the call before it was made by these global leaders and have already taken steps to answer it through our clinical trial development program.

An example of our potential can be seen in the images provided by Hunter Regional Medical Institute showing a severe asthmatic's dramatic improvement response to very expensive monoclonal therapy. Equally important to the clinician, we have also seen examples where the patient hasn't responded thus avoiding ineffective and expensive treatment to continue. With biomarker tools like Technegas we can assist the clinician in delivering on the tenants of precision medicine which are:

- the right therapy
- to the right patient
- at the right time.

### SLIDE 23: Existing Market Development Strategy

Cyclopharm takes a multi-faceted approach to developing the market for our technology.

This includes efforts to leverage new and complementary imaging technologies to improve diagnostic outcomes in our traditional PE market and expand our core Technegas product into additional indications.

We continue to invest in clinical trials using Technegas for the diagnosis and management of COPD and Asthma, two markets that are significantly larger than the Pulmonary Embolism market.

We are proactively seeking approvals to enter the US and Russian markets and leveraging the relationship across our existing market network to introduce and accelerate the adoption of new products like Ultralute<sup>TM</sup>.

The launch of Ultralute<sup>TM</sup> in Europe has been delayed due to our restructuring efforts. Furthermore, to gain faster acceptance we have decided to voluntarily reclassify the



product as a designated medical device from its current approved laboratory equipment classification.

## SLIDE 24: Technegas – Global Indication Expansion

As mentioned before, the development of modern imaging technologies and analytics software is creating market opportunities for Technegas with the potential to 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 3<sup>rd</sup>.

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 and management.

### SLIDE 25: 2018 Strategic Priorities and Outlook

2017 was a year of significant investment in the strategic priorities that have created the foundations of a 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.

In 2017, \$2.58 million was invested to progress USFDA regulatory approval.

This year, we expect to invest a further \$5.3 million on our Phase 3 USFDA clinical trial of Technegas and anticipate a successful conclusion to the trial with approval for sales in 2019. We also invested over \$0.25 million in a successful clinical trial to expand the use of Technegas into treatment of Chronic Obstruction Pulmonary Disease which represents a much larger market than our current application in the Pulmonary Embolism market.

The timing of Technegas sales from new indications in US, such as COPD and Asthma are not clear, but they represent significant drivers for Cyclopharm's next stage of growth and a step change in financial performance.

We also continued to pursue regulatory approvals to commence sales of Technegas in Russia and additional European markets.

We invested close to \$0.5 million in completing the validation of our exciting Ultralute<sup>™</sup> technology in preparation for its first commercial sales in 2018.

We completed the acquisition of Inter Commerce Medical byba for a consideration of up to  $\notin$ 400,000, net of cash paid over 3 years, to give us greater control over pricing and distribution in our European markets.

In the current year we have continued to invest in our strategic priorities with the acquisition of Medicall Analys our Scandinavian distribution business for \$1.34 million and the funding of a \$387,000 COPD and Asthma trial in Australia.



In 2018 we expect sales in the Technegas business will be supported by several positive trends including continued underlying demand in Generators and PAS sales growth driven by:

- Sales volumes returning in France as inventory destocking unwinds
- Higher margin sales in Germany as restructuring efficiencies gain traction
- IC Medical and Medicall Analys acquisitions to allow for increased use of Technegas beyond the indication for Pulmonary Embolism
- Canada to continue strong sales performance by expanding the use of Technegas in additional applications
- Consumable sales in China in the 3rd Quarter to replenish the sell down of stock purchased in 2016

We will begin to see the revenues from the commercial launch of Ultralute™ in Europe.

We expect Cyclopharm sales and earnings growth in 2018 combined with our strong balance sheet will allow the Group to maintain its healthy capital position and dividend policy.

I look forward to continuing to report on our progress against our strategic objectives and next phase growth drivers which are expected to deliver returns for our investors.

I thank all my colleagues for their commitment and hard work to position Cyclopharm for this next exciting growth phase. I assure you that the Cyclopharm Board and management team remains committed to delivering healthy outcomes for patients and healthy returns for our shareholders.

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

Janu & MCBreyer

James McBrayer Managing Director and Company Secretary

### For more information, please contact:

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