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technegas
cyclopet

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The Manager
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Managing Director's Address

Good morning. It's a pleasure to share with you today an update on your company's achievements and prospects.

SLIDE: 10 Fast Facts

In presenting our message this past year with shareholders and investors, I always like to begin with what I call our 10 Fast Facts. These are:

1. Technegas is a well-established proprietary world leader in functional lung ventilation imaging technology with major revenues generated by single patient consumables
2. Technegas is sold in 55 countries with significant expansion opportunities in the USA following USFDA approval of Phase 3 clinical trials
3. Other lung disease states like Chronic Obstructive Pulmonary Disease (COPD), Asthma and Lung Cancer represent tremendous opportunity for substantial growth world wide
4. Ultralute™, a new innovative technology with global application, will be commercialised in 2016
5. Ultralute™ technology is a platform for additional product development
6. We have a stable management and workforce
7. 2015 was another year of solid financial results with strong foundations for growth to build from

In summary, we are a first rate Australian Biotech that:

8. Is profitable, generating cash & paying dividends.
9. Has net cash on the balance sheet to fund growth and
10. Is set to leverage tangible major growth opportunities.

Cyclopharm is a truly transformational technology business in regards to the work we are doing and the products we are developing.

SLIDE: Introduction

In 2015, Cyclopharm made significant headway on our strategy to deliver a substantial increase in shareholder value through the global manufacture and supply of innovative nuclear medicine technologies.

Today your company is a profitable and fiscally disciplined biotech, with consistent cash flow generated primarily from a line of successful consumable products.

2015 was our second straight year of record revenue and profit.

Technegas, our major revenue generator, is the world's leading functional lung ventilation imaging technology, predominantly used for the diagnosis of Pulmonary Embolism. However, the greatest growth from this product is potentially yet to come as we make continued progress in obtaining approval to sell Technegas in the US and expand the use of Technegas to other indications.

In the nearer term, we are poised to begin sales of our unique Ultralute™ system, which promises to radically improve the economics and clinical practice of nuclear medicine.

These initiatives, as well as our ongoing R&D program, are underpinned by the company's sound financial position and cash flows, giving us the capacity to generate sustainable returns to shareholders.

SLIDE: Our business lines

Cyclopharm has four business lines:

1. Cyclomedica, the division which markets and sells Technegas.

2. Ultralute, which has generated enormous interest in the nuclear medicine industry worldwide and is on the cusp of commercialisation

3. Macquarie Medical Imaging, our medical imaging joint venture with Macquarie Hospital in Sydney, which is producing positive earnings

4. And Cyclopet, which is not currently operational but which holds our highly valuable Cyclotron facility. At the close of 2015 we received an insurance settlement of $2.1m as the result of water damage incurred from a car fire at Macquarie University Hospital. The future of this facility is currently under negotiation and through that process we are evaluating how we can best use the facility for the maximum benefit of shareholders.

SLIDE: 2015 Highlights

Last year was another 12 months of positive achievement and strong financial performance for your company.

Cyclopharm posted record sales of $12.6 million on the back of solid organic growth in sales of Technegas, which itself achieved record earnings of $2.3 million.

The group net profit of $4.8 million, compared with the previous year's $4.1 million, was boosted by strong earnings from Technegas and the proceeds of the insurance settlement.

We were thrilled to be able to reward our shareholders last year with a maiden dividend, a carefully considered, conservative decision that is supported by the group's healthy cashflows, $4.2 million last year ($2.74 million from continuing operations), and cash on the balance sheet of $6.4 million.

2015 was also a year of strategic and operational achievement. We have reengaged with the US Food and Drug Administration to hasten approval of Technegas in the United States and the promising early results of Chinese clinical trials have shown that Technegas has tangible advantages in the treatment and diagnosis of COPD compared with the standard diagnostic methods.

Ultralute™ was officially launched at the European Association of Nuclear Medicine (EANM) Annual Congress in October 2015 and was successfully registered for sale in Europe, with first sales expected there later this year.

We also made progress in the development of the next generation of Technegas generators, which will have substantial improvements on the existing model and will further cement its position as the leading technology globally in this area of nuclear medicine.

I will say more about the specific achievements with these products later.

SLIDE: 2015 Financial Results and Performance

Looking in more detail at our financial performance in 2015, Technegas has healthy financial fundamentals. The divisional earnings increase was driven both by price increases and successful cost reduction initiatives which improved gross margins in that business.

Cyclopharm's healthy operating cashflow was assisted by the $2.1 million insurance settlement but as you can see, underlying earnings, which excludes the benefit of this, still rose strongly.

Minor losses from the suspension of operations at Cyclopet detracted slightly from the overall result, but I emphasise that the closure was a carefully considered, strategic decision made with a long term view to maximizing shareholder value. Importantly, we will still have a valuable, asset in the Cyclotron facility.

SLIDE: Technegas – Expanding the global footprint

Technegas is the prime example of how we will take advantage of new markets for our existing technology.

Technegas is already very successful, with 1500 generators having been sold across 55 countries and more than 3.5 million patients studies conducted since 1986.

However, access to the US market has the potential to surpass our successes thus far, which is why we are so focused on the US clinical trial program and obtaining USFDA approval.

Similarly, Technegas is showing great promise in the management and diagnosis of other diseases, particularly COPD, which will be the third leading cause of death worldwide by 2030.

The early results of the Chinese COPD trials have also shown the potential for Technegas to enhance diagnosis of other diseases such as left heart failure.

Importantly, Technegas is patented until at least 2026, with the option of extending that protection.

SLIDE: USFDA clinical trial program

Half the world's nuclear medicine departments are in the US and it has the potential to become our largest single country market for Technegas.

In United States nuclear medicine, ventilation imaging is performed either with the radiopharmaceutical Xe-133 or Tc99m-DTPA. The market is split 50:50 between these two agents. Despite the extensive use of DTPA, it is not officially approved for use in lung imaging; therefore, the only approved agent for our comparison purposes is Xe133, a product that we know generated $47 million USD in sales last year in the United States.

The overall FDA trial design seeks to show how well Technegas compares with Xe133 in ventilating the lobes of the lung on a non-inferiority basis.

Our protocol is organised into two steps.

The first step, which we refer to as CYC 010, will establish the inter and intra reader variability of Xe133. This step is required in defining the effectiveness of Xe133 scans. This is a desktop review performed by six different nuclear medicine clinicians using images from existing Xe133 scans. The output will be a statistical analysis that will define how well and how consistent Xe133 scans are read by clinicians. This benchmark will be used to determine the number of patients that will be required for the head-to-head study between Xe133 and Technegas. We have already initiated this part of the trial and expect to conclude and analyse this part of the protocol by the end of this year.

The next stage of the clinical trial, CYC 009, compares Xe133 with Technegas head-to-head in an all-comer patient protocol. It is important to note that our protocol is looking at structural/functional ventilation instead of reaching a specific diagnosis. This means that patients suffering any number of disease states may be enrolled in the trial, not just those suffering from a suspected pulmonary embolism. If you recall, patient recruitment was problematic when we focused on just pulmonary embolism. This new approach should eliminate that barrier to success.

At this stage we estimate enrollment to be around 300 patients; however, the final number will be determined by the Xe133 benchmark trial. We are targeting to have 10 centres located throughout the United States involved in the clinical trial. The two-part study has been calculated to cost up to $7 million USD with USFDA approval estimated for around mid-2018.

In September 2015, Jubiliant DraxImage (JDI) and Cyclopharm (ASX: CYC) announced their intention to enter into a licensing agreement for the registration and distribution of Technegas in the United States. As part of this arrangement, in return for exclusive distribution rights, JDI would fund the majority of clinical trial costs. Despite several months of negotiations, the two companies have not been able to reach agreement on the final terms. As a result, Cyclopharm has notified JDI of its decision to independently move forward with the USFDA clinical trial program. The two companies have agreed to continue to discuss potential commercial opportunities once USFDA approval for

Technegas is reached but at this stage we have decided to self-fund the clinical trial program.

SLIDE: Ultralute

Ultralute™, which we unveiled last year, has the potential to radically transform the nuclear medicine industry. It is no overstatement to say this is a truly disruptive technology.

Ultralute™ has multiple benefits for nuclear medicine clinics, patients and the nuclear medicine industry more broadly. It extends the useful life of the Molybdenum-99 generators that produce Tc-99m, the mostly commonly used isotope in nuclear medicine, by up to half, which we estimate will lead to cost savings for clinics of 30-40%.

The process of completion of the commercial Ultralute system is in its final stages, and we expect to record initial sales of the system later this year.

We have received a great deal of interest internationally with respect to our Ultralute™ technology. Most notably, The International Atomic Energy Agency (IAEA), the peak global body for cooperation on nuclear matters, has recognised the importance of Ultralute™. The IAEA represents 168 member countries. I will be meeting with the IAEA in a few weeks' time to discuss possible collaboration and look forward to updating you with the outcome of those meetings.

SLIDE: Ultralute Generation overview

To provide you with a better commercial understanding of our Ultralute technology:

There are 4,000 Mo-99 generators sold worldwide every week. Every nuclear medicine facility across the globe stands to benefit from using Ultralute™.

Further, Ultralute™ has applications throughout the production and dispensing chain for nuclear medicine.

The first generation of the device, launching in European markets this year, will target clinics, the end users in nuclear medicine.

The second generation of Ultralute™ will be designed for radiopharmacies, which prepare and dispense radiopharmaceuticals to clinics, while the third generation will have applications for the manufacturers of Mo-99.

Importantly for shareholders, we expect each stage of development of Ultralute™ will offer Cyclopharm expanded revenue and profit opportunities.

SLIDE: Outlook and Priorities

To summarise our priorities for the coming year:

We are on a firm path to FDA approval for selling Technegas in the US, with the first part of our phase III clinical trials already underway.

We are executing our strategy to expand the clinical applications of Technegas. We have already taken the first step by leveraging off some of the earlier findings of the Chinese

COPD trial outcomes. Once the results are finalized we will use the information as a powerful marketing tool to engage respiratory physicians worldwide. From 2016 onwards we are looking to replicate our China clinical experience in our more established markets of Australia, Canada and select country markets in Europe.

We are working to bring our new technology Ultralute™ to market as quickly as possible. It promises to be a game-changing, disruptive technology throughout the nuclear medicine industry.

More broadly, Cyclopharm will continue to identify and develop new opportunities for expansion, diversification and growing shareholder value.

We are in a strong position to achieve all these things as Cyclopharm is a financially robust company with a clear, consistent strategy and the resources to pursue our objectives in the near term.

In closing I want to thank my team for their dedication to this company. I also want to express my gratitude to my fellow board members, Mr. Gould and Mr. Heaney. I am truly grateful for your support and wise counsel.

Lastly, and most importantly, I want to thank you our shareholders for your belief in the work we do. On your behalf, it is an honour to lead your company. Together we are improving patient healthcare outcomes throughout the world with our products and services. With your ongoing support we will achieve so much more.

I will now hand back to the Chairman.

James McBrayer
Managing Director and Company Secretary

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