cyclopharm

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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

BUSINESS UPDATE

Cyclopharm Limited (ASX: CYC) is pleased to provide the following update on progressing its strategy during the 2019 financial year including expectations for its full year results and progress of certain operational matters, including gaining United States Food and Drug Administration ("USFDA") approval to begin commercial launch of Technegas™ into the US in 2020.

Highlights

- **Documentation for USFDA application nearing completion. Submission expected for first calendar quarter 2020.**
- **US commercial launch expected in 2020 – building sales support for rapid market entry**
- **$3.0 million AusIndustry R&D refund received from the ATO**
- **Update on research to expand Technegas™ market opportunities beyond PE**
- **CYC commences process to register Ultralute™ with TGA**
- **CYC exits Macquarie Medical Imaging Joint Venture**
- **CYC commences further litigation actions to protect its IP**
- **CYC signs agreement with Jubilant Draximage Inc, to sell RUBY-FILL® Generators and Accessories in Europe – leverages CYC's distribution network**
- **FY2019 sales expected to be in line with prior year**

James McBrayer, Managing Director highlighted, "We have made solid progress in executing on our strategic priorities this year. We are in the final stages of completing our application to the USFDA for the approval of Technegas™ in the world's largest diagnostic imaging market. We have had success in protecting our IP and have resolved legacy issues in the portfolio.

2020 promises to be the start of a new substantial growth chapter for CYC. We are already planning for rapid market entrance in the US with commercial launch of Technegas™ expected in 2020. Further ahead we are developing new long-term growth opportunities for our "gold standard" technologies in larger, markets such as COPD and asthma - "Beyond PE"."

USFDA progress

The process for approving Technegas™ sales in the US is in its final stages. The Company has completed the clinical documentation required for the submission for a 505(b)(2) New Drug Application (NDA) for the United States Food and Drug Administration (USFDA). CYC is now finalising, through a US based Clinical Research Organisation, the extensive supporting documentation required for a New Drug Application designated as a drug-device combination product. Given the progress to date, Cyclopharm will be submitting its completed application to the USFDA in the first calendar quarter of 2020.

Recruitment will continue for the Company's clinical trial program CYC-009; however, only a 139-patient safety subset will be included in the 505(b)(2) application.

In parallel, Cyclopharm is progressing the activities that will support a rapid market entry of Technegas™ in the United States with commercial launch expected in 2020, upon USFDA approval. These steps include company registration in the United States, staffing, inventory management and distribution.

The existing market for nuclear medicine ventilation imaging in the USA is estimated to be approximately US $90 million annually, representing approximately 600,000 individual procedures. Based on Cyclopharm's experience in the Canadian market, the directors are confident that Technegas™ can achieve a 50% share of the USA market over 2 to 3 years, post US market entry, with an 80% share representing around 480,000 procedures per annum achievable over a 5 to 7-year period

Cyclopharm Receives $3.0m cash AusIndustry R&D refund from the ATO

Cyclopharm confirms it has completed its Research and Development Tax incentive claim for the 2019 financial year and in November received a cash payment of $3.0 million (vs 2018: $1.9 million).

Expanding market opportunities - Beyond Pulmonary Embolism (PE)

Cyclopharm continues to pursue initiatives to expand the use of Technegas™ in new market opportunities beyond the current application in Pulmonary Embolism.

The University of Newcastle, Hunter Regional Medical Institute and John Hunter Hospital are conducting a study into the use of Technegas™ in patients with severe small airways disease. The 100 patient study has now reached full recruitment. As part of the study, a 39-patient subset of the 100 underwent tests using Technegas™ to determine response to therapy.

The overall study has been designed to test two specific hypotheses:

1. There is ventilation heterogeneity among patients with severe obstructive airway diseases that can be assessed using Technegas™ functional lung ventilation imaging with quantification; and
2. Technegas™ functional lung ventilation imaging with quantification is responsive to change following intervention in patients with severe obstructive airway diseases.

Initial publications for the HRMI study are expected early 2020.

In addition to the Newcastle study, Cyclopharm is active globally in supporting four other clinical initiatives targeting the use of Technegas™ beyond PE. The implication in advancing these initiatives could expand the use of Technegas™ by improving the diagnosis and management of patients with COPD and other small airways diseases. Cyclopharm estimates the global COPD market is 30 times the size of the PE market and over 500 million patients suffering with COPD and Asthma could benefit from the use of Technegas™ in diagnosis and patient management. These markets represent significant opportunities to expand sales of Technegas™ and drive shareholder value over the medium term

Ultralute™ update

As previously advised, the Company has been pursuing registration of our proprietary Ultralute™ technology as a medical device in the European Union. Cyclopharm is also now seeking to register Ultralute™, through the Australian Therapeutic Goods Administration (TGA), as a Class 1 Medical device listed on the Australian Register of Therapeutic Goods.

The EU is currently undergoing a change in the regulatory regime regarding registration of medical devices which includes a requirement for bodies certifying the conformity of medical devices to be reassessed in accordance with the new regulations. The Company has been advised that this reassessment of certifying bodies is taking longer than anticipated and consequently, the time taken to certify medical devices throughout Europe is now longer than would otherwise be the case.

In response, the Company will prioritise Ultralute's registration with the TGA and continue to pursue registration in the EU once certification review times improve.

Cyclopharm to exit Macquarie Medical Imaging Joint Venture

Macquarie Connect and CycloPet have agreed to a business transfer which will result in Macquarie University Hospital becoming the sole owner of Macquarie Medical Imaging (MMI).

Cyclopharm has transferred its 20% equity ownership and is now released from any further obligations under its lease of premises along with the outstanding loans associated with the fit-out and equipment.

Further, Cyclopharm has agreed to issue 300,000 ordinary shares in exchange for the termination of a put option to a shareholder of MMI. The termination of the put option will mean Cyclopharm is no longer required to record a contingent liability in its accounts. The value of that contingent liability at 31 December 2018 was estimated not to exceed $2,838,442.

Ongoing Litigation

Cyclopharm continues to vigorously and successfully defend its valuable Intellectual Property. In 2017, the company recorded bad debt provisions of approximately A$540,000 related to its former General Manager for the German market, Mr Bjorn Altmann and Almedis Altmann GmbH ("Almedis").

In 2019, Cyclopharm successfully brought an initial civil case against Altmann and Almedis which resulted in the Company, being awarded and receiving a payment of approximately A$335,000, which represents 100% of this claim. The company is continuing with its efforts to recover the remainder of this bad debt provision along with other claims.

Cyclopharm has also initiated additional legal proceedings against individuals based in Australia linked with Altmann. This legal action will result in an increase in total litigation costs for the 2019 year to approximately A$1.1 million (vs FY2018 $540k), which the Company will also seek to recover.

Cyclopharm is highly confident of a successful outcome to the current legal proceedings. Until such time, and other than in accordance with its disclosure obligations, the Company does not intend to make further comment on this matter.

Cyclopharm's European distribution business secures new contract

Cyclopharm is pleased to advise its recently acquired European distribution business has signed a 5-year agreement with Jubilant Draximage Inc, to distribute its RUBY-FILL® Generators and accessories in 14 European countries.

This new agreement demonstrates the success of the Company's strategy to pursue revenue from distributing third parties' products, following the recent acquisition of certain of the Company's European distributors.

Sales under the new agreement will commence in early 2020. Subject to achieving certain sales targets, Cyclopharm anticipates the contract will contribute up to approximately €500,000 to gross annual profit before tax by FY2023.

Trading update

Following a review of Cyclopharm's unaudited management accounts to date and expectations for the remainder of the 2019 financial year, the Company anticipates sales for the financial year will be in line with the prior year. Sales for the year have benefited from continued healthy growth in the Canadian market, where Cyclopharm, following last year's publication of the Canadian Association of Nuclear Medicine strong support of Technegas™, has virtually 100% of the addressable market participants. Our improved performance in Canada has been offset by lower sales of patient consumable sales to Europe/Scandinavia resulting from a temporary shortage of MAA. MAA is a perfusion product used in conjunction with Technegas to determine the presence of PE. Sales to the UK were impacted by stocks being run down upon cessation of the distributorship arrangements. From 2020, CYC will commence direct distribution of Technegas™ to our customers in the UK.

The Company expects to release audited results for the twelve months to 31 December 2019 in February 2020.

ENDS

This ASX announcement was approved and authorized for release by James McBrayer, Managing Director, CEO and Company Secretary

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° 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.

RUBY-FILL®
The RUBY-FILL® Rubidium Rb-82 Generator contains accelerator produced Strontium-82, which decays to Rubidium-82. When the generator is eluted with saline it produces a sterile, non-pyrogenic solution of Rb-82 Chloride used for Cardiac Positron Emission Tomography (PET), a non-invasive imaging procedure of the myocardium, to evaluate regional myocardial perfusion in adult patients with suspected or existing coronary artery disease.

Due to the short half-life (75 s) of Rb-82, the use of an elution system is required for delivery of the Rb-82 Chloride into a patient for the purposes of performing Myocardial Perfusion Imaging with PET. The Rubidium Elution System has been exclusively designed for use with the RUBY-FILL® Rubidium 82 Generator and to deliver accurate doses of Rb-82 Chloride to patients