cyclopharm

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

cyclomedica
technegas
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

CYCLOPHARM 2018 FIRST HALF PRELIMINARY HEADLINE UPDATE

Radiopharmaceutical company Cyclopharm Limited (ASX: CYC) today advised that, based on unaudited management accounts for the 6 months to 30 June 2018, the company expects to report sales revenue for the 2018 half year of $6.34 million (1H 2017: $6.06 million), and Underlying EBITDA[1] of approximately $0.46 million (1H 2017: $0.86 million).

Half Year ended 30 June	Preliminary 1H 2018 $'000	Actual 1H 2017 $'000	Inc/(Dec) $'000	% Change
Sales Revenue	**6,342**	**6,057**	**285**	**5%**
Gross Margin	5,002	4,996	6	-
Gross Margin % Sales	78.9%	82.5%	(3.6%)	
Consolidated EBITDA	**(1,173)**	**(1,023)**	**(150)**	**(15%)**
Add Back:				
CPET Division EBITDA	180	242	(62)	(26%)
Other non-operating expenses*	(38)	59	(97)	164%
FDA Expenses	1,456	1,583	(127)	(8%)
Expenses net of writebacks for Almedis Altmann GMBH	34	-	34	100%
Underlying EBITDA	**459**	**861**	**(402)**	**(47%)**

* Realised and unrealised foreign exchange gains and losses

The increase in half year revenues was achieved by sales of Technegas generators to higher margined markets (up $0.13 million) and service revenue increased by $0.14 million. Individual Patient Administration Set (PAS) revenue was consistent at $4.90 million.

Despite the positive 5% gains in consolidated revenue in 1H 2018, PAS revenue in Germany was $0.54 million lower as compared to 1H 2017. The lower revenue is a direct result of the issues previously announced between the company and Almedis Altmann GMBH. The directors remain confident that the matter will be resolved in the second half of 2018.

There was a decline in gross margins in the period from 82.5% to 78.9% reflecting the change in sales mix towards Technegas generators and lower margined markets for PAS.

During the period the company signed an extension to the Technegas distribution agreement with Curium in France to 2020. France remains the largest European country market for Technegas with higher volumes expected in 2018 than in past few years.

At 30 June 2018, Cyclopharm held a net cash balance of $7.6 million.

[1] Underlying EBITDA represents results from the Technegas division excluding realised and unrealised foreign exchange gains and losses, FDA Expenses and expenses for Almedis Altmann GMBH.

UNITED STATES FOOD AND DRUG ADMINISTRATION CLINICAL TRIAL UPDATE

In CYC's previous United States Food and Drug Administration (USFDA) update, the company announced that that it had fully enrolled its first 40 patients in its Phase 3 clinical trial required to gain USFDA approval to market and sell Technegas in the United States market.

The overall trial design is supported by a Special Protocol Assessment agreement between the company and the USFDA. Specifically, the trial is a non-inferiority, structural indication comparing Technegas with Xenon-133 in a total of 240 patients.

Managing Director and CEO Mr James McBrayer confirmed "This first 40 patient interim study review was a milestone agreed to by the USFDA to ascertain the trial's effectiveness. The interim review also provides Cyclopharm the opportunity to engage with the USFDA to review, refine and improve the trial's protocol, which may accelerate the overall rate of recruitment."

Based on the analysis of the first 40 patients, CYC can confirm that the company is pleased with the results to date. Furthermore, a Type 3 meeting request has been applied for and granted by the USFDA. The date of the face to face meeting will be held on 11 October 2018 at the USFDA Headquarters located outside of Washington DC in Silver Spring, Maryland.

The company continues to recruit patients and engage with sites interested in participating in the trial. As at 8 August 2018, there has been 60 patients fully enrolled in the study from a total of five active locations. As expected, recruitment has slowed during the North American summer and is expected to pick up again toward the end of August. Despite this seasonal slowdown, progress has been made with another five clinical trial locations eager to have early access to the Technegas technology.

Mr McBrayer stated that "Our upcoming face to face interaction with the USFDA is an important milestone for CYC and we look forward to updating our shareholders on the meeting outcomes."

Outlook

The Board expects ongoing growth in Cyclopharm's core business in 2018 as well as further progress in the development of the company's key growth opportunities.

Full details of the company's results will be included in Cyclopharm's 2018 Half Year Report Announcement, which is expected to be released to the ASX in late August 2018.

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 2,700o 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.

Ultralute ™
Cyclopharm's patented nuclear medicine technology Ultralute™ extends the useful life of Molybdenum-99 (Mo-99) generators by up to 50%. This technology potentially gives nuclear medicine departments the ability to dramatically improve operating efficiencies and health outcomes for patients. Mo-99 generators are used in diagnostic imaging to harvest Technetium-99m, or Tc-99m, which is the primary isotope used in diagnostic imaging throughout the world. This isotope accounts for approximately 80% of all nuclear medicine diagnostic imaging procedures.