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Technegas™
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FULL YEAR 2022 RECORD REVENUES DRIVEN BY SUBSTANTIAL GROWTH OF THIRD-PARTY SALES AND SOLID TECHNEGAS PERFORMANCE

Radiopharmaceutical company, Cyclopharm Limited (ASX: CYC) today announced its financial results for the year ending 31 December 2022. The Company is pleased to report that it delivered record sales revenue of $23.22 million, including a more than doubling of revenues from its Third-Party Distribution business, and a 0.5 cents per share (cps) final dividend.

Key features of the 2022 Financial Year include:

- **Group sales revenue of $23.22 million, up 31.1% on the prior year**
- **Technegas™ sales of $13.66 million, up 4.1%**
- **Third-Party distribution revenue of $9.22 million up 124.9%**
- **USFDA Complete Response Letter submission is being finalized and will be submitted to the USFDA in the coming weeks**
- **Preparations for a rapid Technegas rollout in the USA is underway following an expected USFDA approval for US sales in 2023**
- **All MDR[1] and MDSAP[2] regulatory approval and renewals have been achieved.**
- **$20.30 million of net cash balances available to fully fund growth strategy**
- **R&D tax incentive payment of $1.64 million received in November 2022**
- **Beyond PE program progressing to drive long term revenues growth**
- **Final unfranked dividend: 0.5 cps (Total FY22 unfranked dividends: 1.0 cps)**

James McBrayer, Managing Director, noted "The record revenue performance in 2022 is highlighted by the rapid growth of Cyclopharm's third-party distribution business. In addition, sales in our core Technegas business also grew 4.1% despite some residual impact from COVID-19 and a shortage of the isotope, impacting final quarter operations, used to make Technegas™.

"The strength of our existing business is pleasing as we finalise our Complete Response Letter (CRL) submission to the USFDA in the coming weeks. Once submitted, the USFDA is expected to take six months to review. Once approval is received a new phase of rapid growth for Technegas™ will be unlocked as it is launched into the US market in 2023. We have also continued to invest in our 'Beyond PE' initiatives targeting substantially larger markets than pulmonary embolism, such as COPD, Asthma and lung cancer with publications expected to be finalised in the first half of 2023. It is an exciting time for Cyclopharm as the company is primed to enter its next substantial growth phase."

[1] MDR- Medical Device Regulation – The recently implemented European Union regulatory framework for Medical Devices in support of CE accreditation
[2] Medical Device Single Audit Program – A single audit regulatory framework that allows medical device manufacturers a compliance pathway for participating countries. Current country participants include Australia, Brazil, Canada, Japan and the United States

FY22 Financial Summary

Cyclopharm generated total sales revenues in 2022 of $23.22 million, up from $17.70 million in 2021. Revenue from sales of Technegas™ generators and Patient Administration Set (PAS) consumables was up 4.1% to $13.66 million, attaining pre-COVID levels with unit sales of each exceeding 2021. Consumable revenue increased 5.2% while a total of 76 Technegas generators were sold compared to 57 in 2021. Third party distribution revenues in Asia-Pacific surged to $4.15 million from $1.10 million in 2021 and grew by 66% to $4.97 million in Europe.

SALES BY REGION ($MILLIONS)	2019	2020	2021	2022	CHANGE 2021 TO 2022
TECHNEGAS™ - CANADA	2.55	1.76	2.44	2.96	21%
TECHNEGAS™ - EUROPE	8.74	8.27	8.51	7.52	(12%)
TECHNEGAS™ - APAC PACIFIC	2.35	2.26	2.17	2.98	38%
TECHNEGAS™ - REST OF WORLD	0.44	0.06	0.09	0.30	233%
THIRD PARTY SALES - EUROPE	0	2.17	3.00	4.97	66%
THIRD PARTY SALES - APAC	0	0	1.10	4.15	277%
TOTAL	**14.08**	**14.52**	**17.31**	**22.88**	**32%**

Cyclopharm's revenue diversification strategy continued to deliver strong results with new third-party distribution agreements generating growing complementary revenues and profits. Third-party distribution consists of a mix of radiopharmaceuticals and capital equipment with associated consumable and service revenues. In 2022, revenue from capital works projects contributed $2.4 million, and ongoing revenues associated consumable sales and service contributed $6.7 million. Cyclopharm expects to expand this revenue stream through a wider range of third-party partnerships into a broader geographic reach in the coming years.

Distribution costs increased to $2.38 million in 2022, from $0.72 million in 2021, due to the significant growth in the distribution of third-party products and the negative impact the pandemic has had on manufacturing, distribution and logistics globally. The recovery of global supply chains in recent months has resulted in some encouraging cost-base improvements.

As anticipated, in 2022 Cyclopharm recorded a loss before tax of $6.03 million, up 38% from $4.35 million in 2021, and a net loss after tax of $6.61 million. This includes a 231% increase in freight expenses from $0.72 million to $2.38 million due to disruptions in global supply chains. $2.97 million of expenses were associated with the USFDA approval process bringing the total invested in USFDA process over the past 9 years to $19.24 million.

Also included in expenses is the $0.95 million of legal costs from protecting Cyclopharm's commercial interests in Europe and Australia. A judgement totalling approximately €0.4 million in favour of Cyclopharm was handed down in Germany in December 2022. Given the timing of receipt of the official judgment and further consequential court actions required to be taken in January 2023 to enable enforcement of the judgment award, this favourable outcome is an event subsequent to the close of 2022 financials. Consequently, the financial benefit will be recorded in 2023. To date €0.3 million has been collected and the Company is aggressively pursuing the remaining balance.

Capital Management

Cyclopharm ended the financial year with cash balances of approximately $20.30 million, reflecting prudent expense and capital management, supported by ongoing operational cashflows and receipt of a R&D Tax incentive payment of $1.64 million. The Company remains appropriately capitalised to fund its ongoing USFDA approval process, the anticipated launch of Technegas™ into the US market, R&D activities and the working capital to fund continuing organic growth.

USFDA Approval Process

Over the course of 2022 the Company invested significant time and resources in addressing items raised by the USFDA in both the site inspection report and the Complete Response Letter. In response to the site inspection, the Company has submitted twelve bi-monthly updates providing the objective evidence that demonstrates process and environmental control improvements along with manufacturing data capture enhancements. These bi-monthly updates will continue until approval is received or until a new inspection is conducted.

Cyclopharm has completed all external testing and is on track to finalise and submit its reply to the USFDA Complete Response Letter in the coming weeks. Once submitted, the USFDA will initiate a six-month review process. This review process is the last step in achieving the approval to sell Technegas in the USA market. Cyclopharm remains confident of commencing US sales in 2023.

US Market Entry Preparation and Sales Model

In 2022, Cyclopharm continued preparations to rapidly commercialise Technegas™ in the USA. These activities include building inventory reserves by $2.78 million to $8.29 million at December 2022. In addition, Cyclopharm is pursuing agreements for distribution, technical service and administrative support for Technegas™ in the USA.

Importantly, US health insurance reimbursement for Technegas™ will be based on established nuclear medicine procedures that are agnostic to the approved agents being used. Therefore, in the US market, Technegas™ will be utilising existing reimbursement codes.

Cyclopharm estimates the US market Technegas™ for diagnosing pulmonary embolism to be US$180 million annually and remains confident that Technegas™ can achieve a 50% share over 2 to 3 years, post entry, rising to an 80% share in 5 to 7-years.

Regulatory Approval in Existing Markets

During 2022 Cyclopharm renewed its Technegas™ CE mark under the updated European Medical Device (MDR) Regulations meaning Technegas™ may continue to be sold freely in any part of the European Economic Area. In addition, Cyclopharm renewed licensing under the Medical Device Single Audit Process (MDSAP) for participating countries to include Canada, Australia, Brazil, Japan and the USA.

Beyond PE – Substantially Expanding Technegas™

The Canadian Association of Nuclear Medicine Guidelines and the updated European Association of Nuclear Medicine Guidelines reinforce the superiority of Technegas™ in diagnosing pulmonary embolism.

In 2022, Cyclopharm continued to sponsor several clinical trials into new applications for Technegas™. The Company invested $0.15 million in Beyond PE trials, which follows on from $0.21 million invested in 2021.

With the advent of improved nuclear medicine imaging techniques, cameras and software, during 2022 Technegas'™ Beyond PE potential was recognised in peer reviewed articles and abstracts for clinical applications to include long-COVID and lung cancer.

The Company is confident that the clinical benefits seen in these early publications have the potential to exponentially expand the market for Technegas™ globally.

Outlook

Cyclopharm is poised to enter its next growth phase in 2023 from a position of strength, having delivered record 2022 sales revenues, robust sales of Technegas™ continued growth in third-party sales and the utilisation of Company's sales and service infrastructure globally.

As a result, the Company is able to sustain a consistent dividend policy with the final dividend for 2022 maintained at 0.5 cps, giving a total dividend for 2022 to 1.0 cps. The final dividend will be paid on 4 April 2023, to shareholders on the register on 28 March 2023.

Cyclopharm is fully funded for an expected entry into the US market in 2023, following a successful conclusion to the USFDA's review the Company's response to the CRL for Technegas™. The Company remains confident sales in the USA will commence in 2023 alongside its well established and profitable existing markets across 64 countries.

Cyclopharm is well placed to extend its clinical leadership in lung imaging and drive ongoing growth in revenue and earnings, while remaining absolutely committed to delivering positive health outcomes for our patients and growing financial rewards to our shareholders.

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

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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.